Filed Pursuant to Rule 424(b)(4)
Registration No. 333-299405

PROSPECTUS

10,555,555 Shares



Bambusa Therapeutics

Common Stock

This is Bambusa Therapeutics, Inc.'s initial public offering. We are selling 10,555,555 shares of our common stock.

The initial public offering price is $16.00 per share. Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the Nasdaq Global Select Market ("Nasdaq") under the symbol "BBTX."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements in this prospectus and may elect to do so in future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves risks that are described in the section titled "Risk Factors" beginning on page 16 of this prospectus.

	Per Share	Total
Public offering price	$ 16.00	$ 168,888,880
Underwriting discounts and commissions[1]	$ 1.12	$ 11,822,222
Proceeds, before expenses, to us	$ 14.88	$ 157,066,658

(1) See the section titled "Underwriting" for additional information on underwriting compensation.

At our request, the underwriters have reserved up to 3.5% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to certain persons associated with us. See the section titled "Underwriting—Reserved Share Program."

The underwriters may also exercise their option to purchase up to 1,583,333 additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about November 2, 2026.

BofA Securities **Evercore ISI** **UBS Investment Bank** **Cantor**

The date of this prospectus is October 29, 2026

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Neither we nor any of the underwriters have authorized anyone to provide you with information that is different than the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor the underwriters take any responsibility for, and cannot provide any assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus or in any applicable free writing prospectus is accurate only as of the date of this prospectus or such free writing prospectus, as applicable, regardless of the time of delivery of this prospectus or any such free writing prospectus or of any sale of the securities offered hereby. Our business, operating results, financial condition, and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It does not contain all the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our," "us," "Bambusa," and the "Company" refer to Bambusa Therapeutics, Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company developing next-generation, long-acting precision bispecific antibodies designed to redefine standards of care in immunology and inflammation ("I&I") and fundamentally improve patient quality of life. Although monoclonal antibodies have transformed the I&I treatment landscape, many patients remain underserved, continuing to experience incomplete responses or residual disease activity. We believe that next-generation therapeutic approaches, particularly bispecific and multi-target biologics that simultaneously modulate complementary and synergistic inflammatory pathways, are necessary to expand responder populations, address the significant unmet medical need, and unify treatment across overlapping disease biology.

Our vision is to deliver transformative medicines for I&I patients across every stage of disease. We use third-party, advanced antibody engineering to create long-acting bispecific antibodies that combine clinically and commercially validated biologic pathways into a single molecule formulated for high-concentration subcutaneous ("SubQ") delivery. Our goal is to improve durability, convenience, and clinical differentiation beyond the current capabilities of existing monotherapies, which we refer to as breaking the therapeutic ceiling. We believe our product candidates have the potential to address unmet medical need across I&I, spanning dermatology, respiratory, gastroenterology, and autoimmune diseases ("AID"), and capture a substantial part of the rapidly growing global I&I market, which is projected to exceed $200 billion by 2030.

Since our inception on March 14, 2024 ("Inception"), we have acquired assets from BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"), that became our lead product candidates, BBT001 and BBT002, secured regulatory clearances to initiate clinical trials for these product candidates across multiple geographical regions, advanced them from preclinical to clinical development, completed dosing and safety follow ups of intravenous ("IV") formulations of these product candidates in healthy volunteers, initiated enrollment and dosing of patients for proof-of-concept ("PoC") readouts, developed high-concentration SubQ formulations of both product candidates, initiated healthy volunteer and PoC substudies of such SubQ formulations, and initiated SubQ dosing of BBT001 in patients. We have also identified two additional promising product candidates, BBT003 and BBT004, in collaboration with our partner BioNTech Zhuhai. We plan to advance BBT003 into clinical development by the end of 2026. We believe this track record reflects our distinctive ability to move with urgency and precision across discovery, development, and operations.

Our lead product candidate, **BBT001**, a next-generation, long-acting bispecific antibody targeting two clinically and commercially validated pathways, interleukin-4 receptor alpha ("IL-4Rα") and interleukin-31 ("IL-31"), is designed to simultaneously address core Type 2 inflammation and chronic itch, the two defining burdens of atopic dermatitis ("AD") and other inflammatory skin diseases. BBT001 has been intentionally engineered using validated half-life extension ("HLE") technology with the goal of enabling extended dosing intervals relative to conventional antibody therapies. We are currently evaluating BBT001 for the treatment of moderate-to-severe AD in a global Phase 1 clinical trial in the United States, Australia, Europe, and New Zealand ("Global BBT001 Study") and in a Phase 1a/1b clinical trial in China ("China AD Study"). We have also initiated a Phase 2a clinical trial of BBT001 for the treatment of chronic spontaneous urticaria ("CSU") in China ("China CSU Study").

In July 2026, we reported positive topline PoC results from our Global BBT001 Study of patients with moderate-to-severe AD who have received neither biologics targeting the same pathways as our product candidate nor Janus kinase ("JAK") inhibitors (we refer to these patients as "bio-naïve") treated with four weeks of an IV

formulation of BBT001 in New Zealand and the United States ("4-week PoC bio-naïve AD data"). We consider clinical studies and substudies that enroll and dose patients (as opposed to healthy volunteers) as PoC studies.

As of the June 8, 2026 data cutoff date, all 17 enrolled patients were evaluable for preliminary safety and clinical response, with a median follow-up of 71 days after the first dose and a range of 33 to 165 days. The topline results that support PoC of BBT001 as a potential treatment for moderate-to-severe AD patients include:

- ***Fast-onset, statistically significant and clinically meaningful improvement in Eczema Area and Severity Index ("EASI")***. BBT001 produced a highly statistically significant placebo-adjusted EASI reduction beginning at Week 1. The placebo-adjusted EASI reduction deepened through Week 6 and remained sustained throughout the course of treatment for patients followed. At Week 6, the placebo-adjusted proportion of patients treated with BBT001 who achieved more than 50% improvement from baseline EASI ("EASI-50") and more than 75% improvement from baseline EASI ("EASI-75") was 82% and 64%, respectively.
- ***Rapid and progressively greater itch relief***. BBT001 reduced Peak Pruritus Numerical Rating Scale ("PP-NRS") scores as early as Day 1, with improvements deepening throughout treatment and remaining sustained for eight weeks after the last dose.
- ***Robust and durable suppression of Type 2 inflammatory biomarkers***. BBT001 produced early and substantial reductions in key biomarkers, including thymus and activation-regulated chemokine ("TARC") and immunoglobulin E ("IgE"), that were sustained for eight weeks after the last dose, demonstrating durable inhibition of Type 2 inflammation.
- ***Favorable safety findings***. BBT001 was observed to be well tolerated, with no cases of conjunctivitis reported, consistent with prior findings in healthy volunteers.
- ***Extended half-life supporting infrequent dosing***. BBT001 demonstrated an extended half-life in patients with AD, consistent with prior observations in healthy volunteers. Based on preclinical and clinical trial results to date, including pharmacokinetics, receptor occupancy, depth of response, and duration of response, we believe a quarterly maintenance dosing regimen will be possible.
- ***Low immunogenicity***. BBT001 demonstrated a low incidence of treatment-emergent anti-drug antibodies that has been low titer with no apparent evidence of neutralizing activity, consistent with prior findings in healthy volunteers.

We expect several additional upcoming clinical data readouts for BBT001 throughout the first half of 2027, including topline PoC results of: (i) bio-naïve patients with moderate-to-severe AD treated with 12 weeks of an IV formulation of BBT001 ("12-week PoC bio-naïve AD data"); (ii) patients with moderate-to-severe AD who have previously received either biologics targeting the same pathways as our product candidate or JAK inhibitors (we refer to these patients as "bio-experienced") treated with 12 weeks of an IV formulation of BBT001 ("12-week PoC bio-experienced AD data"); and (iii) patients with CSU treated with 14 weeks of an IV formulation of BBT001 ("14-week PoC CSU data"). We recently announced the dosing of our first patient in a 12-week PoC substudy of a SubQ formulation of BBT001 in bio-naïve patients with moderate-to-severe AD as part of our Global BBT001 Study and plan to initiate study start-up activities for our Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT001 to treat patients with moderate-to-severe AD ("Phase 2b AD Study") by the end of 2026. The Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

Our second lead product candidate, **BBT002**, a next-generation, long-acting bispecific antibody targeting two clinically and commercially validated pathways, IL-4Rα and interleukin-5 ("IL-5"), is designed to simultaneously address both central pillars of Type 2 inflammation, the interleukin-4 ("IL-4") and interleukin-13 ("IL-13") axis and the IL-5 and eosinophil ("EOS") axis, in a single molecule. BBT002 has also been engineered using the same HLE technology as BBT001 with the goal of enabling extended dosing intervals relative to conventional antibody therapies. We believe BBT002 has the potential to address a number of Type 2 inflammatory disorders across respiratory and allergic diseases. We are currently evaluating BBT002 for: (i) the treatment of chronic obstructive

pulmonary disease ("COPD") in our global Phase 1 clinical trial in the United States, Australia, Europe, Georgia, and New Zealand ("Global BBT002 Study"); and (ii) our Phase 1/2a clinical trial for COPD in China ("China COPD Study"). We are also evaluating BBT002 for the treatment of chronic rhinosinusitis with nasal polyps ("CRSwNP") in a Phase 2a clinical trial in China ("China CRSwNP Study").

In preliminary results from the single-ascending-dose ("SAD") and multiple-ascending-dose ("MAD") healthy volunteer portions of our Global BBT002 Study, BBT002 demonstrated strong pharmacokinetic results with an estimated half-life of approximately 29 days, dose-dependent, rapid, complete, and sustained dual biomarker effects, including reduction of TARC and EOS depletion for more than eight weeks, favorable safety and tolerability data, and low immunogenicity, supporting the potential for quarterly maintenance dosing. We expect several upcoming clinical data readouts for BBT002, including topline PoC results of patients with COPD treated with four weeks of an IV formulation of BBT002 ("4-week PoC COPD data") in the first half of 2027 and patients with CRSwNP treated with 12 weeks of an IV formulation of BBT002 ("12-week PoC CRSwNP data") in the first half of 2027. In addition, we have initiated our global Phase 2a study of a SubQ formulation of BBT002 in patients with asthma ("Phase 2a Asthma Study"), and plan to initiate study start-up activities for a Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT002 in patients with one of the respiratory indications in 2027.

We are also advancing two preclinical product candidates: **BBT003**, a next-generation, long-acting bispecific antibody targeting Tumor Necrosis Factor-like ligand 1A ("TL1A") and the p19 subunit of interleukin-23 ("IL-23p19") for inflammatory bowel diseases ("IBD"), including Crohn's disease ("CD") and ulcerative colitis ("UC"), for which we plan to enter the clinic by the end of 2026, and **BBT004**, a next-generation, long-acting dual B-cell depletion bispecific antibody for autoantibody-driven AID.

Each of our programs is designed to be a "pipeline-in-a-molecule" with the potential for broad applicability across multiple indications. We have, or can obtain under commercially reasonable terms, worldwide rights to all of our programs and are initially pursuing the indications summarized in the figure below. Our programs and key upcoming catalysts, including multiple anticipated PoC data readouts, are summarized in the figure below. Clinical development is a complex and challenging process with uncertain outcomes and is subject to a number of risks. See the section titled "Risk Factors—Risks Related to Research, Development, Regulatory Approval and Commercialization" for more information on risks that can cause delays in completing a trial or reaching a milestone on time.

Our Pipeline and Key Upcoming Catalysts



Our Strengths

We believe that our company and our differentiated programs possess the following attributes that will help us successfully advance and develop new investigational therapies:

- Compelling early data supporting our multi-target approach;
- Broad and deep pipeline with worldwide rights;
- Clinically validated bispecific antibody platform architecture;
- Clinically and commercially validated pathways with complementarity and synergy;
- Reduced immunogenicity and extended half-life;
- Significant commercial opportunity in the large and fast-growing I&I market, including dermatology, respiratory, gastroenterology, and AID;
- Broad expansion potential across I&I through "pipeline-in-a-molecule" design;
- Demonstrated operational efficiency and speed of execution; and
- Experienced leadership team.

Our Strategy

Our vision is to deliver transformative medicines for I&I patients across every stage of disease. We believe our pipeline of bispecific antibodies, designed to simultaneously target multiple clinically and commercially validated pathways, has the potential to redefine the standards of care and bring about the next era of I&I therapeutics. The key elements of our strategy include:

- Advance a portfolio of bispecific antibodies targeting high-value I&I indications by synergistically combining multiple clinically and commercially validated biologic targets;
- Continue to advance our lead product candidate, BBT001, through ongoing clinical development in AD and CSU and pivotal development activities in AD;
- Continue to advance our second lead product candidate, BBT002 through clinical development in COPD, CRSwNP, and asthma;
- Expand late-stage clinical development plans and activities of BBT001 and BBT002 beyond AD, CSU, COPD, CRSwNP, and asthma into additional I&I target indications to unlock their full "pipeline-in-a-molecule" potential;
- Advance BBT003 and BBT004 into clinical development in gastroenterology and AID indications, where simultaneous targeting of established pathways may improve patient outcomes;
- Build corporate infrastructure required for growth, including capabilities to support late-stage clinical development, regulatory execution, and future commercialization; and
- Pursue strategic partnerships and opportunities where appropriate to maximize long-term value.

Our Approach: Rationally Combining Validated Pathways into Long-Acting Bispecific Antibodies

Our approach is to develop long-acting bispecific antibodies for I&I diseases by rationally combining clinically and commercially validated biologic pathways into a single optimized molecule. Many I&I diseases are driven by complex and heterogeneous inflammatory pathways, which can limit the efficacy of single-target therapies and contribute to incomplete responses, persistent symptoms, and treatment burden. We select target pairs based on non-redundant biology, potential for mechanistic synergy, and commercial opportunity, and use third-party advanced

antibody engineering designed to optimize half-life, dual-target engagement, immunogenicity, manufacturability, and SubQ administration. We believe this approach has the potential to generate differentiated product candidates that address limitations of existing therapies and support multi-indication development opportunities across large I&I markets:

- ***Clinically Validated Bispecific Antibody Platform:*** Our bispecific antibody candidates are based on a platform originating from BioNTech Zhuhai, a biopharmaceutical company with expertise in the discovery and development of next-generation antibodies, including bispecific antibodies designed to engage multiple pathways. The underlying antibody construct has been clinically validated through BNT327/PM8002, now known as pumitamig, a bispecific antibody discovered at BioNTech Zhuhai that has been studied in more than 2,000 patients treated in third-party clinical trials to date, including seven ongoing global Phase 3 clinical trials. Although pumitamig shares the same bispecific antibody architecture as our two lead product candidates, the molecules are distinct, have different targets, are being developed for different disease areas, and may not offer the same features or benefits.
- ***Clinically and Commercially Validated Targets***: We leverage our team's deep experience in biologics to identify clinically and commercially validated pathways that are known biologic drivers of disease and have also demonstrated significant commercial potential in large I&I markets. We expect our focus on validated targets will continue to allow us to move quickly and efficiently into and through the clinic, as evidenced by the significant progress we have made since our Inception. Importantly, similar to pumitamig, our product candidates combine two complementary, validated mechanisms into one single molecule. Each product candidate is designed to target orthogonal and non-redundant pathways, which we believe can result in mechanistic synergy to improve patient outcomes beyond what may be achieved by targeting either pathway alone.
    - BBT001 targets both IL-4Rα and IL-31 pathways, which are clinically and commercially validated by approved biologics such as Dupixent and Nemluvio, respectively. The simultaneous blockade of IL-4Rα and IL-31 is designed to address both core Type 2 inflammation and chronic itch in a single bispecific molecule for a number of inflammatory skin diseases.
    - BBT002 targets both IL-4Rα and IL-5 pathways, which are clinically and commercially validated by approved biologics such as Dupixent and Nucala, respectively. The simultaneous blockade of IL-4Rα and IL-5 is designed to address two central and non-overlapping drivers of Type 2 inflammatory disease in a single bispecific molecule. IL-4Rα blockade is designed to inhibit the IL-4/IL-13 axis, which contributes to Type 2 inflammation, mucus production, and airway remodeling, while IL-5 blockade is designed to inhibit EOS-mediated inflammation, a key driver of exacerbations in severe asthma, COPD, and other Type 2 inflammatory respiratory diseases.
    - BBT003 and BBT004 extend this approach to additional I&I target combinations. BBT003 targets TL1A and IL-23p19, pathways that are evaluated and validated by anti-TL1A antibodies in late-stage clinical development, such as Sanofi/Teva's duvakitug, and approved IL-23p19 inhibitors, such as Skyrizi, respectively.
- ***Advanced Antibody Engineering***: Our approach is to translate rational dual-pathway biology into product candidates with attributes we believe are important for chronic I&I treatment. In addition to selecting validated, complementary targets, we design and direct BioNTech Zhuhai to engineer our bispecific antibodies to optimize key properties, including:
    - Durable and simultaneous dual-target engagement;
    - HLE technology;
    - Low immunogenicity;
    - Fit-for-purpose Fc engineering;

- Manufacturability; and
- SubQ delivery.

- ***Broad Expansion Potential Across I&I Indications***: We focus on establishing clinical PoC in well-defined initial indications with high unmet need to efficiently demonstrate clinical activity. From this foundation, we are positioned to expand each asset into a broader set of indications where the underlying biology is shared. Our product candidates are designed as "pipeline-in-a-molecule" opportunities, targeting pathways that underlie multiple indications across I&I. Beyond AD, we believe BBT001 has significant potential across multiple dermatology indications including CSU, prurigo nodularis, alopecia areata, bullous pemphigoid, and chronic pruritus of unknown origin. Similarly, we see meaningful opportunities for BBT002 in COPD, CRSwNP, and asthma as well as CSU and eosinophilic esophagitis. Our earlier-stage programs further extend this pipeline-in-a-molecule strategy: BBT003 is initially focused on IBD, including CD and UC, with potential expansion opportunities in AID and fibrosis, while BBT004 is focused on autoantibody-driven AID.

Our Team, Corporate Progress, and Investors

Members of our leadership team and many of our employees have previously worked together at BioNTech, bringing experience across the discovery, development, and strategic partnering of innovative biologic medicines. This shared history has helped establish a highly integrated organization focused on efficient execution and streamlined decision-making. We are led by our co-founder and Chief Executive Officer, Shanshan Xu, M.D., Ph.D., M.B.A., who previously served as Head of Global External Innovations at BioNTech, where she and her team sourced and executed 13 strategic partnerships and acquisitions, including the identification of the asset now known as pumitamig for an initial strategic partnership, followed by BioNTech's subsequent acquisition of BioNTech Zhuhai (then known as Biotheus). Our co-founder and Chief Development Officer, Thang Ho, Ph.D., who previously served as Clinical Pharmacology and Pharmacometrics Lead at BioNTech, oversees an integrated team spanning preclinical research, translational medicine, toxicology, and clinical pharmacology. Our Chief Financial Officer, Jonathan I. Lieber, M.B.A. also serves part-time as Chief Financial Officer of Rallybio Corporation, a publicly-traded clinical-stage biotechnology company, and previously served as Chief Financial Officer of two other publicly-traded companies, Applied Genetic Technologies Corporation and Histogenics Corporation.

Since our Inception, we have acquired assets from BioNTech Zhuhai, prior to the acquisition of Biotheus by BioNTech, that became our lead product candidates, BBT001 and BBT002, secured regulatory clearances to initiate clinical trials for these product candidates across multiple geographical regions, advanced them from preclinical to clinical development, completed dosing and safety follow ups of IV formulations of these product candidates in healthy volunteers, initiated enrollment and dosing of patients for PoC readouts, developed high-concentration SubQ formulations of both product candidates, initiated healthy volunteer and PoC substudies of such SubQ formulations, and initiated SubQ dosing of BBT001 in patients. In addition to our operational execution across multiple programs, as of June 30, 2026, we have raised $136.1 million in gross proceeds through multiple private financings with leading healthcare investors, including ATHOS, BVF Partners, Dawn Biopharma (a platform controlled by KKR), INCE Capital, RA Capital, and Salvia. The investors listed above are included solely to identify certain significant stockholders. The inclusion of any investor name above should not be construed as an endorsement by such investors of our company, business, or prospects, and such investors have not been involved in the preparation of this prospectus. Prospective investors should not rely on the past investment decisions of our investors, as our investors may have different risk tolerances and acquired their shares in prior offerings at prices lower than the price offered to the public in this offering, see "Certain Relationships and Related Party Transactions—Convertible Preferred Stock Financings" for more information.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. The following is a summary of the principal risks we face:

- We have a limited operating history, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- Since our formation, we have incurred, and anticipate that we will continue to incur, significant losses and negative cash flows for the foreseeable future. Our most advanced product candidates are currently in early clinical development and we may never achieve or maintain profitability.
- We face substantial competition, including from other biotechnology and pharmaceutical companies, who may discover, develop, or commercialize therapies before or more successfully than we do.
- Clinical development is expensive, time consuming, and inherently unpredictable, and we are subject to regulatory requirements of multiple countries where we are conducting clinical trials. If we are unable to obtain regulatory approval for our product candidates in the desired jurisdictions, on budget, and on time, our business will be substantially harmed.
- Our business depends entirely on the success of our product candidates, and we cannot guarantee that we will successfully complete clinical development, receive regulatory approval, or successfully commercialize any or all of our current or future product candidates.
- Although our product candidates are designed to target clinically validated pathways, there is no guarantee that our approach will be safe or accelerate clinical development. In fact, regulatory authorities may require us to conduct studies we did not anticipate.
- Although our product candidates use third-party advanced antibody engineering that have demonstrated benefits in other third-party molecules, these benefits may not apply to our product candidates or there may be other consequences. For example, extended half-life has its benefits, but it could also be problematic if adverse events are slow to resolve.
- Even if any of our product candidates receives regulatory approval, such product may fail to achieve market acceptance by physicians, patients, and others in the medical community, or may be subject to unfavorable pricing regulations, reimbursement practices, or healthcare reform initiatives, and the market opportunity for these product candidates may be smaller than we estimate.
- Even if this offering is successful, we will require substantial additional capital to finance our operations, which may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or current or future product candidates.
- Our management has concluded that there is substantial doubt as to our ability to continue as a going concern. If we cannot continue as a going concern, our stockholders may lose some or all of their investment.
- We will need to substantially grow our organization, and we may experience difficulties in managing our growth and expanding our operations, and attracting, retaining, and motivating our key leaders and other qualified personnel, which could adversely affect our business, financial condition, results of operations, and prospects.
- Positive results from preclinical studies and early clinical trials are not necessarily predictive of the results of later clinical trials of our current or future product candidates, and any interim, topline, and preliminary data that we announce or publish from time to time may change as more patient data become available or as we complete our audit and verification procedures.

- Additional time may be required to obtain marketing authorizations for any product candidates that we develop as biologic-device combination products.
- Our product candidates could be associated with adverse events or other risks, as a result of the performance of other products or product candidates that target the same pathways or have other similarities, that could delay, impede, or preclude approval or market acceptance, or result in other consequences that could severely harm our business, operations, financial condition, and prospects.
- Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events or deteriorating U.S.-China trade relations, could adversely affect our business, financial condition, results of operations, or prospects.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies, including in multiple foreign jurisdictions.
- If we are unable to enter into new collaborations or licenses, or if we fail to comply with our obligations under existing agreements, or such agreements are terminated, or if we otherwise fail to realize the benefits of any current or future collaborations or licensing arrangements, our business, financial condition, results of operations, and prospects could be adversely affected.
- If the third parties on which we rely to conduct our preclinical studies and clinical trials do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, or terminate the relationship, our ability to complete clinical development could be delayed, become more costly, or be unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.
- We are currently dependent on third-party manufacturers and suppliers to supply our product candidates, many of which are sole-source manufacturers and suppliers.
- We may out-license or sell one or more of our product candidates, which could reduce our pipeline and adversely affect our business and the value of our common stock.
- Our stock price may be volatile, which could result in substantial losses for investors purchasing shares in this offering.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

The risks and uncertainties set forth in the section titled “Risk Factors” are not guarantees or intended to imply that no such conditions exist as of the date of this prospectus and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

Channels for Disclosure of Information

Investors, the media, and others should note that, following the effectiveness of the registration statement of which this prospectus forms a part, we intend to announce material information to the public through filings with the Securities and Exchange Commission (“SEC”), the investor relations page on our website, press releases, public conference calls, and webcasts. The information disclosed by the foregoing channels could be deemed to be material information. However, information disclosed through these channels does not constitute part of this prospectus and is not incorporated by reference herein. Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

Corporate Information

We were incorporated in Delaware in March 2024. Our principal executive offices are located at 22 Boston Wharf Road, Floor 7, Boston, Massachusetts 02210. Our telephone number is (617) 848-6188. Our website is www.bambusatx.com. Information contained on, or that can be accessed through, our website is not a part of, and is not incorporated by reference into, this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We use Bambusa, the Bambusa logo, and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). As such, we may take advantage of reduced disclosure and other requirements otherwise generally applicable to public companies, including:

- presentation in this prospectus of only two years of audited financial statements and related financial disclosure;
- exemption from the requirement to have our registered independent public accounting firm attest to management's assessment of our internal control over financial reporting;
- exemption from compliance with the requirement of the Public Company Accounting Oversight Board ("PCAOB") regarding the communication of critical audit matters in the auditor's report on the financial statements;
- reduced disclosure about our executive compensation arrangements; and
- exemption from the requirement to hold non-binding advisory votes on executive compensation or golden parachute arrangements.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates as of the last business day of the most recently completed second quarter; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of this public offering.

As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations, and we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies unless it otherwise irrevocably elects not to avail itself of this exemption. We have elected to use this extended transition period for complying with new or revised accounting standards until we are no longer an emerging growth company or until we affirmatively and irrevocably opt out of the extended transition period. As a result, our consolidated financial statements may not be comparable to the

financial statements of companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We will continue to be a smaller reporting company in any given year if either (i) the aggregate market value of our common stock that is held by non-affiliates is less than $250.0 million as of the last business day of the most recently completed second quarter or (ii) we have less than $100.0 million in revenue in the most recently completed fiscal year and the aggregate market value of our common stock that is held by non-affiliates is less than $700.0 million as of the last business day of the most recently completed second quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING

Common stock offered by us	10,555,555 shares.
Option to purchase additional shares from us	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to 1,583,333 additional shares from us at the initial public offering price, less underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	50,942,430 shares (or 52,525,763 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately $152.4 million (or approximately $176.0 million if the underwriters exercise their option to purchase additional shares in full), based upon the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities, primarily as follows: • approximately $90.0 million to fund the continued development of our lead product candidate, BBT001, including the initiation of our planned Phase 2b AD Study; and • approximately $40.0 million to fund the continued development of our second lead product candidate, BBT002, including the expected initiation of a Phase 2b clinical trial in one of the respiratory indications. We intend to use the remaining proceeds to fund additional research and development of our two preclinical product candidates, BBT003 and BBT004, including advancing BBT003 into clinical development, as well as for capital expenditures, working capital, and general corporate purposes, including the additional costs of operating as a public company. See the section titled "Use of Proceeds" for additional information.
Reserved share program	At our request, the underwriters have reserved 3.5% of the shares of common stock to be offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, distributors, dealers, business associates and related persons. If purchased by these persons, these shares will not be subject to a lock-up restriction, except in the case of shares purchased by any director, executive officer or employee. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. See the section titled "Underwriting—Reserved Share Program" for additional information.
Risk factors	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq trading symbol	"BBTX"

The number of shares of common stock that will be outstanding immediately after this offering is based on 40,386,875 shares of our common stock outstanding as of June 30, 2026 (which includes 2,866,703 shares of unvested restricted common stock), after giving effect to the following, as if they had occurred as of June 30, 2026:

- the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 27,391,561 shares of common stock upon the closing of this offering (the "Preferred Stock Conversion"); and
- the issuance of 621,192 shares of common stock (based on the initial public offering price of $16.00 per share) upon the vesting and settlement of restricted stock units ("RSUs") granted subsequent to June 30, 2026, which vest upon both a liquidity condition (which will be satisfied in connection with this offering) and a service condition in an amount calculated based on the volume-weighted average price of the Company's common stock for the 20-day trading period immediately following the date of this prospectus, not to exceed 701,797 shares (the "Liquidity Event RSU Settlement").

The number of shares of common stock outstanding as of June 30, 2026 excludes the following:

- 1,550,428 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2026, with a weighted-average exercise price of $0.90 per share;
- 1,621,449 shares of common stock issuable upon the exercise of outstanding options granted subsequent to June 30, 2026, with a weighted-average exercise price of $12.66 per share;
- 379,102 shares of common stock issuable upon the exercise of options approved subsequent to June 30, 2026, which were granted contingent and effective upon the pricing of this offering with a price per share equal to the initial public offering price (the "IPO Options");
- 758,204 shares of common stock issuable upon the vesting and settlement of performance-based RSUs approved subsequent to June 30, 2026, which were granted in connection with this offering (the "IPO PSUs");
- 5,898,951 shares of common stock reserved for future issuance under our 2026 Equity Incentive Plan ("2026 Plan") (which include the shares issuable under the IPO Options and the IPO PSUs), which became effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part (including 338,788 shares of common stock reserved for future issuance under our 2024 Stock Plan ("2024 Plan"), which number of shares was added to the shares of our common stock reserved under our 2026 Plan in connection with its effectiveness, at which time we ceased granting awards under our 2024 Plan);
- 505,469 shares of common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan ("ESPP"), which became effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part; and
- securities or other consideration which may be issuable upon the settlement of outstanding value appreciation rights ("VARs") as of June 30, 2026.

The 2026 Plan and the ESPP each provide for annual automatic increases in the number of shares of our common stock reserved thereunder, and the 2026 Plan also provides for increases to the number of shares of our common stock that may be granted thereunder based on shares underlying the awards granted under the 2024 Plan that expire, are forfeited, or are repurchased by us, as more fully described in the section titled "Executive Compensation—Employee Benefit and Stock Plans."

Except as otherwise indicated, all information in this prospectus assumes or gives effect to the following:

- the Preferred Stock Conversion;
- no exercise of outstanding options described above;
- other than the Liquidity Event RSU Settlement, no settlement of outstanding RSUs described above;

- no settlement of outstanding VARs described above;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise of the underwriters' option to purchase additional shares; and
- a 1.54485-for-1 forward stock split effected on October 23, 2026 (the "Stock Split").

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our consolidated financial data as of, and for the periods ended on, the dates indicated. The condensed consolidated statement of operations data for the six months ended June 30, 2026 and 2025, and the condensed consolidated balance sheet data as of June 30, 2026, are derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations for the year ended December 31, 2025 and the period from Inception to December 31, 2024 are derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. We have prepared the unaudited condensed consolidated financial statements on the same basis as the audited financial statements and have included all adjustments that, in management's opinion, are necessary to state fairly the information set forth in those condensed consolidated financial statements. You should read this data together with our consolidated financial statements and condensed consolidated financial statements and related notes appearing elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results and our interim results are not necessarily indicative of the results that may be expected for the full fiscal year or any other future period. The summary consolidated financial data in this section are not intended to replace, and are qualified in their entirety by, the consolidated financial statements and condensed consolidated financial statements and related notes included elsewhere in this prospectus.

Consolidated Statement of Operations Data:

	Six Months Ended June 30,		Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024
(in thousands, except share and per share amounts)	**2026**	**2025**		
Operating Expenses:				
Research and development	$ 20,646	$ 11,892	$ 38,096	$ 13,025
General and administrative	3,413	3,556	5,910	855
Total operating expenses	24,059	15,448	44,006	13,880
Loss from operations	(24,059)	(15,448)	(44,006)	(13,880)
Other income (expense):				
Interest income	1,313	732	2,171	131
Research and development incentive	1,513	1,236	3,310	—
Change in fair value of preferred stock tranche right obligation	—	(454)	(454)	—
Other income, net	67	37	125	8
Total other income, net	2,893	1,551	5,152	139
Loss before income taxes	(21,166)	(13,897)	(38,854)	(13,741)
Income tax provision	1,194	850	2,233	—
Net loss	$ (22,360)	$ (14,747)	$ (41,087)	$ (13,741)
Comprehensive loss:				
Net loss	$ (22,360)	$ (14,747)	$ (41,087)	$ (13,741)
Unrealized (losses) gains on marketable securities	(79)	60	60	—
Comprehensive loss	$ (22,439)	$ (14,687)	$ (41,027)	$ (13,741)
Net loss attributable to common stockholders[1]	$ (22,360)	$ (12,989)	$ (39,332)	N/A
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (2.56)	$ (2.30)	$ (6.08)	N/A
Weighted-average common shares outstanding, basic and diluted[1]	8,727,671	5,657,176	6,474,305	N/A
Pro forma net loss per share, basic and diluted (unaudited)[2]	$ (0.61)		$ (1.52)	
Weighted average shares used in computing pro forma net loss per share, basic and diluted (unaudited)[2]	36,740,424		33,559,895	

(1) See Note 15 to our audited consolidated financial statements and Note 14 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share.

(2) Pro forma net loss per share, basic and diluted, is calculated giving effect to (1) the Preferred Stock Conversion and (2) the Liquidity Event RSU Settlement, and the associated stock-based compensation expense of $10.0 million, of which $9.4 million is expected to be recognized upon the closing of this offering. Pro forma net loss does not include the shares expected to be sold and related proceeds to be received in this offering. Unaudited pro forma net loss attributable to common stockholders for the six months ended June 30, 2026 and the year ended

December 31, 2025 were calculated using the weighted-average common shares outstanding, including the pro forma effect of (1) the Preferred Stock Conversion and (2) the Liquidity Event RSU Settlement, as if they had occurred on January 1, 2025.

Consolidated Balance Sheet Data:

	As of June 30, 2026		
(in thousands)	**Actual**	**Pro Forma[1]**	**Pro Forma As Adjusted[2]**
Cash and cash equivalents	$ 46,534	$ 46,534	$ 198,967
Marketable securities	24,941	24,941	24,941
Working capital[3]	63,076	63,076	217,253
Total assets	77,496	77,496	228,185
Total liabilities	12,223	12,223	10,479
Convertible preferred stock	136,231	—	—
Total stockholders' (deficit) equity	(70,958)	65,273	217,706

(1) The pro forma column in the balance sheet data table above reflects (a) the Preferred Stock Conversion, and (b) the Liquidity Event RSU Settlement, as if they had occurred on June 30, 2026, and (c) the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the effectiveness of our amended and restated bylaws, which will occur immediately prior to the completion of this offering.

(2) The pro forma as adjusted column in the balance sheet data table above gives effect to (a) the pro forma adjustments set forth in footnote 1, and (b) the sale and issuance by us of 10,555,555 shares of common stock in this offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Working capital is defined as current assets less current liabilities. See our financial statements appearing elsewhere in this prospectus for further details regarding our current assets and current liabilities.

Recent Developments

Certain Preliminary Financial Information (Unaudited)

Our financial statements for the three and nine months ended September 30, 2026 will not be available until after this offering is completed and, consequently, will not be available to you prior to investing in our securities. Based upon preliminary estimates and information available to us as of the date of this prospectus, we had approximately $57.2 million of cash, cash equivalents, and marketable securities as of September 30, 2026. These amounts are not expected to be sufficient to fund our operations for at least 12 months from the date our financial statements were available to be issued. Therefore, based on our current cash, cash equivalents, and marketable securities position, there is substantial doubt about our ability to continue as a going concern.

This estimate of our cash, cash equivalents, and marketable securities as of September 30, 2026 is preliminary, has not been audited, is based on information available to us only as of the date of this prospectus, and is subject to change. Additional information and disclosure would be required for a more complete understanding of our financial position as of September 30, 2026. This preliminary financial information has been prepared by, and is the responsibility of, our management. Our independent registered public accounting firm has not audited, reviewed, examined, compiled or applied agreed-upon procedures with respect to this preliminary information and, accordingly, does not express an opinion or any other form of assurance about it. The report of our independent registered public accounting firm included elsewhere in this prospectus relates to our previously issued financial statements. It does not extend to this preliminary financial information and should not be read to do so.

RISK FACTORS

An investment in our common stock involves a high degree of risk. In deciding whether to invest, you should carefully consider and read the following risk factors, as well as the financial and other information contained in this prospectus, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our consolidated financial statements and related notes included elsewhere in this prospectus. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Any of the following risks could have a material adverse effect on our business, financial condition, results of operations, or prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us.

Risks Related to Our Business, Limited Operating History and Financial Position

We are a clinical-stage biotechnology company with a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical-stage biotechnology company with a limited operating history. Since our Inception, we have devoted substantially all of our resources since that time to research and development activities for our product candidates, including BBT001 and BBT002, recruiting management and technical staff, and raising capital to support these operations. Our most advanced product candidates, BBT001 and BBT002, are in early clinical development, and all of our other product candidates remain in preclinical or non-clinical development. We have not had and do not have any products approved for sale and have not generated any revenue from product sales or royalties to date. We do not know whether we will be able to develop any product candidates that succeed through preclinical and clinical development or products of commercial value. We do not expect to generate product revenues unless and until we obtain regulatory approval for a product candidate. While we have demonstrated operational efficiency and speed of execution in our short operating history, our operational efficiency and speed of execution may not be sustainable in the long run. Consequently, it may be more difficult to evaluate our business and predictions about our future success and viability may not be as accurate as they could be if we had a longer operating history. Investing in biotechnology product development is highly speculative because of the significant risk that, despite significant investment, any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval, and become commercially viable.

We have incurred significant losses and negative cash flows from operations since our formation, and we anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have not had and do not have any products approved for sale. From Inception to June 30, 2026, we have funded our operations primarily with proceeds from the sale and issuance of convertible preferred stock in an aggregate amount of $136.1 million. We have not generated any revenue from product sales or royalties to date and we have accumulated significant operating losses since our Inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses were $41.1 million and $13.7 million for the year ended December 31, 2025 and the period from Inception to December 31, 2024, respectively, and $22.4 million and $14.7 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $77.2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue research and development efforts for our product candidates, advance our product candidates through preclinical studies and clinical trials, and seek regulatory approvals for our product candidates.

We anticipate that our expenses will increase substantially as we:

- continue to progress the development of our product candidates, BBT001 and BBT002, including expanded enrollment of additional clinical trials;

- continue to progress research and development of our product candidates, BBT003 and BBT004, including advancing BBT003 into clinical development;
- expand our pipeline of development candidates, including through our own discovery and development efforts or through acquisition or in-licensing;
- seek regulatory approvals for any of our current product candidates or any future product candidates;
- acquire or in-license other product candidates and technologies, or any related intellectual property rights, including the cost of acquiring any additional rights to product candidates from BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"), under the BioNTech Zhuhai Option Agreement;
- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- establish a sales, marketing, manufacturing, and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval, if any;
- attract, hire, and retain additional qualified clinical, scientific, manufacturing, operations, administrative, and management personnel;
- add and maintain operational, financial, and information management systems;
- protect, maintain, enforce, and expand our rights in our intellectual property portfolio or acquire or in-license intellectual property and technologies from third parties;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates, including as a result of macroeconomic conditions, geopolitical conflicts, or other factors; and
- incur additional legal, accounting, or other expenses in operating our business, including the costs associated with operating as a public company following the completion of this offering.

To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining regulatory approval for product candidates, manufacturing, marketing, and selling products if we obtain regulatory approval, obtaining market acceptance for such products, and satisfying any post-regulatory requirements. We may not succeed in any or all of these activities and, even if we do, we may not generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and the price of our common stock, and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our common stock also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business, financial condition, results of operations, and prospects. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

Our business depends entirely on the success of our product candidates, and we cannot guarantee that any or all of our current or future product candidates will successfully complete clinical development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested the majority of our efforts and financial resources in the development of our product candidates, each of which is still in preclinical or clinical development, and expect that we will continue to invest heavily in the development of these product candidates, as well as in any future product candidates we may develop. Our business and our ability to generate revenue are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, the establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events ("AEs") or failure to achieve primary endpoints in clinical trials.

The success of our product candidates will depend on several factors, including, but not limited to, the following:

- successful and timely completion of clinical and preclinical development of our current and future product candidates;
- successful initiation and completion of preclinical studies with favorable results, including certain studies designed to be compliant with good laboratory practice ("GLP") requirements;
- allowance to proceed with clinical trials under Investigational New Drug applications ("INDs") by the FDA, or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates;
- the initiation and successful patient enrollment and completion of our planned and ongoing clinical trials, as well as any necessary additional clinical trials, in each case in accordance with good clinical practice ("GCP") requirements and with favorable results and on a timely basis;
- establishing and maintaining relationships with contract research organizations ("CROs"), and clinical sites for the clinical development, both in the United States and internationally, of our current and future product candidates;
- the frequency and severity of AEs in clinical trials;
- safety, purity, and potency (or efficacy) and tolerability results that are satisfactory to the U.S. Food and Drug Administration ("FDA") or any comparable foreign regulatory authority for regulatory approval;
- timely receipt of regulatory approvals from applicable regulatory authorities for any of our current and future product candidates for which we successfully complete clinical development, including approvals of Biologics License Applications ("BLAs") from the FDA, and maintaining any such approvals;
- completing any required post-marketing commitments or requirements agreed to with or required by applicable regulatory authorities;
- developing an efficient and scalable manufacturing process, either directly or through a third-party contract manufacturing organization ("CMO"), for our product candidates, including obtaining finished products that are appropriately packaged for sale;

- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet any potential market demand for product candidates that we develop, if approved;
- our ability to locate and retain alternate suppliers for the various components of our product candidates on commercially reasonable terms;
- identifying, assessing, and developing new product candidates;
- obtaining, maintaining, and expanding patent protection, trademark protection, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing, or other arrangements that may be necessary or desirable to develop, manufacture, or commercialize our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring, and retaining qualified personnel.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights, and the manufacturing, marketing, distribution, and sales efforts of any future collaborator.

Although our product candidates share the same bispecific antibody construct as a third-party bispecific antibody that has been studied in more than 2,000 patients treated in third-party clinical trials to date, including seven ongoing global Phase 3 clinical trials, the molecules are distinct, they target different targets, are being developed for different disease areas, and are being developed by different entities who have significantly greater resources than us. Sharing the same scaffold architecture does not mean that our product candidates will have the same features or benefits. Additionally, sharing the same antibody construct can also confer risks that if the third-party bispecific antibody does not perform clinically or commercially, that such results may impact the perceived risks of our product candidates.

Although our product candidates are designed to target clinically validated pathways, there is no guarantee that targeting multiple pathways will be safe, additive, or superior or that our approach will accelerate clinical development; in fact, in some cases, combining targets can introduce unpredictable toxicity or immune effects not seen with monotherapies, which could delay clinical development. Regulatory authorities may require us to conduct studies we did not anticipate. Our product candidates were designed to target pathways that we believe are complementary and have synergy, but there is no guarantee that the product candidates will demonstrate complementarity or synergistic benefit.

Although our product candidates use third-party advanced antibody engineering that have demonstrated benefits in other third-party molecules, these benefits may not apply to our product candidates. As an example, the type of half-life extension technology that we use may not translate to larger and diverse patient populations as we advance our clinical development program. Extended half-life has its benefits, but it could be problematic if adverse events are slow to be resolved. Additionally, there is no guarantee that our product candidates will be approved for dosing intervals necessary to differentiate our product candidates in a competitive market, even if our product candidates are demonstrated to be long-acting.

Even if our product candidates are successful in clinical trials, we will not be permitted to market or promote any of our product candidates until we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive regulatory approval to allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States

or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations, and prospects.

The FDA or comparable foreign regulatory authorities may also consider their approvals of competing products concurrently with their review of our INDs, clinical trial applications ("CTAs"), or other submissions. That review may lead to changes in the review requirements that had been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate the withdrawal of our INDs, CTAs, or other submissions.

Even if any of our product candidates receives regulatory approval, such product candidate may fail to achieve market acceptance by physicians, patients, and others in the medical community, and the market opportunity for these product candidates, if approved, may be smaller than we estimate.

If our product candidates are approved for marketing by applicable regulatory authorities, our ability to generate revenue from any approved products will depend on our ability to:

- receive regulatory approval for the desired target patient populations and claims that are necessary or desirable for successful marketing and commercialization;
- manufacture products through CMOs in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- price our products competitively such that third-party and government reimbursement supports broad product adoption;
- address any competing therapies and technological and market developments;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our products through our own marketing and sales activities, and any other arrangements to promote these products that we may otherwise establish;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect, and enforce patent and other intellectual property rights and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization, including interactions with healthcare professionals, patient advocacy groups, and communication of healthcare economic information to payors and formularies;
- achieve market acceptance of our products by patients, the medical community, and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further timely product delivery to commercial clinical sites; and
- ensure that our product will be used as directed and that additional unexpected safety risks will not arise.

Although our product candidates are designed to target commercially validated pathways, there is no guarantee that our approach will accelerate clinical development, or that our products will receive regulatory approval. The molecules that achieved significant commercial sales are distinct, they are sometimes being developed for different disease areas, and importantly, they are being developed by different entities, who have significantly greater resources and experience than us. Even if we achieve benefits in clinical development, there is no guarantee that our product candidates will have the commercial value that we expect or reach such potential. We may not execute clinical development efficiently or strategically, or we may invest resources in the wrong indications or strategy.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, and continue our operations.

Furthermore, our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties, as well as management's knowledge and experience in our industry. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and/or fail to accurately reflect market opportunities. If any of our assumptions or estimates or any of these publications, research, surveys, or studies prove to be inaccurate, then the actual market for our product candidates may be smaller than we expect, which would have an adverse material impact on our business, financial condition, and results of operations.

We face substantial competition, which may result in others discovering, developing, or commercializing therapies before or more successfully than we do.

The development and commercialization of new therapies is highly competitive. The I&I market is saturated, with multiple companies commercializing products and developing product candidates in the indications we intend to pursue. We face and will continue to face competition from third parties, including larger and better-funded pharmaceutical, biopharmaceutical, and biotechnological companies, developing treatments for the indications that we have decided to pursue. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization of new therapies.

Many of our competitors have significantly greater financial, technical, manufacturing, supply, marketing, and sales resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing, and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives by being more effective, safer, less expensive, or more successfully marketed and sold. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

In addition, our competitors may obtain approval from the FDA or comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve regulatory approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive, or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce, or eliminate one or more of our research and development programs or future commercialization efforts.

We expect to have three product candidates in clinical development by the end of 2026. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since our Inception. We expect to continue spending substantial amounts of cash to advance our current and future preclinical and clinical development programs and seek regulatory approval for our product candidates.

As of June 30, 2026, we had $71.5 million in cash and cash equivalents and marketable securities. Based on our current plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents and short-term marketable securities will be sufficient to fund our operations into late 2028. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Additionally, because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate.

Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results, and costs of discovery, preclinical development, laboratory testing, and planned clinical trials for our current or future product candidates, including additional expenses attributable to adjusting our development plans;
- the scope, prioritization, and number of our research and development programs and clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review of our current or future product candidates;
- our ability to establish or maintain collaboration, assignment, or license agreements and the achievement of milestones or occurrence of other developments that trigger payments under any existing or additional collaboration, assignment, or license agreements;
- the costs associated with acquiring or licensing additional product candidates, technologies, or assets, including the timing and amount of any milestones, royalties, or other payments due in connection with acquisitions and licenses;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the potential increase in the number of our employees or expansion of our physical facilities to support preclinical studies and clinical trials;
- the costs associated with being a public company;
- the cost of securing manufacturing arrangements for clinical and commercial production and establishing or contracting for sales and marketing capabilities, if we obtain regulatory clearances to market our current or future product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including marketing, sales, and distribution, for any of our product candidates for which we receive regulatory approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval;

- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage or adequate reimbursement from third-party payors; and
- the impact of inflation, rising interest rates, monetary policy changes, implementation of tariffs, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Until such time we can generate significant revenue from sales of our product candidates, if ever, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations, and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy. As a result, we may have to delay, reduce the scope of, suspend, or eliminate one or more of our research-stage programs, clinical trials, or future commercialization efforts.

Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or current or future product candidates.

The expected net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will not be sufficient for us to fund all of our product candidates through regulatory approval, and we will need to raise substantial additional capital in order to do so. Even if we believe that we will have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if there are specific strategic considerations for doing so. To the extent that we raise such additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted and the terms of such securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring and distributing dividends, and may be secured by all or a portion of our assets.

If we raise funds by entering into collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs, or product candidates, or grant licenses on terms that may not be favorable to us, any of which may harm our business, financial condition, results of operations, and prospects.

Further, if banks and financial institutions with whom we hold accounts enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash may be threatened and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our management has concluded that there is substantial doubt as to our ability to continue as a going concern. If we cannot continue as a going concern, our stockholders may lose some or all of their investment.

Our audited consolidated financial statements included elsewhere in this prospectus were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and satisfy our liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from our inability to continue as a going concern. As reflected in the audited consolidated financial statements, we have incurred significant operating losses in the past, and we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. To date, we have relied primarily on preferred stock financings to fund our operations. Our net losses were $41.1 million and $13.7 million for the year ended December 31, 2025 and the period from Inception to December 31, 2024, respectively, and $22.4 million and $14.7 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $77.2 million. As of June 30, 2026, we

had $71.5 million in cash and cash equivalents and marketable securities. Our management concluded that, based on our expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern for the 12 months after the date our audited consolidated financial statements were available to be issued. After this offering, we expect to continue raising additional financing and may not achieve the funding we require such that substantial doubt about our ability to continue as a going concern continues. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. If we cannot continue as a going concern, our stockholders may lose some or all of their investment in us.

Our business entails a significant risk of product liability and an inability to obtain sufficient insurance coverage for those or other claims could adversely affect our business, financial condition, results of operations, and prospects.

We do not carry insurance for all categories of risk that our business may encounter, and we do not know if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms, and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage, and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations, and growth.

As we conduct preclinical studies and clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing, and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an investigation by the FDA or comparable foreign regulatory authorities focused on the safety, efficacy, and potency of our current or future product candidates, our manufacturing processes and facilities, or our marketing programs. Such an investigation may potentially result in a recall of our products or a more serious enforcement action, limitations on the approved indications for which the product may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, product liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain to cover product liability or other claims may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability or other claims that could adversely affect our business, financial condition, results of operations, and prospects.

We or the third parties upon whom we depend may be adversely affected by natural disasters or public health crises and our business continuity may not adequately protect us from a serious disaster.

Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure, or other natural or manmade accidents or incidents that result

in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and CROs could cause delays in our preclinical studies and clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a public health crisis, natural disaster, power outage, or other event occurred that prevented us from using our clinical sites, that impacted clinical supply or the conduct of our preclinical studies and clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations, and prospects.

Our future success depends on our ability to retain and to continue to receive adequate attention from our key leaders, as well as on our ability to attract, retain, and motivate qualified personnel.

We are highly dependent upon Shanshan Xu, M.D., Ph.D., M.B.A., our co-founder, President, and Chief Executive Officer, Thang Ho, Ph.D., our co-founder and Chief Development Officer, Jonathan I. Lieber, M.B.A. , our Chief Financial Officer, and Crystal MacKay, our Chief Operating Officer, and losing the services of any of these individuals could delay or prevent the successful development of our product candidates, the initiation or completion of our preclinical studies and clinical trials, or the commercialization of our product candidates. Dr. Xu's employment agreement with us is terminable by her at will and, therefore, we may not be able to retain her services as expected. Similarly, Dr. Ho's employment agreement with us is terminable by him at will and, therefore, we may not be able to retain his services as expected. In addition, because we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees, we may not have adequate compensation for the loss of the services of these individuals.

Finally, our success also depends in part on our continued ability to attract, retain, and motivate highly qualified management and clinical and scientific personnel. We may not be successful in continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology, and other businesses and academic institutions, particularly in the greater Boston area.

If we are not able to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, or if members of our team are required to devote substantial amounts of time to other professional responsibilities that limit their ability to devote necessary time to our affairs, we may experience constraints that significantly impede the achievement of our business objectives, our ability to raise additional capital, and our ability to implement our business strategy.

We will need to substantially grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business, financial condition, results of operations, and prospects.

As of September 30, 2026, we had 30 full-time employees, 24 of whom were engaged in research and development. As our development plans and strategies progress, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial, and other resources. In addition, as our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators, partners, suppliers, and other organizations. We may have difficulty identifying, hiring, and integrating new personnel or experience challenges when personnel are required to take on greater responsibilities or we do not

manage promotions effectively. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate, promote, and integrate current and additional employees, consultants, and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures. We may not be able to effectively manage the expansion of our operations, which may give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Even if our product candidate achieves success in one indication, we may fail to successfully expand into other indications that are more profitable and fail to realize the full potential of our programs.

Our current and future employees, independent contractors, consultants, collaborators, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could adversely affect our business, financial condition, results of operations, and prospects.

We are exposed to the risk of fraud or other misconduct by our current and future employees, contractors, consultants, collaborators, and vendors. Misconduct by these parties could include failures to comply with FDA regulations or comparable foreign regulations, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with federal, state, or foreign healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely, or accurately, to disclose unauthorized activities to us, or to comply with comparable foreign requirements. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign equivalents, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

In the normal course of business, we periodically enter into commercial, service, collaboration, licensing, consulting, and other agreements that contain indemnification provisions. With respect to our commercial agreements, we sometimes indemnify our vendors from any third-party product liability claims that could result

from the production, use, or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

If our obligations under an indemnification provision exceed or do not qualify for applicable insurance coverage or if we were denied insurance coverage, our business, financial condition, results of operations, and prospects could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition, results of operations, and prospects could be adversely affected.

We are and may be required to make additional, contingent, or other future payments to our current and future collaborators or in connection with in-licenses or acquisition of assets and technology. Such payments may have an adverse impact on our business, financial condition, results of operations, and prospects.

We have entered into, and may in the future enter into, collaborations and in-licensing arrangements that contemplate contingent or other future payments. In the event we are deemed to have achieved certain milestones in connection with such contingent or other future payments, we may be required to pay such amounts in full or in part. For example, under the BioNTech Zhuhai Assignment Agreement, we were obligated to share a portion of a platform fee owed by BioNTech Zhuhai to Alloy Therapeutics, LLC ("Alloy") until May 2026 and are obligated to pay additional program-based fees and milestone payments that flow through BioNTech Zhuhai's agreement with Alloy, with aggregate development milestone payments that could reach approximately $1.8 million per program and aggregate commercial milestone payments that could reach $11.0 million per program. Additionally, under the BioNTech Zhuhai License Agreement, we are obligated to pay BioNTech Zhuhai an annual license fee until the first commercial sale of the first licensed product, with aggregate development milestone payments that could reach $6.9 million, aggregate first commercial sale milestone payments that could reach $57.5 million, and additional aggregate sales milestones that could reach $217.5 million, as well as royalties in a low-single-digit percentage of net sales of licensed products by us, our affiliates, or sublicensees, subject to certain customary reductions. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" for additional information regarding our deferred consideration obligations. Contingent or other future payments may have an adverse impact on our business, financial condition, results of operations, and prospects.

We may engage in various acquisitions and strategic partnerships in the future, including additional licensing arrangements with third parties or acquiring complementary products or product candidates, intellectual property rights, technologies, or businesses, joint ventures, or other collaborations. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership or in order to manage a collaboration or develop acquired products, product candidates, or technologies;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain relationships with key suppliers, manufacturers, or customers and any other key business relationships of any acquired business;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;

- higher than expected collaboration, acquisition, or integration costs, write-downs of assets or goodwill, or impairment charges; and
- our inability to generate revenue from acquired intellectual property, technology, and/or product candidates sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

As a result, if we enter into acquisitions, in-licensing, or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following an acquisition, strategic transaction, or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

We may out-license or sell one or more of our product candidates, which could reduce our pipeline and adversely affect our business and the value of our common stock.

As part of our ongoing corporate strategy, we regularly evaluate strategic opportunities with respect to our product candidates, including potential out-licensing arrangements, partnerships, and dispositions. We may determine that it is in our best interest to out-license or sell one or more of our current product candidates to a third party, which could occur at any time. Any such transaction could occur at an early stage of development, before the full commercial potential of the relevant product candidate is established, and we may not receive terms, milestone payments, or royalties that reflect the ultimate value of such product candidate. We may also lose control over the development and commercialization strategy for any out-licensed or divested product candidate, including decisions regarding indications, clinical trial design, regulatory submissions, and commercialization. Any announcement of such a transaction could cause the market price of our common stock to decline. There can be no assurance that we will be able to enter into any such transaction on terms favorable to us, or at all, or that any such transaction will ultimately generate the anticipated benefits we seek.

We may become subject to litigation, which could result in substantial costs and divert management's attention and resources from our business.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business or otherwise, including claims related to employment matters, security of patient and employee personal data, product liability, intellectual property rights, and contractual relations with current or past collaborators or licensors. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" for additional information regarding our future payment obligations. Any litigation that involves us could be costly and time-consuming and we cannot assure you that we would ultimately prevail. If we receive an adverse judgment in any litigation, we could be required to pay substantial damages that may not be covered by our insurance in full or at all. Expenses and damages relating to litigation can be difficult to predict. Regardless of its merit, litigation can be complex, extend for a protracted period of time, divert management's attention and resources, and be expensive. Litigation initiated by us could also result in counterclaims against us, which could increase the costs associated with the litigation and result in our payment of damages or other judgments against us.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, could adversely affect our business, financial condition, results of operations, or prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced extreme volatility and disruptions in the past several years. A severe or prolonged economic downturn, or global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved, or impair our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance,

including our ability to execute on our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments, which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers and contractors, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, continued market volatility or a general economic downturn could cause our stock price to decline.

Events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. If any of the banks that hold our cash deposits were to be placed into receivership, we may be unable to access our cash and cash equivalents and short-term marketable securities, which would adversely affect our business. In addition, if any of the third parties on whom we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds through certain financial institutions, such parties' ability to fulfill their obligations to us could be adversely affected.

Our business is subject to the risks associated with doing business in China.

As a result of our reliance on certain service providers, such as WuXi Biologics, BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"), and Tigermed, each with substantial operations in China, and other entities such as CROs and CMOs or regulatory consultants that we may currently or in the future use in China, our results of operations, financial condition, and prospects are subject to a significant degree to economic, political, and legal developments in China including government control over capital investments or changes in tax regulations that are applicable to us. China's economy differs from the economies of most developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate and control of foreign exchange, and allocation of resources. Since we rely on entities located in China, our business is subject to the risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- requirements relating to China's data security rules and regulations;
- requirements relating to China personal information protection laws;
- changes and volatility in currency exchange rates;
- unexpected or unfavorable changes in regulatory requirements; and
- difficulties in managing foreign relationships and operations generally.

For example, the BIOSECURE Act was recently signed into law as Section 851 of the 2026 National Defense Authorization Act (the "BIOSECURE Act"). The BIOSECURE Act restricts federal government agencies from entering into contracts, grants, and loans with companies that use biotechnology equipment or services produced or provided by select Chinese biotechnology companies (each, a "biotechnology company of concern"), as part of such companies' performance of those agreements with the U.S. government. The BIOSECURE Act and its implementing regulations, or similar legislation in the future, could adversely impact our current or future third-

party arrangements with certain companies (e.g., CMOs), including those in China or Chinese-owned U.S. companies, which could delay or impact our clinical trials and consequently delay or obstruct successful commercialization of our product candidates. Even if we do not seek any covered federal government contracts, grants, or loans, it is possible that commercial partners, government agencies, or other third parties may view our business less favorably if we contract with entities that are ultimately designated as biotechnology companies of concern. Other U.S. legislation, regulations, and trade restrictions, as well as other foreign regulatory requirements, could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, restrict or even prohibit our ability to work with foreign CMOs, or have an adverse effect on our ability to secure significant commitments from governments to purchase potential therapies.

In addition, other U.S. national security laws and regulations could also affect the transfer of certain types of data abroad, including to China. For example, the Department of Justice issued a final rule entitled "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons" (the "Data Security Program" or "DSP"), which took effect in April 2025 that places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in China and other designated countries, or with other specified links to China and other designated countries. These rules also may broadly require us to extract promises from other third-party service providers that they will not transfer data we share with them onward to parties linked to countries of concerns. If we fail to comply with these new regulations, we could be subject to civil and criminal penalties, harm to our reputation, and other adverse consequences. Additional compliance investment and potential business process changes may be required to address risks arising from the DSP. The recently proposed draft regulations under the Comprehensive Outbound Investment National Security Act of 2025 (the "COINS Act") also seek to impose prohibitions on U.S. investment in certain entities that are organized in, headquartered in or otherwise affiliated in particular ways with entities in certain countries of concern, including China, when such entities are engaged in the development of certain biotechnology-related technologies. To the extent that COINS Act rules ultimately take effect in largely the proposed form, our ability to collaborate with China-affiliated parties in certain types of transactions may be diminished or eliminated.

Moreover, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partners, licensors, suppliers, manufacturers, or collaborators in China which could have an adverse effect on our business, financial condition, results of operations, and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. Furthermore, if one or more of our manufacturers or suppliers in China, including WuXi Biologics, is deemed to be a biotechnology company of concern, our operations and financial condition may be negatively impacted as a result of any delays or increased costs arising from the trade restrictions and other foreign regulatory requirements affecting such third parties. In addition, while we may work to establish relationships with CROs and CMOs outside of China, moving to those suppliers in the event of a geopolitical instability affecting our collaborators in China could introduce delays into the development program.

U.S.-China trade relations may adversely impact our supply chain operations and business.

The U.S. and Chinese governments have taken certain actions that change trade policies, including tariffs that affect certain products which are manufactured in China and mutual exchange of certain types of data. Due to our reliance on WuXi Biologics and BioNTech Zhuhai to supply and manufacture our product candidates and their components, we are reliant on collaborating with a company with significant operations in China. It is unknown whether and to what extent new tariffs, laws, or regulations will be adopted that increase the cost or feasibility of importing and/or exporting products, components, and information from China to the United States and vice versa. Further, the effect of any such new tariffs or actions on our industry and customers is unknown and difficult to predict. As additional new tariffs, legislation, and/or regulations are implemented, or if existing trade agreements are renegotiated or if China or other affected countries take retaliatory trade actions, such changes could have a material adverse effect on our clinical development plans, business, financial condition, results of operations, or cash flows.

Our hybrid in-person and international remote workforce subjects us to certain operational challenges and risks and potential harm to our business.

We, and many of our third-party providers, operate a hybrid work environment in which a significant portion of our workforce works either in-person on a part-time basis or remotely on a permanent basis. As a result, we are subject to the challenges and risks of having a remote and hybrid workforce. For example, certain security systems in homes or other remote workplaces may be less secure than those used in our offices, which may subject us to increased security risks, including cybersecurity-related events or incidents, and expose us to risks of data or financial loss and associated disruptions to our business operations. Members of our workforce who work remotely may not have access to technology that is as robust as that in our offices, which could cause the networks, information systems, applications, and other tools available to those remote workers to be more limited or less reliable than in our offices. We may also be exposed to risks associated with the locations of remote workers, including compliance with local laws and regulations or exposure to compromised internet infrastructure. Allowing members of our workforce to work remotely may create intellectual property risk if employees create intellectual property on our behalf while residing in a jurisdiction with unenforced or uncertain intellectual property laws. Further, if employees fail to inform us of changes in their work location, we may be exposed to additional risks without our knowledge. Hybrid in-person as well as remote working may also subject us to other operational challenges and risks. For example, hybrid working arrangements may adversely affect our ability to recruit and retain personnel who prefer a fully remote or fully in-person work environment. Operating our business with both remote and in-person workers, or workers who work in flexible locations and on flexible schedules, could have a negative impact on our corporate culture, decrease the ability of our workforce to collaborate and communicate effectively, decrease innovation and productivity, or negatively affect workforce morale and retention rates. In addition, we expect to incur costs related to a hybrid workforce including, among other things, facilitating permanent remote work for a portion of our workforce and updating our offices to offer more collaborative workspaces. If we are unable to effectively operate a hybrid workforce, manage the cybersecurity and other risks of remote work, and maintain our corporate culture and workforce morale, our business could be harmed or otherwise negatively impacted.

Risks Related to Research, Development, Regulatory Approval and Commercialization

Our two most advanced product candidates are currently in early clinical development. We have never successfully completed any large-scale or pivotal clinical trials with our product candidates, and we may be unable to do so for any product candidates we develop.

As of the date of this prospectus, we have only two product candidates in clinical development. Our other product candidates are in preclinical development. We have not yet successfully completed any large-scale or pivotal clinical trials, obtained regulatory approvals, manufactured a commercial scale product (or arranged for a third party to do so on our behalf), or conducted sales and marketing activities necessary for successful commercialization of any of our product candidates. Our experience conducting clinical trials with our product candidates is limited. Aside from BBT001 and BBT002, our other product candidates will need to progress through IND-enabling studies and receive clearance or authorization from the FDA or a comparable foreign regulatory authority under an IND, CTA, or other submission prior to initiating clinical trial activities. We may not be able to submit INDs, CTAs, or other applications, or obtain the requisite clearance or authorization from applicable regulatory authorities, for any of our other product candidates on the timelines we expect, or at all. Even if we submit an IND, CTA, or other application for a product candidate, the FDA or a comparable foreign regulatory authority may not clear the IND, CTA, or other application, may request additional information, require amendments to the study protocol, or raise other issues, any of which may cause us to suspend our clinical development or delay the timeline for clinical trials. The timing of submissions of INDs, CTAs, or other applications for our product candidates will be dependent on the preclinical data, success of our manufacturing process, ongoing regulatory compliance, and ongoing safety, efficacy, and potency data. Commencing each of these clinical trials is subject to finalizing the trial design and protocol based on discussions with the FDA and comparable foreign regulatory authorities. Any feedback we receive from the FDA or comparable foreign regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs, the clinical endpoints selected, proposed indication or labeling, and the adequacy of data to support

approval, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- fail to obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements; or
- be required to have the product removed from the market after obtaining regulatory approval.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome. We or our collaborators may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

As of the date of this prospectus, we have only two product candidates in clinical development. Our other product candidates are in preclinical development. The risk that our product candidates fail to successfully proceed through clinical development is high. We expect it will be many years before we commercialize any product candidate, if ever. The product candidates we are developing are novel and unproven, which makes it difficult to accurately predict the challenges we may face with respect to our product candidates as they proceed through development. It is also impossible to predict whether our clinical trials will proceed through registrational trials and when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain.

Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a comparable foreign regulatory authority. Even after we make our submission, the FDA or comparable foreign regulatory authority could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our trial design, which may require us to complete additional studies or trials, amend our protocols, or impose stricter conditions on the commencement of clinical trials.

We expect to continue to rely in part on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive regulatory approval or commercialize our current and any future product candidates, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulators, such as the FDA or comparable foreign regulatory authorities, Institutional Review Boards (“IRBs”), or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or require that we modify or amend our clinical trial protocols;
- delays in reaching, or failing to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;

- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate, or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries;
- the cost of clinical trials may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a BLA;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability, efficacy, or potency concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability, efficacy, or potency, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon development of certain product candidates.

We have and may in the future experience participant withdrawals or discontinuations from our trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

We could also encounter delays if a clinical trial is suspended, put on clinical hold, or terminated by us, the IRBs of the institutions where such trials are being conducted, the FDA, or comparable foreign regulatory authorities, or if a clinical trial is recommended for suspension or termination by a data safety monitoring board or data monitoring committee (“DSMB”), for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our CROs to perform in accordance with GCPs or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues, or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also conduct preclinical and clinical research in collaboration with academic, pharmaceutical, and biotechnology entities in which we combine our development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, or the need to obtain agreement from multiple parties, and may increase our future costs and expenses.

Further, conducting clinical trials in foreign countries, as we are doing for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Our product development costs will increase if we experience delays in clinical testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations, and prospects.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates or obtain limited regulatory approval, our business will be substantially harmed.

All of our current product candidates and any future product candidates will be subject to extensive governmental regulations relating to research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing, sale, and distribution of products. Rigorous preclinical studies, clinical trials, and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product may be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain, and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them and any delay or failure in obtaining required approvals could adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the discretion of the regulatory authorities. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or elsewhere until we receive regulatory approval of our product candidates through a BLA from the FDA or similar marketing application in another jurisdiction. The FDA and other comparable foreign regulatory authorities may delay, limit, or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA or other comparable foreign regulatory authorities that any of our product candidates are safe, pure, and potent (or effective) for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the trial design, sample size, statistical plan, primary and secondary endpoints, surrogate endpoint for accelerated approval, or the conduct or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- the FDA or comparable foreign regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the benefits of any of our product candidates outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the data collected from preclinical studies and/or clinical trials of any of our product candidates may not be sufficient to support the submission of an IND, CTA, or other application for regulatory approval;

- an advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy ("REMS") and foreign regulatory authorities may require a risk management plan ("RMP") as a condition of approval for new products, among other additional requirements;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations; and
- the FDA or comparable foreign regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

Any of these regulatory authorities may also change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or comparable foreign regulatory authorities may require that we conduct additional clinical, preclinical, manufacturing validation, or quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or comparable foreign regulatory authorities for granting approval.

In addition, the FDA or comparable foreign regulatory authorities may approve a product candidate for fewer or more limited patient populations than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions, or contraindications, or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS, RMP, or comparable foreign risk management approaches. The FDA or comparable foreign regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Further, the FDA or comparable foreign regulatory authorities may respond to any BLA or comparable marketing application that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of any of our product candidates or any future product candidates.

Additionally, we expect that any product candidate that we develop with an autoinjector pen presentation, pre-filled syringe, or on-body device will be regulated as a combination product that consists of both a biologic and a medical device. Developing and obtaining regulatory approval for combination products can pose unique challenges because they involve components that are regulated under different types of regulatory requirements and potentially by different FDA centers. As a result, such product candidates may raise regulatory, policy, and review management challenges. Differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, AE reporting, promotion and advertising, user fees, and post-approval modifications. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing, and third-party reimbursement, and may in the future become subject to additional ones. The regulatory approval process varies among countries and may include all of the risks

associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval in foreign jurisdictions may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, financial condition, results of operations, and prospects.

The successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in a trial until its conclusion. We may not be able to initiate, continue, or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for any of our product candidates if we are unable to locate, enroll, and retain a sufficient number of eligible patients to participate in these clinical trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new treatments approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies; and
- other factors outside of our control, such as the effects of global economic conditions and volatility in the credit and financial markets, inflationary pressures, the Russian invasion of Ukraine, the conflicts in the Middle East, and other geopolitical conditions.

We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Other pharmaceutical companies with more resources and greater experience in research, development, and commercialization are targeting similar treatments, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, some of the diseases our product candidates are designed to address have existing treatments which may make it more difficult to recruit patients. Because the number of qualified clinical investigators and clinical trial sites is also limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites, and may delay or make it more difficult to fully enroll our

clinical trials. We also rely on CROs and clinical trial sites to enroll subjects in our clinical trials and, while we have agreements governing their services, we will have limited influence over their actual performance.

These factors may make it difficult for us to enroll and retain enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Positive results from preclinical studies and early clinical trials of our current or future product candidates are not necessarily predictive of the results of later clinical trials of our current or future product candidates. If we cannot replicate the positive results from our preclinical studies of our current or future product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for, and commercialize our current or future product candidates.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. In addition, the data from our preclinical comparison studies discussed in the section titled "Business" may not be replicated in clinical trials, and our competitors may advance different compounds than those we studied. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or potency or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of such product candidates. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Failures of products or product candidates that target the same target, or are being developed in the same indications, or have other similarities to our product candidates may result in a perception that our product candidates have similar defects or will experience similar failures. Our product candidates target chronic diseases and indications and may require repeat dosing – low titer anti-drug antibodies and other measures demonstrating low immunogenicity in early clinical trials that have shortened treatment periods may not reveal immunogenicity or other adverse effects that may emerge after repeat or extended dosing or in larger patient populations with greater heterogeneity. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our current or future product candidates, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Interim, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data from clinical trials that we may complete are further subject to the risk that one or

more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock. As a result, interim data should be viewed with caution until the final data are available, as they are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between topline, preliminary, or interim data and final data could significantly harm our business prospects.

Moreover, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our value in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically a significant volume of data and other information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations, or prospects.

Additional time may be required to obtain marketing authorizations for any product candidates that we develop as biologic-device combination products.

We expect our current injectable product candidates will be regulated as combination products, as the subcutaneous formulations of our product candidates may be designed to be administered by a patient using a low-volume autoinjector pen, pre-filled syringe, or on-body device marketed together with such product candidate, if approved. Development of a product candidate as a combination product candidate requires close coordination within the FDA and within comparable regulatory agencies for review of each of the biologic and device components that comprise the product and would typically be reviewed by different centers within the FDA if offered for use as standalone products. For example, the FDA's review of a marketing application for a biologic-device combination that has a primary mode of action as a biologic would likely be subject to a BLA with the Center for Biologics Evaluation and Research as the lead center, with coordination with the Center for Devices and Radiological Health for the review of the device component. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Furthermore, regulatory bodies like the FDA may require a human factors study, sometimes also known as a usability study, to evaluate how people interact with biologic-device combination products in real-world settings to ensure they can be used safely and effectively, and the requirement to conduct a human factors study may delay or prevent approval of a biologic-device combination product. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the marketing authorization application for underlying product candidate, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device, which may delay the approval of the combination product.

We may attempt to seek approval from the FDA for one or more of our product candidates through the use of the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek accelerated approval for one or more of our product candidates. Under the accelerated approval pathway, the FDA may approve a product candidate for a serious or life-threatening disease or condition with unmet medical need based on a determination that the product has an effect on a surrogate endpoint

that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's predicted clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. Products granted accelerated approval are subject to certain post-marketing requirements, which typically include a requirement to conduct one or more post-approval studies to confirm the clinical benefit of the product. In addition, during the pre-approval review period, FDA regulations require that sponsors of products granted accelerated approval submit copies of all promotional materials intended to be used within 120 days following regulatory approval. After 120 days following regulatory approval, unless otherwise informed by the FDA, the sponsor must submit all promotional materials at least 30 days prior to use.

There can be no assurance that we will be able to use the accelerated approval pathway or any other form of expedited development, review, or approval pathway for any of our product candidates. For example, the FDA may not agree with our conclusion that an endpoint we select is reasonably likely to predict clinical benefit, and thus the FDA may not agree that accelerated approval is appropriate based on that endpoint (even if the results on that endpoint are statistically significant). FDA may also disagree with the design of our confirmatory trial. Also, if any of our competitors receives full approval for an indication for which we are seeking accelerated approval before we receive accelerated approval for any one of our product candidates, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need, and our product candidate may become ineligible for accelerated approval. Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review, or approval.

A failure to obtain accelerated approval would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace. Even if we are able to obtain accelerated approval, if we do not complete the required post-approval studies, or if the FDA determines that the completed post-approval studies do not confirm clinical benefit, then FDA may withdraw approval of our product using expedited procedures.

We have sought Fast Track designation, and may in the future seek Fast Track or Breakthrough Designation for current or future product candidates, but we might not receive such designation, and even if we do, we may not maintain such designation. Such designation may not lead to faster development, regulatory review, or approval, and will not increase the likelihood that the product candidate will receive regulatory approval.

We have sought, but did not receive, Fast Track designation for one of our product candidates, and may in the future seek a Breakthrough Therapy or Fast Track designation for our current or future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biologics that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the

number of patients placed in ineffective control regimens. Drugs or biologics designated as Breakthrough Therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the marketing application is submitted to the FDA. The FDA also has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. New drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied.

The FDA has broad discretion as to whether or not to grant Breakthrough Therapy or Fast Track designation to any product candidate. Accordingly, even if we believe that a product candidate meets the criteria for designation as a Breakthrough Therapy or a Fast Track designation, the FDA may disagree and instead determine not to make such a designation. Even if we receive a Breakthrough Therapy or Fast Track designation, the receipt of that designation may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not increase the likelihood that such product candidate will receive approval by the FDA. Many product candidates that have received Breakthrough Therapy or Fast Track Designation have ultimately failed to obtain approval. In addition, even if a product candidate qualifies as a Breakthrough Therapy or for Fast Track designation, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Our approach to clinical development relies on developing product candidates across a number of I&I indications. We may not be successful in our efforts to discover additional product candidates or we may expend our limited resources to pursue a particular product candidate in specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Given our broad approach seeking to identify multiple novel targets in a wide variety of indications, we will need to carefully allocate our limited financial and managerial resources among our selected product candidates in certain selected indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. If we are unable to discover and develop additional product candidates, our ability to commercialize product candidates or partner product candidates may be negatively impacted. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Even if we are successful in obtaining approval for one of our product candidates, the approved product may not achieve broad market acceptance, and the revenue that we generate from the sales may be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, side effect profile, efficacy, potency, tolerability, cost and ease of administration, and other marketed benefits of our product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;

- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to such product candidates or to which we agree as part of a mandatory REMS or RMP or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy, potency, and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

The market opportunities for our product candidates and forecasts of market growth may not be accurate, and the actual market for our product candidates may be smaller than we estimate. Even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors' products, scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect in general, or as to their applicability to our business. Further, new trials may change the estimated incidence or prevalence of these diseases. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost, efficacy, and potency of competing therapies or therapies in development, acceptance by the medical community and patients, pricing, and reimbursement. The number of patients in the United States, other major markets, and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations, and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our programs may be delayed and our expenses may increase and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our programs may be delayed or never achieved and, as a result, our stock price may decline. Additionally, delays are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving the desired development milestones.

Use of our product candidates could be associated with side effects, AEs, or safety risks, which could cause us to suspend or discontinue clinical trials, cause us to abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label, or result in other significant negative consequences that could severely harm our business, results of operations, financial condition, and prospects.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that our current and future product candidates are safe, pure, and potent (or effective) for use in such product candidate's target indication. Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to generate desired safety, efficacy, and potency data despite having progressed through preclinical studies and initial clinical trials. It is not uncommon in the biopharmaceutical and biotechnology industries to suffer significant setbacks in advanced clinical trials due to lack of efficacy or potency or unacceptable safety issues, notwithstanding promising results in earlier trials.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The treatment-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, results of operations, financial condition, and prospects and may cause us to interrupt, delay, or abandon the development of any such product candidate or limit development to more narrow uses or subpopulation.

Patients in our ongoing and planned clinical trials may in the future suffer significant AEs or other side effects not observed in our preclinical studies or previous clinical trials. For example, while no serious adverse events ("SAEs") have been observed in clinical studies of BBT001 and BBT002 as of the data cutoff dates of December 5, 2025 and January 19, 2026, respectively, it is possible that testing in additional human subjects may reveal greater side effects in our clinical programs for BBT001 and BBT002 than observed in our clinical testing as of such data cutoff dates. Patients treated with our product candidates may also be undergoing other medical treatments, which can cause side effects or AEs that are unrelated to our product candidate, but may still impact the success of our clinical trials.

We, the FDA, other comparable foreign regulatory authorities, or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations, and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA or comparable foreign regulatory authorities could require us to adopt a REMS or RMP, as applicable, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring or distribution systems, and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Other potentially significant negative consequences include:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

Changes in product candidate manufacturing methods, manufacturing sites, formulation, or analytical methods may result in additional costs or delay, which could adversely affect our business, financial condition, results of operations, and prospects.

As product candidates are developed through preclinical studies to later-stage clinical trials toward approval and future commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, formulation, or analytical methods, are altered in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials or utilizing different analytical methods. Such changes also may require additional testing, or notification to, or authorization by, the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, or jeopardize our ability to commence product sales and generate revenue.

A variety of risks associated with conducting research and clinical trials abroad, including in Australia, China, Europe, Georgia, and New Zealand and seeking to market our product candidates internationally, could materially adversely affect our business, financial condition, results of operations, and prospects.

We are and plan to further globally develop our product candidates. In addition, our enrollment timelines for our product candidates depend on initiating clinical trial sites outside of the United States. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing standards with respect to data integrity;

- differing standards and requirements regarding privacy, data protection, and security for the conduct of clinical trials;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates to the patient at the relevant trial site abroad;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- changes to or the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions, tariffs, and restrictions on currency exchange or the transfer of funds;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing, workforce uncertainty, and managing foreign operations;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 ("FCPA") or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- challenges with obtaining any local supply of treatments or agents used with our product candidates, which are required by certain local clinical trial sites before conducting any study;
- business interruptions resulting from health epidemics or pandemics, or natural or man-made disasters, including earthquakes, tsunamis, fires, medical epidemics, or geo-political developments, including war and terrorism;
- failure to observe local or international GCPs, including data integrity, rules leading to rejection of safety or effectiveness data by regulatory authorities; and
- failure to observe local data privacy, data protection, or security rules leading to prohibitions on data transfer.

We are conducting and intend to conduct certain of our clinical trials globally. However, the FDA and comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

The healthy volunteer portions of our clinical trials for BBT001 and BBT002 were conducted in Australia and we have enrolled patients in our clinical trials for BBT001 and BBT002 at multiple sites in Australia, China, Georgia (BBT002 only), Europe, and New Zealand, in addition to our U.S. sites. In addition, we currently intend to conduct additional future clinical trials in a number of other countries around the world, which may include countries in the Middle East. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all, including as a basis for later-stage clinical trials. In cases where data from foreign clinical trials is intended to serve as the basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (among other prerequisites) (i) the data are

applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence in accordance with applicable GCPs; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign regulatory authority approval process, and we currently, and will need to continue to, contract with manufacturers who can meet our and all applicable FDA or comparable foreign regulatory authority requirements on an ongoing basis.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign authority approval process, and any contractors with which we contract for manufacturing must meet all applicable FDA or comparable foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or comparable foreign regulatory authority, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA or comparable foreign regulatory authority to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us (including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restrictions, and criminal prosecutions), delay approval of our product candidates, impair commercialization efforts, or increase our cost of goods, any of which would have an adverse effect on our business, financial condition, results of operations, and prospects. Our future success depends on our ability to manufacture our products, on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality and complying with applicable regulatory requirements. An inability to do so could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures.

We rely on third-party CMOs to manufacture and supply the product candidates for our clinical studies for BBT001 and BBT002 and we expect to rely on third-party CMOs for our future clinical trials.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured our product candidates ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates;

- reduced control over the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- international or multi-national activities that are related to business activities outside of our scope, but may have an impact on a CMO's ability to conduct business in a manner consistent with governmental or our regulatory and ethical standards; and
- our ability to synchronize operations and standards to ensure that all aspects of manufacturing are consistent without deviations across facilities.

Should we continue to use CMOs, we may not succeed in maintaining our relationships with our current CMOs or establishing relationships with additional or alternative CMOs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. If our CMOs were to cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate, or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Moreover, if we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, recall, operating restrictions, suits under the civil False Claims Act ("FCA"), corporate integrity agreements, consent decrees, or withdrawal of product approval.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we are unable to obtain, maintain, protect, defend, and enforce patent and other intellectual property coverage for our technology and product candidates, our competitors could develop and commercialize technology and product candidates similar or identical to ours, and our ability to commercialize our technology and product candidates may be adversely affected.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend, and enforce patents, trade secrets, and other intellectual property protection for our product candidates and proprietary technologies and their uses, as well as our ability to operate without infringing, misappropriating, or otherwise violating the

intellectual property and proprietary rights of others. We rely on patent, copyright, trade secret, and trademark laws in the United States and certain other countries to protect our proprietary technology. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies, and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties, but the efforts we and our current and future licensors take to protect our intellectual property may provide only limited protection. In particular, the development of our product candidates and technology is at an early stage and consequently, our patent portfolio is also at an early stage. Presently, our patent portfolio is pending in prosecution, and we do not own or in-license any issued patents. In addition, given the early stage of our patent portfolio, we anticipate most patents not to issue from our currently owned or in-licensed patent applications for at least four years. There can be no assurance that we or our current and future licensors will obtain any issued patents or that any issued patents we or our current and future licensors obtain will provide us with any competitive advantage. Any failure to obtain adequate patent protection for our product candidates and technology would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our current and future licensors will result in additional patents being issued or that any such issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts in the United States and abroad. The degree of future protection for our intellectual property and proprietary rights, and the rights of our current and future licensors, is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates and technology could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign jurisdictions, or those of our current and future licensors, will be considered patentable by the United States Patent and Trademark Office (“USPTO”), courts in the United States, or by the patent offices and courts in foreign countries, nor can we be certain that any issued claims will not be found invalid or unenforceable if challenged. Additionally, our provisional applications may never result in issued patents. A U.S. provisional patent application expires 12 months from its filing date, and its subject matter can only be claimed in an issued patent if, among other things, we file a non-provisional patent application making a valid priority claim to that provisional patent application before it expires. If we do not timely file a non-provisional patent application, we may lose the benefit of the priority dates of our provisional patent application, and intervening prior art may jeopardize patent protection on the inventions disclosed in such a provisional patent application. While we intend to timely file non-provisional patent applications claiming the benefit of the priority dates of our provisional patent applications, and otherwise diligently prosecute our patent rights, we cannot predict whether any of our current and future patent applications for our product candidates and technology will result in the issuance of patents that effectively protect our product candidates and technology. Additionally, our owned pending PCT patent applications are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. If we or our licensor do not successfully obtain patent protection, or if the scope of the patent protection we or our licensor obtain is not sufficiently broad, valid, and enforceable, we may be unable to prevent others from using our technology, developing or commercializing similar or identical technology and products, or marketing competing products and technologies. Any failure to obtain or maintain patent protection with respect to our technology and product candidates would have a material adverse effect on our business, financial condition, results of operations, and prospects.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current and future licensors or potential future collaborators will be successful in protecting our product candidates and technology by obtaining, enforcing, and defending adequate patent coverage. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, narrowed in scope, or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates and limiting the scope of our protection in countries outside the United States.

The patent prosecution process is also expensive and time-consuming, and we and our licensor may not be able to file, and prosecute, maintain, or license all necessary or desirable patent applications or to maintain, defend, and enforce patents and patents that may issue based on pending patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our licensor will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties, including our competitors, from using any of our technology that is in the public domain to compete with our technology and product candidates.

Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If the scope of any patent protection that we or our licensors obtain is not sufficiently broad, or if we or our licensors lose any of our patent protection, such ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of any patent rights are highly uncertain. Presently, our patent

portfolio is pending in prosecution, and we do not own or in-license any issued patents. In addition, given the early stage of our patent portfolio, we anticipate most patents not to issue from our currently owned or in-licensed patent applications for at least four years. Our pending and future patent applications and those of our licensor may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates or otherwise provide any commercial advantage.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Our competitors or other third parties may avail themselves of safe harbor under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) to conduct research and clinical trials and may be able to circumvent our or our licensors' patent rights by developing similar or alternative technologies or products in a non-infringing manner. Any future potential patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed, revoked, rendered unenforceable, or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will ultimately be protectable or remain protected by valid and enforceable potential future patents. Our competitors or other third parties may be able to circumvent our future potential patents or those of our licensor by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

While we believe our owned and in-licensed intellectual property allows us to pursue our current development programs, several companies are pursuing alternative drug candidates for immunology and inflammatory disorders and have built intellectual property around these approaches and methods. In addition, we may not be aware of all third-party intellectual property rights potentially relating to our technology and product candidates. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we and our licensor cannot be certain that we or our licensor was the first to make the inventions claimed in any owned or any licensed potential future patents or pending patent applications, or that we or our licensor was the first to file for patent protection of such inventions. If a third party can establish that we or our licensor was not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. Furthermore, applications filed before November 29, 2000 and certain applications filed on or after that date for which proper nonpublication requests are filed and that will not be filed outside the United States may remain confidential until a patent issues.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and the inventorship, ownership, scope, validity, or enforceability of our potential future patents or the potential future patents of our licensor may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, reissue, interferences, post-grant review ("PGR") and *inter partes* review ("IPR"), or other similar proceedings challenging any patents that we may own or in-license. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our potential future owned patents or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, our potential future owned patents or licensed patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. Moreover, our potential future patents or the potential future patents of our licensor may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our potential future patents and current and potential future patent applications and those of our licensor. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could

limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our potential future patents and current and potential future patent applications or the potential future patents and current and potential future patent applications of our licensor is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating, or otherwise violating patents and other intellectual property and proprietary rights of third parties. Claims by third parties that we infringe, misappropriate, or otherwise violate their intellectual property or proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts and could have a material adverse effect on the success of our business.

Our commercial success depends in part on avoiding infringement, misappropriation, or other violation of the patents, intellectual property, and proprietary rights of third parties. However, our research, development, and commercialization activities may be subject to claims that we infringe patents owned or controlled by third parties. Other entities may have or obtain patents that could limit our ability to make, use, sell, offer for sale, or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings, and PGR proceedings before the USPTO and corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. Given the vast number of patents in our field of technology, we cannot be certain or guarantee that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement, misappropriation, or other violation of the patent or other intellectual property rights of third parties. If any third-party claims that we infringe, misappropriate, or otherwise violate any of the above-referenced patent rights or any other patent rights, such claims would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability and damages to third parties, including treble damages if we are found to willfully infringe third-party intellectual property; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of infringement, misappropriation, or other violation of patent or other intellectual property rights against us as of the date of this prospectus, there can be no assurance that we will not be subject to such claims in the future that could prevent our product candidates from being marketed. Furthermore, we may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our product candidates and technology. In addition, we may incorrectly conclude that a third-

party patent is invalid, unenforceable, or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates and technology. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we or our licensor was the first to make the inventions claimed in any owned or licensed potential future patents or pending patent applications or that we or our licensor was first to file a patent application related to our product candidates and technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates and technology may infringe. In addition, identification of third-party patent rights that may be relevant to our product candidates and technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale, or import our product candidates that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our product candidates and technology infringes upon these patents.

Third parties may assert claims of patent infringement against us directed at any of our product candidates based on our existing patent applications or patents that may be granted in the future, regardless of their merit. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary, and we could encounter delays in the introductions of our product candidates while we attempt to develop alternative technology and product candidates to avoid infringing third-party intellectual property rights. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses on commercially acceptable terms, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition, and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects.

Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. There is no assurance that a court would find in our favor on questions of infringement, validity, ownership, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other future product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the

invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent or find that our technology did not infringe any such claims. Further, even if we were successful in defending against any such claims, such claims could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings, the third parties may assert a claim of patent infringement directed at our product candidates.

In addition, our agreements with some of our suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Many pharmaceutical companies, biotechnology companies, and academic institutions may have patents and patent applications potentially relevant to our business. We may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders, for example, in order to avoid infringing these third-party patents. We may also require licenses from third parties for certain technologies for use with future product candidates. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates and technology at a reasonable cost or on commercially reasonable terms, or at all. Any in-licenses we are able to obtain may be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, or could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These more established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our potential future patents or our current and future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our potential future patents or those of our current and future licensors could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, our potential future patents also may become involved in inventorship, priority, or validity disputes. In a patent infringement proceeding, a court may decide that a patent we may own or in-license is not valid, is unenforceable, or is not infringed. If we or any of our current or future licensors were to initiate legal proceedings against a third party to enforce our potential future patent or the patent of our current or future licensors directed to one of our product candidates, the defendant could counterclaim that such patent is invalid or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, failure to claim patent-eligible subject matter, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading or inconsistent statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in the revocation or cancellation of, shortening the term of, or amendment to our potential future patents, or those of our current and future licensors, in such a way that they no longer cover our product candidates or technology or prevent third parties from competing with our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our current or future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we or our current or future licensors are aware, but which we or our current or future licensors do not believe affects the validity or enforceability of a claim in our potential future patents and patent applications or the potential future patents and patent applications of our current or future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current and future product candidates and technology. In any patent infringement proceeding, there is a risk that a court will decide that a current or future patent of ours or our current or future licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patent is upheld, the court will construe such patent's claims narrowly or decide that we do not have the right to stop the other party from using the technology at issue on the grounds that our or our current or future licensors' potential future patent claims do not cover the invention, or decide that the other party's use of our or our current or future licensors' potential future patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

In addition, if the breadth or strength of protection provided by our patent applications or potential future patents or the potential future patents and patent applications of our current and future licensors is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct

such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own potential future patented product candidates and practicing our own potential future patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or the patents or patent applications of our licensor. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to the technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industries involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our potential future owned and licensed patents and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of current or future issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our potential future patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how patent laws in the United States are interpreted. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. In addition to heightened patentability requirements, the interpretation

by the Supreme Court and Federal Circuit of biosimilar product approval under the Biologics Price Competition and Innovation Act of 2009 has evolved in recent years, affecting the "patent dance" provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our patents that may issue in the future and the patents we might obtain or license in the future.

In 2012, the European Union Patent Package, or the EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023, and has become a common forum for challenging European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our owned or licensed potential future European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our owned or licensed potential future European patents from the UPC but doing so may preclude us from realizing the benefits of the UPC. Moreover, if the patent owner of our owned or licensed future European patents does not meet all of the formalities and requirements for opt-out under the UPC, any potential future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our owned or licensed potential future European patents and allow for the possibility of a competitor to obtain a pan-European injunction in UPC member states. Such a loss of potential future European patent protection could have a material adverse impact on our business and our ability to commercialize our current or future platform technologies and any of our current or future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations, and prospects in Europe. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

We or our current or future licensors may be subject to claims challenging the inventorship or ownership of our owned patent applications or in-licensed patent rights and other intellectual property.

We or our current or future licensors may be subject to claims that former employees or other third parties have an ownership interest in our owned or in-licensed patent applications, potential future patents, trade secrets, or other intellectual property rights as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issued thereon being unenforceable. We or our current or future licensors may have inventorship disputes arising from conflicting obligations of employees, consultants or other third parties who are involved in developing our current or future product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our or our current or future licensors' patent applications, potential future patents, trade secrets, or other intellectual property rights. If we or our current or future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property rights that are important to our current or future product candidates. It may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees, and any litigation or the threat of litigation may adversely affect our reputation or ability to hire employees or contract with independent contractors.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our current or future in-licensed patents, they may be able to license

such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

In addition, while it is our policy to require our employees, consultants, advisors, contractors, and other third parties who may be involved in the conception or development of intellectual property rights to execute agreements assigning such intellectual property rights to us, we or our licensor may be unsuccessful in executing such agreements with each party who, in fact, conceives or develops intellectual property rights that we regard as our own. The assignment of intellectual property rights may not be self-executing or sufficient in scope, or the assignment agreements may be breached, and we or our current or future licensors may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property rights. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party and thus an agreement with us or our current or future licensors may be ineffective in perfecting ownership of inventions developed by that individual. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained in the future, once the patent life has expired, we may be open to competition from competitive products including generics or biosimilars. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our portfolio of patent applications and potential future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and equivalent extensions outside of the United States for our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA regulatory approval of our product candidates, one or more of our potential future U.S. patents or those of our current or future licensors may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it, or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

However, if we own or in-license patents in the future, we may not be granted any extensions for which we apply in the United States or any other foreign jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a potential future patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If approved, our product candidates that are regulated as biological products (biologics) may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), was enacted as part of the Patient Protection and Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable with an FDA-licensed reference biologic product. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product or sponsor's data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material effect on the future commercial prospects for our biological product candidates.

We believe that any of the current product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our current or potential future product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

If competitors are able to obtain regulatory approval for biosimilars referencing our current or potential future product candidates, such product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our current or future product candidates in these other regions could adversely affect our business in those regions. To the extent that we do not receive any anticipated periods of regulatory exclusivity for our current or potential future product candidates, it could adversely affect our business, financial condition, results of operations, and prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, enforcing, and defending patents in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our current or future licensors' inventions in all countries outside the United States, even in jurisdictions where we or our current or future licensors do pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have potential future patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates,

and our potential future patents, the potential future patents of our current or future licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our potential future patents or our current or future licensors' potential future patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and China, may have a heightened standard for patentability compared to the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we and our current or future licensors may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can potentially be secured in the United States and other jurisdictions. Proceedings to enforce our or our current or future licensors' potential future patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our potential future patents or those of our current or future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our current or future licensors at risk of not issuing, and could provoke third parties to assert claims against us. We or our current or future licensors may not prevail in any lawsuits that we or our current or future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner or exclusive licensee may be compelled to grant licenses to third parties, including governmental agencies. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner or exclusive licensee may have limited remedies in certain circumstances, which could materially diminish the value of such a patent. If we or our current or future licensors are forced to grant a license to third parties with respect to any potential future patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Presently, our patent portfolio is pending in prosecution, and we do not own or in-license any issued patents. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees will be due to the USPTO and various foreign patent offices outside of the United States at various points over the lifetime of our owned patent applications and potential future patents and/or those of our current and future licensors. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our current and future licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse or non-compliance with such requirements can sometimes be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business, financial condition, and results of operations.

The USPTO and various foreign patent offices outside of the United States require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner, and the nature of the subject matter to be

disclosed, for example, items related to national security or national defense. In some, but not all cases, for example in China, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may also be dependent on our current and future licensors to take the necessary actions to comply with these requirements with respect to our in-licensed intellectual property.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products, if commercialized, but we do not yet own a U.S. registered trademark for our corporate name, "Bambusa Therapeutics." Our future trademark applications in the United States and in foreign jurisdictions may not be allowed or may subsequently be opposed. Once filed and registered, our potential future trademarks or trade names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing, misappropriating, or violating on other marks. We may not be able to protect our rights to these potential future trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As a means to enforce our potential future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings, which can be expensive and time-consuming. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our potential future registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Additionally, our potential future registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our potential future trademark applications and registrations, and our potential future trademarks may not survive such proceedings. If we do not secure registrations for our potential future trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any name we may propose to use with any of our current or future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate, or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection to protect the intellectual property underlying our product candidates and technology, we also rely on the protection of our trade secrets, including unpatented know-how, technology, and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties who have access to such information, and confidential information and invention assignment agreements with employees and other third parties involved in the development of intellectual property, we cannot guarantee that we and our current and future licensors have entered into such agreements with each party that may have had access to our trade secrets or proprietary information or that has been involved in the development of intellectual property. Additionally, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

We may also need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. In addition, competitors could purchase our products, if commercialized, and attempt to replicate or improve some or all of the competitive advantages we derive from our development efforts, reverse engineer our proprietary technologies, and design their products around our protected technologies or develop their own competitive technologies that fall outside of our intellectual property rights.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but such security measures may be breached, and we may not have adequate remedies for any such breach. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees, consultants, advisors, or contractors have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property, and other third parties. We may become subject to litigation where a third party asserts that we or our employees or other third parties inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful

in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition, and prospects.

We may be subject to claims asserting that we have wrongfully hired an employee from our competitors or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees, or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients, or that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

In addition, former employees, consultants, advisors, or other third parties may assert ownership right in our own or in-licensed patent applications or potential future patents. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in claims of potential future patents being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and products, without payment to us, or could limit the duration of the patent protection covering our product candidates or technology. Such challenges may also result in our inability to develop, manufacture, or commercialize our product candidates or technology without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our own or in-licensed patent applications or potential future patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We have entered into a license agreement with BioNTech Zhuhai pursuant to which we have acquired the exclusive right to certain patent applications relating to our product candidates and technology and have entered into various other agreements with BioNTech Zhuhai and other third parties. We may enter into additional license agreements in the future with other third parties to advance our research or allow commercialization of our product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patent applications or potential future patents will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our current and future licensors fail to prosecute,

maintain, enforce, and defend such patent applications or potential future patents, or lose rights to those patent applications or potential future patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected.

Our current and future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensor is not the sole and exclusive owner of the patent applications that we in-licensed. If other third parties have ownership rights to our in-licensed patent applications, they may be able to license such patent applications to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Additionally, our licenses may be subject to certain rights of third parties, and, as a result, our current and future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Our current license imposes, and our future licenses likely will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with any of these or other obligations in our current and future license agreements, we may be required to pay damages and current and future licensors may have the right to terminate the licenses. Termination by the current and future licensors would cause us to lose valuable rights, and could prevent us from developing and commercializing our product candidates and proprietary technologies. Our business would be seriously harmed if any current or future licenses terminate, if the current and future licensors fail to abide by the terms of the license, if the current and future licensors fails to enforce licensed patents against infringing third parties, if the current and future licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. If our current and future license agreements terminate, or we experience a reduction or elimination of licensed rights under these agreements, we may have to negotiate new or reinstated licenses with less favorable terms or we may not have sufficient intellectual property rights to operate our business.

Moreover, our current and future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensors' rights. In addition, while we cannot currently determine the amount of royalty obligations we would be required to pay on the sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize any product candidates, we may be unable to achieve or maintain profitability.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensor, or if any of our material license agreements are terminated, we could lose license rights that are important to our business.

Disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate, or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense potential future patents and other rights to third parties;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement or lack of involvement in the prosecution, defense, and enforcement of potential future licensed patents and our licensors' overall enforcement strategy of potential future issued patents;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the amounts of royalties, milestones, or other payments due under the license agreement;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our collaborators and partners; and
- the priority of invention of the technology in potential future patents.

Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have in-licensed, or in-license in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current or future licensing arrangements on commercially acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property rights, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our current and potential future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing our ability to develop and commercialize our product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying potential future patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Alternatively, current and future licensors could abandon the patent

rights, which would reduce the barrier to entry into the market. If these in-licenses are terminated, or if the potential future in-licensed patents fail to provide the intended exclusivity, and if competitors circumvent any regulatory exclusivity, competitors would have the freedom to market products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. For example, we may agree to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects, and we may be required to identify and license replacement technology from third parties, which may not be available on reasonable terms, if at all.

The patent protection and prosecution of patent applications and potential future patents for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance, and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patent applications and potential future patents relating to our product candidates are controlled by our licensor, potential licensors, or collaboration partners. If any of our licensor, potential licensors, or collaboration partners fail to prosecute, maintain, and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patent applications and potential future patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected, and we may not be able to prevent competitors from making, using, and selling competing products. In addition, even where we have the right to control patent prosecution of patent applications and potential future patents we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors, and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may file or in-license patent applications that were generated through the use of U.S. government funding or grants, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercises its march-in rights in such intellectual property rights generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that

provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of current and future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patent applications or potential future patents that we own or license;
- we or our current or future licensors or collaborators might not have been the first to make the inventions covered by the patent applications or potential future patents that we own or license now or may own or license in the future;
- we or our current or future licensors or collaborators might not have been the first to file patent applications or potential future patents covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned or licensed intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- potential future issued patents that we may hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a nonexclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these or similar events occur, it could significantly harm our business, results of operations, and prospects.

Risks Related to Government Regulation

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which will require significant resources, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unexpected issues with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, AE reporting, advertising, promotion, sampling, import,

export, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, potency, and other post-market information, including both federal and state requirements in the United States and similar requirements imposed by comparable foreign regulatory authorities, such as continued compliance with cGMP (and comparable foreign requirements) and GCP requirements for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs and other applicable regulations and standards.

Any regulatory approvals that we receive for our product candidates may be subject to limitations for the approved indications, including, for example, requirements for post-marketing testing, including post-approval clinical trials, and safety monitoring requirements. The FDA may also require a REMS program as a condition of approval of our product candidates, which could require long-term patient follow-up, a medication guide, physician communication plans, or additional requirements to ensure patient safety, such as restricted distribution methods, patient registries, and other risk mitigation tools. In some cases, the FDA may require a black box warning.

If we or our contractors fail to comply with regulatory requirements and standards or if problems occur after the product reaches the market, the FDA may impose consent decrees, withdraw our approval, recall of our products, or other restrictions. Unanticipated SAEs may result in revisions to the approved labeling to add new safety information, require post-market studies or clinical trials to assess new safety risks, or require distribution restrictions or other restrictions under a REMS program. Other potential consequences include without limitation:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue, require significant time and resources to address the issues and to implement corrective actions, and increase our exposure to product liability. The policies of the FDA and other comparable regulatory authorities may change over time and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates, or increase our compliance burden. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative actions in the United States or in other jurisdictions. If we are slow or unable to adapt to regulatory changes or new requirements or policies, or if we or our contractors are not able to maintain regulatory compliance, we may not be able to commercialize our products and we may not achieve or sustain profitability.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The BPCIA created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for

the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of its product.

We believe that any of our future product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products will depend on a number of specific marketplace and regulatory factors that are still developing. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

Even if we receive regulatory approval for our current or future product candidates in the United States, we may never receive regulatory approval to market our product candidates outside of the United States.

Before we can commercialize or market any of our product candidates, we must obtain the requisite regulatory approval from applicable regulatory authorities in that jurisdiction. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. We plan to seek regulatory approval of our current or future product candidates outside of the United States in the future. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy, potency, and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The regulatory approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of any of our product candidates in certain countries. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations, and prospects. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

The FDA and other comparable regulatory authorities actively enforce laws prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising, and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet, and off-label promotion. Any regulatory approval that the FDA grants is limited to the specific indications for which the biologic product was approved or deemed to be safe, pure, and potent (or effective) by the FDA. While healthcare professionals in the United States may use or prescribe drugs for uses that are not described in the approved drug labeling, subject to state law, manufacturers may only promote or market drug products for uses within the scope of the FDA approval, consistent with the FDA-approved labeling. Similar requirements may apply in foreign jurisdictions.

If we, or our contractors or agents, are found to have promoted any approved products for off-label uses, we may become subject to significant liability. The U.S. federal government can impose significant civil and criminal fines and penalties against companies for alleged improper promotion of off-label use, including consent decrees or permanent injunctions. If we cannot successfully manage the promotion of any approved product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition. In addition, any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for uses for which they are not approved, which could lead to product liability suits that may require significant resources and that could harm our reputation.

Even if we are able to commercialize any product candidates, those products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which could harm our business.

The regulations that govern regulatory approvals, pricing, and reimbursement for new biologics vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be certain that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will continue to be available for any product that we may develop that receives coverage and adequate reimbursement from one or more third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Accordingly, coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which treatments they will cover and the amount of reimbursement. These groups have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-

party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical, and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. Specifically, the Centers for Medicare & Medicaid Services ("CMS"), imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. The Department of Health and Human Services ("HHS") has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years and single-source biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year, up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program, and potential negative pricing effects in other market channels, on a per unit basis.

In June 2026, the CMS issued a proposed rule that would codify policies established in guidance documents for the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and beyond. CMS plans to release guidance in 2026 to implement policies related to the effectuation of the maximum fair price ("MFP") for the Medicare Drug Price Negotiation Program for 2028, consistent with sections 11001(c) and 11002(c) of the Inflation Reduction Act. This guidance will specify the requirements that will be applicable to manufacturers and Part B providers for the effectuation of the MFP in 2028. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through which U.S. patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs or that increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, our ability to set adequate pricing for new drugs to recover research and development costs, ability to attract potential investors and potential buyers in the future, or the pricing of our products, if approved, in the United States and in foreign countries. The impact of these and future measures implemented by the government on us and the pharmaceutical industry as a whole is unclear.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access, marketing cost disclosure, drug price reporting, other transparency measures, and other measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products, if approved, or put pressure on our pricing, which could negatively affect our business, financial condition, results of operations, and prospects.

Additionally, there may be significant delays in obtaining coverage and reimbursement for newly approved therapies, and coverage may be more limited than the purposes for which the therapies are approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a therapy will be paid for in all cases or at a rate that covers our costs, including costs related to research and

development, manufacturing, and sale and distribution efforts. Interim reimbursement levels for new therapies, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the therapies and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost therapies, and may be incorporated into existing payments for other services. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

We expect to experience pricing pressures in connection with the sale of all of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives, and additional legislative changes. Net prices for therapies may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of therapies from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Recently enacted legislation, future legislation, and other healthcare reform measures may increase the difficulty and cost for us to obtain regulatory approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved therapies and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (“ACA”) was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken. Further, on July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS, and related agencies. These actions, presently directed by executive orders, memoranda, or proposed rules from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the manufacturers to offer most-favored nation pricing equal to or lower than those paid in other developed nations for certain prescription drugs under Medicaid and for certain newly launched products across all market channels in the United States, with additional mandates for direct-to-patient discounts through a direct to consumer platform such as TrumpRx and repatriation of certain foreign revenues. In late 2025, HHS proposed three payment models that would test most-favored nation pricing in Medicaid, Medicare Part D, and Medicare Part B. On November 6, 2025, CMS announced the “GENErating cost

Reductions fOr U.S." ("GENEROUS") model under which manufacturers can provide most-favored nation pricing to state Medicaid agencies on a voluntary basis. On December 19, 2025, CMS published proposed rules for two mandatory drug pricing models for Medicare: the "Global Benchmark for Efficient Drug Pricing" ("GLOBE") model for products payable under Medicare Part B and the "Guarding U.S. Medicare Against Rising Drug Costs" ("GUARD") model for products covered under Medicare Part D. If GLOBE and GUARD are finalized, pharmaceutical manufacturers would be required to pay most-favored nation-based rebates on eligible products for 25% of eligible Medicare beneficiaries during the applicable testing period.

In addition, the current administration has taken other action that could affect our business such as (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again ("MAHA") Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand most-favored nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's *Loper Bright* decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass healthcare related legislation that could impact the approval process and make changes to the Medicare Drug Price Negotiation Program.

We expect these and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved. Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future, including by requiring changes to our manufacturing arrangements, modifications to product labeling, increasing the difficulty and cost for our drug supply chain and to commercialize our product candidates, if approved, and the pricing of our products, any of which could adversely affect the operation of our business.

Our relationships with healthcare providers, physicians, and third-party payors may be subject to applicable anti-kickback, fraud, and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Any arrangements we may have with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. Such laws and regulations may constrain the business or financial arrangements and relationships through which we research and, if approved, sell, market and distribute our product candidates. In particular, the research of our product candidates, as well as the promotion, sales, marketing and business arrangements of our product candidates, is subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or

covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;

- the federal civil and criminal false claims laws, including the FCA, which prohibit individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the healthcare fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;

- furthermore, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, also imposes obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their respective subcontractors that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the civil monetary penalties statute, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs that may be used in the calculation of reimbursement or discounts on approved products;

- the federal Physician Payments Sunshine Act and its implementing regulations, which require applicable manufacturers of covered drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners) and teaching

hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive licensing, record keeping, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state, and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties, and settlements in the healthcare industry. Ensuring that business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages, and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, financial condition, results of operations, and prospects.

Changes in U.S. policy that impose substantial changes to fiscal, tax, healthcare, trade, and other federal policies may adversely affect our business.

Changes to U.S. policy implemented by the U.S. Congress and various executive orders issued by the current administrations can significantly impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation, and other areas. For example, budget cuts and reduction in federal funding and federal workforce can impact the normal operations and priorities of agencies, like the FDA. In addition, the current presidential administration has announced new tariffs on imported materials and goods from certain foreign countries, including Canada, Mexico, and China. It is not possible to predict the outcome of such congressional, executive, or regulatory activity, any of which could adversely affect us. Similarly, we cannot predict whether pending or future federal or state legislation or court proceedings will change various aspects of current government programs, nor can we predict the impact any changes of this nature will have on our business operations or financial results, but the effects could be materially adverse. In addition, changes in the leadership of the FDA and other federal agencies under the current presidential

administration may result in changes in the funding, operations, and policies of the FDA and other federal agencies, which may negatively impact, among other things, our clinical development plans, timelines, and the cost of product development.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about clinical development and the diseases that our product candidates are being developed to treat. We may utilize appropriate social media, such as LinkedIn, in connection with communicating business updates. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged AE during a clinical trial. When disclosures of this nature occur, we may fail to monitor and comply with applicable AE reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

We are subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws. Anti-corruption laws generally prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector.

We expect our non-U.S. activities to increase over time, including the engagement of third parties for clinical trials or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. persons, as well as their employees, agents, and other collaborators, from paying, offering, authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate, and other related parties for the purpose of influencing any act or decision of the foreign entity or to obtain, retain, or direct business. The FCPA also obligates companies whose securities are publicly listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all of the company's transactions, including those of its international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

Export control and economic sanctions laws may restrict, or even prohibit, the provision of certain items, technology, and services to countries, governments, and persons targeted by sanctions programs. Governmental regulation of the import or export of our product candidates, or our failure to obtain any required import or export authorization for our product candidates, when applicable, could harm our operations. If we further expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates

outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with Trade Laws may result in substantial civil and criminal fines and penalties, imprisonment, the loss of trade privileges, suspension or debarment from government contracting, reputational harm, and other consequences. The U.S. Securities and Exchange Commission ("SEC") also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could adversely affect our business, financial condition, results of operations, and prospects.

We and our current and future CMOs are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our future commercialization efforts, research and development efforts, and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws, and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures used by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case, and we may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state, federal, or other applicable authorities may curtail our use of certain materials or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes or our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Further, the current presidential administration has undertaken efforts to reduce the size and spending of the federal government. As part of this initiative, the administration has taken action aimed at reducing the workforce of the federal government and eliminating other expenditures, such as facility leases used by the federal government and its component agencies. A consequence of these developments and other actions taken by the current presidential administration generally could be reduced resources, employees, and contractors at the FDA. In addition, these efforts have led to a number of experienced government officials being fired, resigning from, or otherwise departing government service, including many with significant institutional knowledge.

Disruptions at the FDA and other agencies may also slow the time necessary for new therapies to be reviewed or approved by necessary government agencies, which would adversely affect our business, financial condition, results of operations, and prospects. For example, over the last several years, the U.S. government has shut down several times, including most recently for an extended period in 2025, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If another prolonged government shutdown occurs or there are other changes which limit the FDA's ability to perform its necessary activities in a timely

manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Data Privacy, Data Protection, and Security

If our information technology systems, or those used by our CROs, CMOs, clinical sites, or other vendors, contractors, or consultants with whom we work, or our data, are or were compromised or otherwise insufficient, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or action, litigation, fines and penalties, disruptions of our business operations, reputational harm, and other adverse consequences.

In the ordinary course of our business, we, and the third parties with whom we work, collect, store, retain, use, disclose, transfer, transmit, and otherwise process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information, which we collectively refer to as sensitive data. As a result, we and the third parties with whom we work face a variety of evolving threats that could cause security breaches or incidents. Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work.

Our information technology systems and those of our CROs, CMOs, clinical sites, and other third parties with whom we work are vulnerable to cyberattacks, computer viruses, bugs, worms or other malicious codes, malware (including as a result of advanced persistent threat intrusions) and other attacks by computer hackers, brute force attacks, application security attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks facilitated or enhanced by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. Remote work has increased these risks to our information technology systems and sensitive data, as our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations.

These types of threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of sensitive data, loss of income, significant extra expenses to restore data or systems, reputational loss, and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of attacks for geopolitical reasons, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to continue our research and development efforts or produce, sell, and distribute our product candidates, if approved. Third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Furthermore, future business transactions (such as acquisitions) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in the systems and technologies of any acquired entities. Additionally, we may discover security-related issues that were not found

during due diligence of such acquired entities, and it may be difficult to integrate companies into our information technology environment and security program.

It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security breach or incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security breach or incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

In addition, our reliance on third parties could introduce new security risks and vulnerabilities. We rely on third parties and third-party technologies to operate critical business systems and to collect, store, retain, use, disclose, transfer, transmit, and otherwise process sensitive data in a variety of contexts, including cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third-party CROs and CMOs to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place. If our third-party service partners experience a security breach or incident or other security-related disruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service partners fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover any such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

We have implemented measures designed to identify, protect, detect, respond to, and recover from vulnerabilities within our information systems, including those related to hardware, software, and third-party providers. Despite our efforts, they may not be sufficient and we may not detect and remediate all such vulnerabilities including on a timely basis. There can also be no assurance that our security risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with, or effective in protecting our systems and sensitive information. In some cases, we have and may in the future experience delays in developing and deploying necessary remediation measures and security patches. These undetected or unaddressed vulnerabilities could be exploited, potentially leading to security breaches or incidents, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. The introduction of AI has increased the sophistication of incoming attacks and threat actors can evolve more rapidly than the tools meant to protect against them. As such, evolving threats pose a risk to the integrity of our data and cyber infrastructure.

Any of the previously identified or similar threats may cause a security breach or incident or other security-related disruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption or disclosure of, or access to, our sensitive data or our information technology systems, or those of the third parties with whom we work. A security breach or incident or other security-related disruption could disrupt our ability (and that of third parties with whom we work) to provide our services, including clinical trials, or continue our target discovery programs.

The costs related to significant security breaches or incidents, or other security-related disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites, and other vendors, contractors, and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

If a breach or incident of this nature was to occur, it could result in a disruption of our business and operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any disruption or security breach or incident could result in the loss of or damage to our sensitive data or applications, or inappropriate disclosure of sensitive data, and could delay development of any product candidates and cause us to incur liability. Applicable privacy, data protection, or security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, future customers, regulators, and investors, of security breaches or incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security breach or incident or are perceived to have experienced a security breach or incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements or oversight, restrictions on processing sensitive data, litigation (including class actions), significant incident response, system restoration or remediation and future compliance costs, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, financial loss, and other similar harms. Security breaches or incidents and material attendant consequences may negatively impact our ability to grow and operate our business and may result in a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

We and the third parties with whom we work are and may become subject to stringent and evolving U.S. and foreign laws, regulations and rules, and contractual obligations, industry standards, policies, and other obligations related to privacy, data protection, or security. Any actual or perceived failure to comply with these obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation (including class claims), negative publicity, or other adverse consequences that could negatively affect our operating results and business.

In the ordinary course of business, we and our partners collect, store, retain, use, disclose, transfer, transmit, and otherwise process sensitive data. As a result, we and our partners are or may become subject to numerous data privacy and security obligations, such as various federal, state, and foreign laws, rules and regulations, and binding guidance, industry standards, external and internal privacy and security policies and notices, contractual requirements, and other obligations relating to data privacy, data protection, and security. In the United States, numerous federal, state, and local governments have enacted various laws and regulations, including state data breach notification laws, state health information privacy laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act ("FTCA")), and other similar regulations (e.g., wiretapping) that govern the collection, storage, retention, use, disclosure, transfer, transmission, and other processing of sensitive data, including health information.

For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and the collection, storage, retention, use, disclosure, transfer, transmission, and other processing of individually identifiable protected health information. We may obtain such information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we do not believe that we are directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if, for example, we knowingly disclose individually identifiable health information we obtain from a HIPAA covered entity in a manner that violates HIPAA.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal data secure may constitute unfair acts or practices in or affecting commerce in violation of the FTCA. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits even stronger safeguards.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. Failure to comply with these laws, where applicable, can result in significant fines, penalties, enforcement actions, and other liabilities. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, the "CCPA") gives California residents the right to access, delete, and opt-out of selling and certain sharing of their personal information, and to receive detailed information about how it is used and shared. The CCPA provides for civil penalties and statutory damages for violations, and the law created a private right of action for certain security breaches that result in the loss of personal information. The California Privacy Protection Agency continues to adopt new regulations implementing the CCPA, expanding into new areas such as certain applications of AI, among others. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. Similar privacy laws have been passed in other states, and are being considered at the state and federal level, which may add additional complexity, variation in requirements, restrictions, and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data, and could result in increased compliance costs or changes in business practices and policies. For example, Washington State enacted the Washington My Health My Data Act, which broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements, and grants consumers certain rights with respect to their health data, including to request deletion of their information. The existence of privacy laws in different states in the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Outside the United States, an increasing number of laws and regulations, including Australia's Privacy Act, the European Union's General Data Protection Regulation ("EU GDPR"), and the United Kingdom's General Data Protection Regulation ("UK GDPR," and, together with the EU GDPR, the "GDPR"), may also apply to our processing of sensitive data, including health-related and other personal data.

The GDPR, for example, imposes stringent requirements for processing personal data. The GDPR, together with national legislation, regulations, and guidelines of the European Union ("EU"), member states of the European Economic Area ("EEA"), and the United Kingdom governing the processing of personal data, imposes strict obligations and restrictions on the ability to collect, store, retain, use, disclose, transfer, transmit, and otherwise process personal data, including health-related data obtained from clinical trials or processed in connection with AE reporting. If we are or are perceived to fail to comply with the GDPR, we could be subject to enforcement actions by data protection authorities in the EEA and/or the UK, including regulatory investigations, significant penalties (of up to the greater of €20.0 million or £17.5 million, respectively, or 4% of annual worldwide turnover), and/or orders to cease or change our processing of personal data subject to these laws and regulations. Implementing mechanisms to address compliance with the GDPR and relevant local legislation in EEA member states and the UK may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects.

In addition, we may be unable to transfer personal data from the EEA and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. The EU, the UK, and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EU and other member states of the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy, data protection, or security laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the United States or other third countries in compliance with law, such as the EU's standard contractual clauses, the United Kingdom's International Data Transfer Agreement /

Addendum, and the EU-U.S. Data Privacy Framework (the "Framework") and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States or other third countries. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom, or other jurisdictions to the United States or other countries in which we operate, or if the requirements for a legally compliant transfer are too costly or onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as a member state of the EEA) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors, and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Additionally, the DSP places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities with significant links to countries of concern, or who are designated as such by the U.S. Attorney General). DSP restrictions may impact certain of our business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investment agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The DSP applies regardless of whether data is anonymized or de-identified, key-coded, pseudonymized, or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in certain transactions or agreements with certain third parties in the future.

We are bound by other contractual obligations related to privacy, data protection, and security, and our efforts to comply with those obligations may not be successful. Our actual or perceived failure to comply with these obligations could subject us to complaints, litigation and related damages, reputational harm, and other liabilities.

While we strive to publish and prominently display privacy policies and notices that are accurate, comprehensive, and compliant with applicable laws and regulations, we cannot ensure that our policies, notices, and other statements or representations regarding our practices will be sufficient to protect us from claims, proceedings, liability, or adverse publicity relating to privacy, data protection, or security. Although we endeavor to comply with our applicable policies, notices, and statements relating to these matters, we may at times fail to do so or be alleged to have failed to do so. Enforcement actions and investigations by regulatory authorities (such as the FTC or U.S. states' attorneys general) related to security breaches and incidents, alleged unfair or deceptive acts concerning privacy practices, and other matters relating to privacy and cybersecurity continue to increase. If our public statements about our use, collection, disclosure, retention, transfer, or other processing of personal data, whether made through our privacy notices, information provided on our website, press statements, or otherwise, are alleged to be deceptive, unfair, or misrepresentative of our actual practices, or if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, or requirements of certain rules, standards, or other actual or asserted obligations to which we may be or may become subject, including changes in laws, regulations, rules, standards, and obligations or new interpretations or applications of laws, regulations, rules, standards, and obligations, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, enforcement actions, other proceedings, loss of export privileges and fines, penalties, obligations to cease processing certain data or take other actions, other liabilities, or severe criminal or civil sanctions, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Our employees and personnel use generative artificial intelligence ("AI") and/or automated decision-making technologies to perform their work, and the disclosure and use of personal information in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI and/or automated decision-making technologies. For example, the EU AI Act establishes, among other things, a risk-based governance framework for regulating AI systems operating in the EU. This framework categorizes AI systems, based on the risks associated with such AI systems' intended purposes, as creating unacceptable or high risks, with all other AI systems being considered low risk. Because AI technologies are highly complex and rapidly developing, it is not possible to predict all of the legal or regulatory risks that may arise relating to our use of such technologies. Further, the cost to comply with such laws or regulations could be

significant and would increase our operating expenses, which could adversely affect our business, financial condition, and results of operations. If we are unable to use AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

Obligations related to privacy, data protection, and security (and consumers' expectations regarding privacy, data protection, and security) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, policies, and practices and to those of any third parties that process personal data on our behalf.

Compliance with U.S. and foreign privacy, data protection, and security laws, rules, regulations, and other legal or contractual obligations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, store, retain, use, disclose, transfer, transmit, and otherwise process sensitive data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws, rules, regulations, and obligations can be subject to varying interpretations. Any actual or perceived failure to comply with privacy, data protection, or security laws, rules, regulations, or obligations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, or adverse publicity and could negatively affect our operating results and business. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to collect, store, retain, use, disclose, transfer, transmit, and otherwise process the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Our Reliance on Third Parties

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, or terminate the relationship, our ability to complete development of our product candidates could be delayed, become more costly, or be unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs, and clinical data management organizations to conduct, supervise, and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality, and other aspects of preclinical studies and clinical trials than we would have if we were to conduct them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, these parties may have contractual relationships with other entities (some of whom may be our competitors), which may draw time and resources from our programs. For example, we rely on CROs located or operating in China, among others, to conduct certain of our preclinical research and discovery activities and/or our clinical trials. It is unknown how the status of current or future U.S.-China relations or the ongoing conflict in Ukraine will affect our ability to rely on these CROs to conduct our current and future preclinical studies or clinical trials. To the extent military conflicts, political unrest, unstable economic conditions, or other events adversely impact our ability to enroll patients or complete enrollments in process or adversely impact the ability of our suppliers to produce and distribute the supplies we need for our current or future clinical trials, we may be required to enroll patients at other sites which could increase the cost or delay the timing for completing such trial.

Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety, efficacy, or

potency for that indication. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners, or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory, and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that certain of our preclinical studies is conducted in accordance with GLPs and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites, and certain third parties, including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCPs. Moreover, our business may be significantly impacted if our CROs, clinical investigators, or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations, or healthcare-related laws regarding privacy, data protection, and security.

If we need to repeat, extend, delay, or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed, or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors or vendors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship

between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We are currently dependent on third-party manufacturers and suppliers to supply our product candidates, many of which are sole-source manufacturers and suppliers. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business, financial condition, results of operations, and prospects.

We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture our product candidates and components thereof, many of which are sole-source manufacturers and suppliers. Reliance on third-party CMOs may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development supplies will not be limited, interrupted, terminated, or will be of satisfactory quality or be available at acceptable prices, including as we expand the size and number of clinical trials. In addition, replacing a CMO could require significant effort and time because there may be a limited number of qualified replacements. For example, a subsidiary of WuXi Biologics carries forward the majority of the IND-enabling CMC for some of our product candidates. We have the ability to conduct a technology transfer of the manufacturing process to another third-party CMO from WuXi Biologics, if needed, but such transfer could require more effort, time, or funds than expected or the transfer may not be successful.

The manufacturing process for our product candidates is subject to review by the FDA and other foreign regulatory authorities to the extent applicable. We and our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current good manufacturing practices ("cGMPs"). Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are dependent on our CMOs for manufacturing in compliance with current regulatory requirements. If any of our manufacturers fail to comply with those requirements or to perform its obligations in relation to quality, timing, or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, delayed, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do in a timely manner or on reasonable terms, or at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on a CMO or require us to obtain a license from that CMO to enable us to manufacture, or to have another third party manufacture, our product candidates. If we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines and we may be required to repeat certain clinical or non-clinical studies. The delays and costs associated with the verification of a new CMO could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party CMOs if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMPs, quality control, quality assurance, and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party

manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our, or a third party's, failure to execute on our manufacturing requirements, comply with cGMPs, or maintain a compliance status acceptable to the FDA or other applicable foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- a delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- a loss of the cooperation of existing or future collaborators;
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products; and
- regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, requirements to cease distribution of the products, product seizure, detention, or recall, operating restrictions, suits under the civil FCA, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes, unstable political environments, natural disasters, epidemics, or outbreaks, among other things. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants if approved, would be jeopardized.

The operations of our suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations, and prospects.

Certain of our suppliers are located outside of the United States. As a result, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, inhibit our suppliers' ability to procure certain

materials, or delay or increase the cost of our non-clinical or clinical studies, any of which could harm our business, financial condition, results of operations, and prospects.

CMOs may become subject to legislation, trade restrictions, sanctions, tariffs, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, and as discussed above, the BIOSECURE Act and its pending implementing regulations could adversely impact our current or future third-party arrangements with certain companies (e.g., CMOs), including those in China or Chinese-owned U.S. companies, which could delay or impact our clinical trials and consequently delay or obstruct successful commercialization of our product candidates Furthermore, other U.S. executive action (e.g., the imposition of higher tariffs on imports into the United States, potential sanctions), legislative action, or other governmental regulations affecting trade between the United States and other countries - and any retaliatory actions by such other countries - could materially impact our ability to work with certain biotechnology companies. In addition, U.S. executive agencies may designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Such disruption could have adverse effects on the development of our product candidates.

Additionally, we may explore future manufacturing of our product candidates with CDMOs in certain other countries. If our ability to work with such CDMOs is restricted through their designation under the BIOSECURE Act or as a result of other government actions, we will need to identify and implement alternative manufacturing plans and alternative future drug substance and drug product supply for our product candidates. If, as a result, supplies are interrupted, or the quality of ingredients provided by such alternative sources does not meet our specifications, it could cause delays in our supply chain and increase the cost of manufacturing our product candidates, which could materially harm our business.

We have entered, and may in the future enter into, additional collaborations or licensing arrangements, which are important to our business. If we are unable to enter into new collaborations or licenses, or if we fail to realize the benefits of any current or future collaborations or licensing arrangements, our business, financial condition, results of operations, and prospects could be adversely affected.

A key part of our strategy has been and is to strategically evaluate and, as we deem appropriate, enter into collaborations or partnerships, including with major biotechnology or pharmaceutical companies to advance our current or future product candidates. We have previously entered into a research collaboration with BioNTech Zhuhai to conduct various research and development activities. We have limited capabilities for development and do not yet have any capability for commercialization. Accordingly, we may continue to enter into collaborations with other companies in the future to provide us with funding for our programs and technology. Any of our existing or future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our current product candidates are designed to address targets that we believe are of high interest to pharmaceutical partners.

Our current collaborations and any future collaborations we enter into pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial or test results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates, if approved;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution, or marketing of a product candidate or product;
- collaborators with marketing, manufacturing, and distribution rights to one or more of our product candidates that achieve regulatory approval, if any, may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out the marketing and distribution of such product or products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays or terminations of the research, development, or future commercialization of product candidates, if approved, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may seek to amend or modify the terms of any collaboration;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in such a way as to invite actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or future commercialization of any product candidate licensed to it by us.

If our collaborations do not result in the successful discovery, development, and future commercialization of product candidates, if approved, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments we are owed under such collaboration and could be required to raise additional capital to pursue further development or future commercialization of the applicable product candidates. Additionally, if one of our collaborators terminates its agreement with us, we may lose rights that are important to our business or find it more difficult to attract new collaborators, and our perception in the business and financial communities could be adversely affected.

In addition, as part of our business strategy, we may determine that it is in our best interest to out-license or sell one or more of our current or future product candidates to one or more strategic partners. Any such transaction could result in our loss of rights to the development and commercialization of such product candidate, and we may not receive milestone payments, royalties, or other economic value from such product candidate that meet our expectations or that we would have realized had we retained and advanced such product candidate ourselves. Such transactions could also divert management attention and resources from our remaining programs, and there can be no assurance that any such transaction would be completed on terms favorable to us or at all.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies.

Collaborations are complex, expensive, and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Additionally, our collaboration agreements may contain non-compete provisions that could limit our ability to enter into strategic collaborations with future collaborators or restrict our ability to commercialize products on our own, if approved.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development or one or more of our other product candidates, delay its potential commercialization, if approved, reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or future commercialization activities at our own expense. If we elect to increase our expenditures to fund development or future commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and future commercialization activities, we may not be able to further develop our product candidates, bring them to market, if approved, and generate revenue from sales of such products or continue to develop our technology, and our business, financial condition, results of operations, and prospects could be adversely affected. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of any approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and future commercialization of our product candidates, if approved, and reduce their competitiveness even if they reach the market. See the section titled "Business—Our Collaboration, License, and Services Agreements" for more information on our collaboration agreements.

Risks Related to This Offering and Ownership of Our Common Stock

An active and liquid trading market for our common stock may not develop and you may not be able to resell your shares of common stock at or above the initial public offering price, if at all.

Prior to this offering, no market for shares of our common stock existed. Although our common stock has been approved for listing on Nasdaq under the symbol "BBTX", an active or liquid trading market for our common stock may never develop or be sustained following the consummation of this offering. To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliated public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors, and affiliated stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell your shares, if at all. Moreover, the initial public offering price for our common stock was determined through negotiations with the underwriters, and may vary from the market price of our common stock following this offering. As a result of these and other factors, you may be unable to resell

your shares of our common stock at or above the initial public offering price, at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

Further, our directors, officers, employees, distributors, dealers, business associates and related persons have the opportunity to purchase up to 3.5% of the shares offered by this prospectus, at the initial public offering price through a reserved share program. To the extent any of our directors, officers or employees purchase shares in this offering, fewer shares may be actively traded in the public market because these stockholders will be restricted from selling the shares by a 180-day lock-up restriction, which would reduce the liquidity of the market for our common stock.

Our stock price may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- results of our preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- volatility and instability in the financial and capital markets;
- announcements by competitors that impact our competitive outlook;
- developments with respect to our product candidates, or similar products or product candidates against which we compete;
- the results of our efforts to discover, develop, acquire, or in-license additional current or future product candidates;
- additions or departures of key personnel;
- developments with respect to patents or other intellectual property rights;
- announcements of technological innovations, new product candidates, new products, or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, dispositions, collaborations, licenses, or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equity research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales or the perception of potential sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- expiration of market standoff or lock-up agreements described in the section titled “Underwriting”;
- regulatory developments within, and outside of, the United States, including changes in the structure of healthcare payment systems;

- litigation or arbitration;
- pandemics, natural disasters, or major catastrophic events; and
- general economic, political, and market conditions and other factors, including any such changes specific to the pharmaceutical and biotechnology sectors.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering.

We or our directors or officers may be subject to securities litigation, which is expensive and could divert management attention.

We may be the target of securities litigation in the future, including based on volatility in the market price of our stock. The stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. The market price of our common stock is likely to be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Our directors or officers have in the past and may in the future also become involved in securities or other litigation in the context of any roles with other public companies. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from, any such proceeding) can be expensive and time-consuming, damage our reputation, and divert our management's and board of directors' attention from other business concerns, which could seriously harm our business, financial condition, results of operations, and prospects.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will suffer immediate and substantial dilution with respect to the common stock you purchase in this offering. Specifically, based on the initial public offering price of $16.00 per share and assuming that the underwriters do not exercise their option to purchase additional shares of common stock in this offering, you will incur immediate dilution of $11.73 per share. That number represents the difference between the initial public offering price of $16.00 per share and our pro forma as adjusted net tangible book value per share as of June 30, 2026, after giving effect to (i) the conversion of all of our outstanding shares of our convertible preferred stock into an aggregate of 27,391,561 shares of our common stock pursuant to the Preferred Stock Conversion immediately prior to the closing of this offering, (ii) the issuance of 621,192 shares of common stock pursuant to the Liquidity Event RSU Settlement, based on the initial public offering price of $16.00 per share, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering.

Furthermore, pursuant to our 2026 Plan, adopted in connection with this offering, our management is authorized to grant stock awards to our employees, directors, and consultants. A total of 5,560,163 shares of our common stock are reserved for issuance pursuant to our 2026 Plan. In addition, the shares reserved for issuance under our 2026 Plan will include (i) shares that remained available for grant under our 2024 Plan as of the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part and (ii) shares of our common stock subject to or issued pursuant to awards granted under our 2024 Plan that, on or after the effective date of the registration statement of which this prospectus forms a part, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by us for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by us due to failure to vest (provided that the maximum number of shares that may be added to the 2026 Plan pursuant to (i) and (ii) is 4,208,339 shares). The number of shares of our common stock reserved for issuance under the 2026 Plan will automatically increase on the first day of each fiscal year for a period of ten years, beginning with our 2027 fiscal year, in an amount equal to the lesser of: (i) 5.0% of the total number of shares of our fully-diluted common stock outstanding on the last day of the immediately

preceding fiscal year and (ii) such other number of shares as the administrator of the 2026 Plan may determine. Further, pursuant to our ESPP, adopted in connection with this offering, the aggregate number of shares of our common stock available for sale under our ESPP is 505,469 shares. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year for a period of ten years, beginning with our 2027 fiscal year, in an amount equal to the lesser of (i) 1.0% of the total number of shares of our fully-diluted common stock outstanding on the last day of the immediately preceding fiscal year; (ii) 1,516,407 shares of our common stock; and (iii) such other number as the administrator of the ESPP may determine. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

For a further description of the dilution you will experience immediately after this offering, see the section titled "Dilution."

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations that may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including, among other things, the results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such preclinical studies or clinical trials.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends. Investors in this offering may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

We have broad discretion in how we use the net proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Our board of directors will be authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation, which will be effective immediately prior to the closing of this offering, will authorize our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations, and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences, and rights of the shares of each such series and the qualifications, limitations, or restrictions thereof. The powers, preferences, and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees, and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees, and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

We may engage in a variety of strategic transactions, including acquisitions, dispositions, joint ventures, or making investments in other companies or technologies, that could negatively affect our operating results, dilute our stockholders' ownership, create or increase indebtedness, or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical, or commercial stage products or product candidates, or businesses, dispose of certain of our product candidates or businesses, and enter into strategic alliances, joint ventures, and collaborations, all in order to expand our existing technologies and operations or otherwise generate capital to advance our product candidates.

Any potential transaction may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness, contractual obligations, or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property, and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing a strategic transaction;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. If we engage in a disposition, we may have difficulty replacing the assets we sold or in separating our continuing operations from those of the business we sold. Any future acquisitions also could result in the incurrence of debt, contingent liabilities, or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition, and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance, or joint venture.

To finance certain transactions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, or acquire intangible assets that could result in significant amortization expense. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our common stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

A significant portion of our total outstanding shares of our common stock after this offering will be restricted from immediate resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on 40,386,875 shares of our common stock outstanding as of June 30, 2026 (which includes 2,866,703 shares of unvested restricted common stock), after giving effect to the Preferred Stock Conversion and the Liquidity

Event RSU Settlement, we will have outstanding a total of 50,942,430 shares of our common stock upon completion of this offering, assuming no exercise of the underwriters' option to purchase additional shares. The 10,555,555 shares of our common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will (unless they are purchased by one of our affiliates or by directors, officers or employees in our reserved share program) be freely tradable, without restriction, in the public market immediately following this offering. See the section titled "Shares Eligible For Future Sale" for more information.

Our directors, executive officers, and holders of substantially all of our capital stock and securities convertible into or exchangeable for our common stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us pursuant to which they may not, with certain exceptions, for a period of 180 days from the date of this prospectus, offer, sell, or otherwise transfer or dispose of any of our securities, without the prior written consent of BofA Securities, Inc. and Evercore Group L.L.C. However, BofA Securities, Inc. and Evercore Group L.L.C. may permit our directors, officers, and other security holders who are subject to the lock-up and market standoff agreements to sell shares prior to the expiration of the lock-up and market standoff agreements at any time in their sole discretion. See the section titled "Underwriting." Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up and market standoff agreements expire, an additional 39,750,360 shares of our common stock will be eligible for sale in the public market, of which 32,568,026 shares are held by directors, executive officers, and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, we filed a Form S-8 registration statement to register shares reserved for future issuance under our equity compensation plans. Subject to the satisfaction of applicable vesting restrictions and the expiration or waiver of the market standoff agreements and lock-up agreements referred to above, the shares issued upon exercise of outstanding stock options and settlement of RSUs will be available for immediate resale in the public market. The 1,550,428 shares of our common stock that are subject to outstanding options under the 2024 Plan as of June 30, 2026 and the shares of common stock issuable upon the Liquidity Event RSU Settlement will become eligible for sale in the public market after this offering, to the extent permitted by the provisions of various vesting schedules, the lock-up and market standoff agreements (and the exceptions thereto), and Rule 144 and Rule 701 under the Securities Act. If these additional shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 39,750,360 shares of our outstanding common stock, or approximately 98.4% of our total outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares of our common stock) based on 40,386,875 shares outstanding as of June 30, 2026 (after giving effect to the conversion of all of our outstanding shares of our convertible preferred stock into an aggregate of 27,391,561 shares of our common stock immediately prior to the closing of this offering and the Liquidity Event RSU Settlement), will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up and market standoff agreements described above. See the section titled "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act.

Sales of our common stock as restrictions end or pursuant to registration rights may make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of our common stock to fall and make it more difficult for you to sell shares of our common stock at a time and price that you deem appropriate.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

Our principal stockholders and management own a significant percentage of our common stock and will be able to control matters subject to stockholder approval.

Prior to the closing of this offering, our executive officers, directors, and holders of 5% or more of our capital stock beneficially owned approximately 80.9% of our voting stock as of June 30, 2026 (after giving effect to the Liquidity Event RSU Settlement, as if it had occurred on June 30, 2026), and, upon the completion of this offering, that same group will beneficially own approximately 64.3% of our outstanding voting stock (without giving effect to any purchases by our officers, directors, stockholders who owned more than 5% of our outstanding common stock before this offering, and their affiliated entities, and without giving effect to any purchases that certain of these holders may make through our reserved share program, and assuming no exercise of the underwriters' option to purchase additional shares of our common stock). The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent our change of control, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or of our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time and resources to new compliance initiatives.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations, and prospects. We plan to hire additional financial reporting, internal control, and other finance personnel or consultants in order to develop and implement appropriate internal control and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations, and prospects may be significantly harmed.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2025 and the period from March 14, 2024 (Inception) to December 31, 2024, material weaknesses in our internal control over financial reporting were identified. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

As indicated above, material weaknesses in our internal control over financial reporting exist. We concluded that we did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources with an appropriate level of knowledge, experience and training to establish effective processes and controls. This material weakness contributed to the following additional material weaknesses:

- We did not design and maintain effective controls over the preparation and review of journal entries and account reconciliations, as well as not maintaining adequate segregation of duties.
- We did not design and maintain effective information technology ("IT") general controls for information systems that are relevant to the preparation of our financial statements and the effectiveness of IT dependent controls. Specifically, we did not design and maintain:
    - program change management controls to ensure that program and data changes are identified, tested, authorized and implemented appropriately; and
    - user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel.

These material weaknesses did not result in a material misstatement to the financial statements, but could result in misstatements of substantially all of the Company's accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel, hiring a third-party accounting firm, including specialists, to assist us with designing and implementing segregation of duties, designing and implementing effective controls over IT general controls for information systems, and initiating design and implementation of our financial control environment. This will include implementing upgraded accounting software to strengthen internal controls including automated controls and workflows. The material weaknesses will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of Section 404 of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of Section 404 of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, we identify any additional material weaknesses, or are unable to otherwise develop and maintain adequate internal control over financial reporting, we could fail to timely and accurately report our financial results or prevent fraud, potentially resulting in restatements of our financial statements, we may be unable to maintain compliance with securities law

requirements regarding timely filing of periodic reports and applicable Nasdaq listing requirements, investors may lose confidence in our financial reporting, our stock might be delisted, we could be subject to litigation from investors and stockholders, we could be subject to sanctions or investigations by the SEC, Nasdaq, or other regulatory authorities, our access to the capital markets may be restricted, and the trading price of our common stock could suffer.

In the future, if we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of this offering. When we lose our status as an "emerging growth company" and do not otherwise qualify as a non-accelerated filer, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. In connection with this offering, we intend to begin the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls entails substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. We may discover significant deficiencies in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if in the future we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively commercialize our product candidates.

If we are unable to maintain effective disclosure controls and procedures, our business, financial position, and results of operations could be adversely affected.

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or other internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the fact that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our ability to use our net operating loss ("NOL") carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

As of December 31, 2025, we had $13.3 million and $11.1 million of U.S. federal and state NOL carryforwards, respectively. The federal NOL carryforwards are not subject to expiration and the state NOL carryforwards begin to expire in 2044. These NOL carryforwards are available to reduce future federal and state taxable income, if any. Under the Internal Revenue Code of 1986, as amended (the "Code"), our U.S. federal NOL carryforwards will not expire and may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to no more than 80% of current year taxable income (with certain adjustments). In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Since our Inception, we have not recorded any income tax benefits in the United States for the net losses we have incurred or for the research and development tax credits earned in each period and interim period, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

We have not completed a Section 382 study to assess whether an ownership change has occurred, and there have been changes in our ownership that would limit our ability to utilize our tax attribute carryforwards. Furthermore, there may be additional ownership changes in the future, including in connection with this offering or as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we have undergone or undergo an ownership change, and our ability to use our pre-change U.S. federal NOL carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of state NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase our state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect us.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect us. For example, recent legislation, including the Inflation Reduction Act of 2022 ("IRA") and the OBBBA, enacted many significant changes to U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including a one percent excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission) have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements in this prospectus. We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700.0 million, measured on the last business day of our second fiscal quarter, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year, in which cases we would no longer be an emerging growth company as of the last day of the fiscal year, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, after the closing of this offering, Nasdaq may take steps to delist our common stock. Such a delisting would have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with the listing requirements of Nasdaq.

Anti-takeover provisions in our organizational documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Each of our amended and restated certificate of incorporation and Bylaws that will be effective immediately prior to the closing of this offering contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- authorize our board of directors to issue one or more new series of preferred stock without stockholder approval and create, subject to applicable law, one or more series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter, or repeal our Bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than a majority of all outstanding shares of our capital stock entitled to vote generally in the election of directors, voting as a single class;
- require the approval of not less than 66-2/3% of all outstanding shares of our capital stock entitled to vote generally in the election of directors, voting as a single class, for a stockholder amendment to certain provisions of our amended and restated bylaws (absent approval of our board of directors) and to amend specific provisions of our amended and restated certificate of incorporation; and
- specify the jurisdictions in which certain stockholder litigation may be brought.

In addition, Section 203 of the General Corporation Law of the State of Delaware (the "DGCL") may discourage, delay, or prevent a change in control of us. Section 203 imposes certain restrictions on mergers, business combinations, and other transactions between us and holders of 15% or more of our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might delay, discourage, or prevent a change in control of our company or changes in our management, thereby depressing the market price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the DGCL may discourage, delay, or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws will contain provisions that may make the acquisition of our company more difficult or delay or prevent changes in control of our management. Among other things, these provisions will:

- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;

- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- establish that our board of directors is divided into three classes, Class I, Class II, and Class III, with each class serving staggered three-year terms;
- for so long as our board of directors is classified, and subject to the rights of holders of our preferred stock, provide that our directors may only be removed by stockholders for cause;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- eliminate cumulative voting in the election of directors;
- prohibit stockholders from calling a special meeting of stockholders; and
- require a super-majority vote of stockholders to amend some of the provisions described above.

These provisions, alone or together, could delay, discourage, or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause us to take other corporate actions they desire, any of which, under certain circumstances, could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws will designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Exchange Act or the Securities Act, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.

Our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, stockholders, officers, or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or (4) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware), except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction.

Section 22 of the Securities Act establishes concurrent jurisdiction for federal and state courts over Securities Act claims. Accordingly, both state and federal courts have jurisdiction to hear such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws will also provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Exchange Act or the Securities Act against any person in connection with any offering of our securities.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the

application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our current or former directors, officers, stockholders, or other employees, which may discourage such lawsuits against us and our current and former directors, officers, stockholders, and other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions.

Further, the enforceability of similar exclusive forum provisions in other companies' organizational documents have been challenged in legal proceedings, and it is possible that a court of law could rule that these types of provisions are inapplicable or unenforceable if they are challenged in a proceeding or otherwise. If a court were to find either exclusive forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur significant additional costs associated with resolving such action in other jurisdictions, all of which could harm our results of operations.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the frequency of or content and opinions included in their reports, and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us or do not publish reports on us on a regular basis, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property, or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, and expenses that are not readily apparent from other sources. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates, or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact contained in this prospectus, including statements regarding our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans, or intentions relating to product candidates and markets and business trends are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions.

These statements involve known and unknown risks, uncertainties, and other factors which may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the potential beneficial characteristics, safety, efficacy, and positive effects of our product candidates across various diseases and indications;
- the likelihood of our clinical trials demonstrating safety, efficacy, and potency of our product candidates, and other positive results;
- the timing, progress, and results of our ongoing and planned clinical trials for our current product candidates, including plans for enrollment and the timing and content of any data we may release;
- our plans relating to the clinical development of our product candidates, including the size, number, and areas to be evaluated, and which indications we may pursue;
- our estimates regarding the total addressable market for our product candidates;
- our plans and strategy relating to commercializing, manufacturing, and marketing any of our current or future product candidates, if approved, including the geographic areas of focus;
- our competitive position and the success of competing products that are or may become available;
- the rate and degree of market acceptance by physicians and patients, and others in the medical community, including the perceived clinical benefit and risk of our current product candidates and other product candidates we may develop;
- the timing, scope, and likelihood of regulatory filings and approvals for our current product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our expectations regarding third-party coverage, reimbursement policies, and pricing regulations applicable to our product candidates, if approved;
- the impact of existing laws and regulations and regulatory developments in the United States and other jurisdictions;
- our ability to maintain compliance with our license agreement with BioNTech Zhuhai, including efforts to meet the development and commercial milestones thereunder, and otherwise maintain our intellectual property rights thereunder;
- our ability to obtain, and negotiate favorable terms of any, collaboration, partnership, licensing, or other arrangements that may be necessary or desirable to develop, manufacture, or commercialize our product candidates;

- our ability to out-license or sell one or more of our current or future product candidates to one or more third parties on favorable terms and the potential impact of any such transaction on our common stock;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our current product candidates;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for clinical trials and commercialization of our product candidates, if approved;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our financial performance and the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing, and the period over which our existing cash and cash equivalents and short-term investments will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will remain an emerging growth company and smaller reporting company under the JOBS Act;
- remediating the material weaknesses in our internal control over financial reporting; and
- our anticipated use of the proceeds from this offering.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, operating results, financial condition, and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors, including those described in the section titled “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. We cannot assure you that the results, events, and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

Neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Moreover, the forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. You should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates and information concerning our industry, including the size of the markets in which we participate, which are based on various third-party sources, industry publications, and reports, as well as our own internal information. In some cases, we do not expressly refer to the source from which this data is derived. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates and information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause actual results to differ materially from the estimates and information contained in this prospectus concerning our industry, including the size of the markets in which we participate. Although we are responsible for all of the disclosure contained in this prospectus and we believe that the data we use from third parties are reliable, we have not separately verified such data. Further, while we believe that our internal information is reliable, such information has not been verified by any third party. You are cautioned not to give undue weight to any such estimates and information.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $152.4 million (or approximately $176.0 million if the underwriters' option to purchase additional shares of common stock is exercised in full) from the sale of the shares of common stock offered by us in this offering, based upon the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our common stock, facilitate future access to the public equity markets by us, our employees, and our stockholders, and increase our visibility in the marketplace. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, primarily as follows:

- approximately $90.0 million to fund the continued development of our lead product candidate, BBT001, including the initiation of our planned Phase 2b AD Study; and
- approximately $40.0 million to fund the continued development of our second lead product candidate, BBT002, including the expected initiation of a Phase 2b clinical trial in one of the respiratory indications.

We intend to use the remaining proceeds to fund additional research and development activities of our two preclinical product candidates, BBT003 and BBT004, including advancing BBT003 into clinical development, as well as for capital expenditures, working capital, and general corporate purposes, including the additional costs of operating as a public company. Our expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above.

In addition, opportunities may exist from time to time to expand our current business through license or acquisitions of, or investments in, complementary businesses, products, or technologies. While we have no current agreements, commitments, or understandings for any specific licenses, acquisitions, or investments at this time, we may use a portion of the net proceeds for these purposes.

Based on our current plans, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into late 2028. This belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

The expected net proceeds from this offering, together with our existing cash and cash equivalents and short-term investments, will not be sufficient for us to fund all of our product candidates through regulatory approval, and we will need to raise substantial additional capital in order to do so.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, any funding we may obtain through future collaborations, if any, and any unforeseen cash needs.

Pending the use of the proceeds from this offering, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments permitted under our investment policy, including AAA-rated money market mutual funds, certificates of deposit, and direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend upon, among other factors, our operating results, financial condition, contractual restrictions, and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by any future debt instruments or preferred securities incurred or issued by us.

CAPITALIZATION

The following table summarizes our cash and cash equivalents and marketable securities and capitalization as of June 30, 2026:

- on an actual basis;
- on a pro forma basis to give effect to (1) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 27,391,561 shares of common stock pursuant to the Preferred Stock Conversion, (2) the issuance of 621,192 shares of common stock pursuant to the Liquidity Event RSU Settlement, based on the initial public offering price of $16.00 per share, and (3) the filing and effectiveness of our amended and restated certificate of incorporation; and
- on a pro forma as adjusted basis to reflect (1) the pro forma adjustments set forth above and (2) the issuance and sale by us of 10,555,555 shares of common stock in this offering at the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of June 30, 2026		
(in thousands except per share data)	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents and marketable securities	$ 71,475	$ 71,475	$ 223,908
Convertible preferred stock, $0.00001 par value per share, 27,391,592 shares authorized, 27,391,561 shares issued and outstanding, actual; no shares authorized, issued, or outstanding, pro forma and pro forma as adjusted	$ 136,231	$ —	$ —
Stockholders' (deficit) equity:			
Preferred stock, $0.00001 par value per share, no shares authorized, issued, or outstanding, actual; 200,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.00001 par value per share, 46,346,000 shares authorized, 12,374,122 shares issued and outstanding, actual; 1,000,000,000 shares authorized, 40,386,875 shares issued and outstanding, pro forma; 1,000,000,000 shares authorized, 50,942,430 shares issued and outstanding, pro forma as adjusted	—	—	1
Additional paid-in capital	6,249	152,431	304,863
Accumulated other comprehensive loss	(19)	(19)	(19)
Accumulated deficit	(77,188)	(87,139)	(87,139)
Total stockholders' (deficit) equity	(70,958)	65,273	217,706
Total capitalization	$ 65,273	$ 65,273	$ 217,706

The foregoing tables and calculations are based on 40,386,875 shares of our common stock outstanding as of June 30, 2026 (which includes 2,866,703 shares of unvested restricted common stock), after giving effect to the Preferred Stock Conversion and the Liquidity Event RSU Settlement, as if they had occurred on June 30, 2026, and excludes:

- 1,550,428 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2026, with a weighted-average exercise price of $0.90 per share;

- 1,621,449 shares of common stock issuable upon the exercise of outstanding options granted subsequent to June 30, 2026, with a weighted-average exercise price of $12.66 per share;
- 379,102 shares of common stock issuable upon the exercise of options approved subsequent to June 30, 2026, which were granted contingent and effective upon the pricing of this offering with a price per share equal to the initial public offering price (the "IPO Options");
- 758,204 shares of common stock issuable upon the vesting and settlement of performance-based RSUs approved subsequent to June 30, 2026, which were granted in connection with this offering (the "IPO PSUs");
- 5,898,951 shares of common stock reserved for future issuance under the 2026 Plan (which include the shares issuable under the IPO Options and the IPO PSUs), which became effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part (including 338,788 shares of common stock reserved for future issuance under the 2024 Plan, which number of shares was added to the shares of our common stock reserved under our 2026 Plan in connection with its effectiveness, at which time we ceased granting awards under our 2024 Plan);
- 505,469 shares of common stock reserved for future issuance under the ESPP, which became effective in connection with this offering; and
- securities or other consideration which may be issuable upon the settlement of outstanding VARs as of June 30, 2026.

The 2026 Plan and the ESPP each provide for annual automatic increases in the number of shares of our common stock reserved thereunder, and the 2026 Plan also provides for increases to the number of shares of our common stock that may be granted thereunder based on shares underlying the awards granted under the 2024 Plan that expire, are forfeited, or are repurchased by us, as more fully described in the section titled "Executive Compensation—Employee Benefit and Stock Plans."

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Net tangible book value (deficit) per share is determined by dividing our total tangible assets less our total liabilities and the carrying value of our convertible preferred stock, which is not included within stockholders' deficit, by the number of shares of our common stock outstanding (which includes 2,866,703 shares of unvested restricted common stock). Our historical net tangible book deficit as of June 30, 2026 was $(72.7) million, or $(5.88) per share. Our pro forma net tangible book value as of June 30, 2026 was $63.5 million, or $1.57 per share, based on the total number of shares of our common stock outstanding (which includes 2,866,703 shares of unvested restricted common stock) as of June 30, 2026, after giving effect to (i) the conversion of all of our outstanding shares of convertible preferred stock into an aggregate of 27,391,561 shares of common stock pursuant to the Preferred Stock Conversion and (ii) the issuance of 621,192 shares of common stock pursuant to the Liquidity Event RSU Settlement, based on the initial public offering price of $16.00 per share.

After giving effect to the sale by us of 10,555,555 shares of our common stock in this offering at the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2026 would have been $217.7 million, or $4.27 per share. This represents an immediate increase in pro forma net tangible book value of $2.70 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $11.73 per share to investors purchasing shares of our common stock in this offering at the initial public offering price.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis to new investors (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Initial public offering price per share			$	16.00
Historical net tangible book deficit per share as of June 30, 2026	$	(5.88)		
Pro forma increase in net tangible book value per share as of June 30, 2026		7.45		
Pro forma net tangible book value per share as of June 30, 2026		1.57		
Increase in pro forma net tangible book value per share attributable to investors purchasing shares of common stock in this offering	$	2.70		
Pro forma as adjusted net tangible book value per share immediately after this offering				4.27
Dilution in pro forma as adjusted net tangible book value per share to new investors in this offering			$	11.73

If the underwriters exercise their option in full to purchase 1,583,333 additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be $4.59 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be $3.02 per share, and the pro forma as adjusted dilution to new investors purchasing common stock in this offering would be $11.41 per share, in each case based on the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table presents, on a pro forma as adjusted basis to give effect to this offering, as of June 30, 2026, the differences between the existing stockholders and the new investors purchasing shares of our common stock in this offering with respect to the number of shares purchased from us, the total consideration paid or to be paid to us,

and the average price per share paid or to be paid to us at the initial public offering price of $16.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	40,386,875	79 %	$ 136,078	45 %	$ 3.37
Investors participating in this offering	10,555,555	21 %	$ 168,889	55 %	$ 16.00
Total	50,942,430	100 %	$ 304,967	100 %	$ 5.99

The table above assumes no exercise of the underwriters' option to purchase 1,583,333 additional shares in this offering, and no purchases by existing stockholders in our reserved share program. If the underwriters' option to purchase additional shares is exercised in full, the total number of shares of our common stock held by existing stockholders would be reduced to 77% of the total number of shares of our common stock outstanding after this offering, and the total number of shares of common stock held by investors purchasing shares of common stock in the offering would be increased to 23% of the total number of shares outstanding after this offering.

The foregoing tables and calculations are based on 40,386,875 shares of our common stock outstanding as of June 30, 2026 (which includes 2,866,703 shares of unvested restricted common stock), after giving effect to the Preferred Stock Conversion and the Liquidity Event RSU Settlement, as if they had occurred on June 30, 2026, and excludes:

- 1,550,428 shares of common stock issuable upon the exercise of outstanding options as of June 30, 2026, with a weighted-average exercise price of $0.90 per share;
- 1,621,449 shares of common stock issuable upon the exercise of outstanding options granted subsequent to June 30, 2026, with a weighted-average exercise price of $12.66 per share;
- 379,102 shares of common stock issuable upon the exercise of options approved subsequent to June 30, 2026, which were granted contingent and effective upon the pricing of this offering with a price per share equal to the initial public offering price (the "IPO Options");
- 758,204 shares of common stock issuable upon the vesting and settlement of performance-based RSUs approved subsequent to June 30, 2026, which were granted in connection with this offering (the "IPO PSUs");
- 5,898,951 shares of common stock reserved for future issuance under the 2026 Plan (which include the shares issuable under the IPO Options and the IPO PSUs), which became effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part (including 338,788 shares of common stock reserved for future issuance under the 2024 Plan, which number of shares was added to the shares of our common stock reserved under our 2026 Plan in connection with its effectiveness, at which time we ceased granting awards under our 2024 Plan);
- 505,469 shares of common stock reserved for future issuance under the ESPP, which became effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part; and
- securities or other consideration which may be issuable upon the settlement of outstanding VARs as of June 30, 2026.

The 2026 Plan and the ESPP each provide for annual automatic increases in the number of shares of our common stock reserved thereunder, and the 2026 Plan also provides for increases to the number of shares of our common stock that may be granted thereunder based on shares underlying the awards granted under the 2024 Plan that expire, are forfeited, or are repurchased by us, as more fully described in the section titled "Executive Compensation—Employee Benefit and Stock Plans."

We may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that any outstanding options to purchase our common stock are exercised or new awards are granted under our equity compensation plans, or we issue additional shares of our common stock or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. You should review the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" of this prospectus for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company developing next-generation, long-acting precision bispecific antibodies designed to redefine standards of care in immunology and inflammation ("I&I") and fundamentally improve patient quality of life. Although monoclonal antibodies have transformed the I&I treatment landscape, many patients remain underserved, continuing to experience incomplete responses or residual disease activity. We believe that next-generation therapeutic approaches, particularly bispecific and multi-target biologics that simultaneously modulate complementary and synergistic inflammatory pathways, are necessary to expand responder populations, address the significant unmet medical need, and unify treatment across overlapping disease biology.

Our vision is to deliver transformative medicines for I&I patients across every stage of disease. We use third-party, advanced antibody engineering to create long-acting bispecific antibodies that combine clinically and commercially validated biologic pathways into a single molecule formulated for high-concentration subcutaneous ("SubQ") delivery. Our goal is to improve durability, convenience, and clinical differentiation beyond the current capabilities of existing monotherapies, which we refer to as breaking the therapeutic ceiling. We believe our product candidates have the potential to address unmet medical need across I&I, spanning dermatology, respiratory, gastroenterology, and autoimmune diseases, and capture a substantial part of the rapidly growing global I&I market, which is projected to exceed $200 billion by 2030.

Since our formation on March 14, 2024 ("Inception"), we have devoted substantially all of our resources to acquiring the intellectual property rights to our product candidates, research and development activities for our product candidates, including BBT001 and BBT002, recruiting management and technical staff, and raising capital to support these operations. To date, we have not generated any revenue, and we have accumulated significant operating losses. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of, and commercialize any of, our product candidates and we do not know when, or if, that will occur. From Inception through June 30, 2026, we have funded our operations primarily with proceeds from the sale and issuance of convertible preferred stock in an aggregate amount of $136.1 million.

As of June 30, 2026, we had an accumulated deficit of $77.2 million. Our net losses were $22.4 million and $14.7 million for the six months ended June 30, 2026 and 2025, respectively, and $41.1 million and $13.7 million for the year ended December 31, 2025 and the period from Inception to December 31, 2024, respectively. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of our planned expenditures and research and development activities. We expect our operating expenses and capital requirements will increase substantially in connection with our ongoing activities, as we:

- continue to progress the development of BBT001 and BBT002, including expanded enrollment of additional clinical trials;
- continue to progress research and development BBT003 and BBT004, including advancing BBT003 into clinical development;

- acquire or in-license other product candidates and technologies, including the cost of acquiring any additional rights to product candidates from BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai") under our Research Collaboration and Option Agreement with BioNTech Zhuhai (the "BioNTech Zhuhai Option Agreement");
- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- expand our pipeline of product candidates, including through our own discovery and development efforts or through acquisition or in-licensing;
- seek regulatory approvals for any of our current product candidates or any future product candidates;
- establish a sales, marketing, manufacturing, and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval, if any;
- attract, hire, and retain additional qualified clinical, scientific, manufacturing, operations, administrative, and management personnel;
- add and maintain operational, financial, and information management systems;
- protect, maintain, enforce, and expand our rights in our intellectual property portfolio or acquire or in-license intellectual property and technologies from third parties; and
- incur additional legal, accounting, or other expenses in operating our business, including the costs associated with operating as a public company following the completion of this offering.

As a result, we will require substantial additional funding to develop our product candidates to support our continuing operations. Our ability to generate product revenue will depend on the successful development, regulatory approval, and eventual commercialization of one or more of our product candidates. Until such time that we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances, and licensing arrangements. We may also grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical, clinical, and manufacturing development efforts. Due to the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or the timing of when, or if, we will be able to achieve or maintain profitability. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of June 30, 2026, we had cash and cash equivalents, and marketable securities of $71.5 million. These amounts are not expected to be sufficient to fund our operations for at least 12 months from the date our financial statements were available to be issued. Therefore, based on our current cash position, there is substantial doubt about our ability to continue as a going concern. We will need substantial additional capital to support our continuing operations and pursue our strategy. Our management has developed plans to fund our operations, which primarily consist of raising additional capital through one or more of the following: equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements with third parties. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise, and we may be unable to obtain sufficient additional capital. If we are not able to secure sufficient additional capital in the near term, we may need to implement additional cost reduction strategies, which could include delaying, limiting, reducing, or eliminating both internal and external costs related to our operations and research and development programs. For more information, refer to section titled "—Liquidity and Capital Resources."

BioNTech Zhuhai Agreements

BioNTech Zhuhai Assignment Agreement

On March 18, 2024, we entered into an Assignment Agreement with BioNTech Zhuhai, which was amended and restated in its entirety on December 11, 2024 and further amended by Amendment No. 1 to Amended and Restated Assignment Agreement on September 2, 2026 (the "BioNTech Zhuhai Assignment Agreement"). Pursuant to the BioNTech Zhuhai Assignment Agreement, we obtained two bispecific antibody programs from BioNTech Zhuhai: the BBT001 program, which identifies, evaluates, and develops bispecific antibody candidates directed to both IL-4Rα and IL-31, and the BBT002 program, which identifies, evaluates, and develops bispecific antibody candidates directed to both IL-4Rα and IL-5, together with BioNTech Zhuhai's entire right, title, and interest in these bispecific programs, as well as certain related research materials, data packages, and intellectual property rights solely related to the bispecific programs. BioNTech Zhuhai granted us a non-exclusive license under its patent rights and know-how existing as of March 18, 2024 and related to mono-specific antibodies directed to IL-4Rα, IL-31 and IL-5 solely to practice and exploit such intellectual property in connection with the BBT001 and BBT002 programs.

We are obligated to use commercially reasonable efforts to obtain Investigational New Drug ("IND") approval of a product containing the lead antibody candidates in each program.

On a program-by-program basis, until the earlier of five years following the date on which we first obtain IND approval of a product or the termination of the BioNTech Zhuhai Assignment Agreement, BioNTech Zhuhai and its affiliates are restricted from researching, developing, manufacturing, or commercializing or collaborating or partnering with a third party to research, develop, manufacture, or commercialize any antibody directed to (i) both IL-4Rα and IL-31 for the BBT001 program, and (ii) both IL-4Rα and IL-5 for the BBT002 program without our prior written consent, in each case, subject to certain exceptions.

The BioNTech Zhuhai Assignment Agreement will continue in full force until terminated. Either we or BioNTech Zhuhai may terminate the BioNTech Zhuhai Assignment Agreement in the event of the other party's material breach, subject to certain notice and cure periods, and BioNTech Zhuhai may also terminate in the event of our bankruptcy or failure to make any due payment within a certain period. If BioNTech Zhuhai terminates the BioNTech Zhuhai Assignment Agreement, we are obligated to, among other things, assign, transfer, and convey back to BioNTech Zhuhai, free of charge, all right, title, and interest in related intellectual property and regulatory materials to enable BioNTech Zhuhai to continue development and commercialization of such compounds or products.

For additional discussion around the obligations under the BioNTech Zhuhai Assignment Agreement, see the subsection titled "—Contractual Obligations and Commitments" and "Business—Our Collaboration, License, and Services Agreements—BioNTech Zhuhai Agreements—BioNTech Zhuhai Assignment Agreement" included elsewhere in this prospectus.

BioNTech Zhuhai Option Agreement and Exclusive License Agreement

Research Collaboration and Option Agreement

On April 12, 2024, we entered into the "BioNTech Zhuhai Option Agreement", pursuant to which (i) the parties agreed to collaborate with respect to the discovery and preclinical development of novel bispecific antibodies directed to certain target combinations of interest and (ii) BioNTech Zhuhai granted us an exclusive option to license the resulting antibodies developed under such discovery and preclinical development.

We have the right to nominate a certain number (up to 10) of target combinations during the three-year period (through April 12, 2027) following the effective date of the agreement, and for each nominated target combination, BioNTech Zhuhai is responsible for conducting a research program to design, identify, generate, and evaluate bispecific antibody candidates directed to such target combination pursuant to a research plan. We have the right to exercise the option to license such bispecific antibody candidates and upon exercise, the parties will negotiate exclusively and execute a license agreement within a specified period. If we do not exercise the option, or if the

parties fail to execute a license agreement within a specified period, BioNTech Zhuhai is free to develop the applicable target combination and related compounds or enter into a license agreement with a third party on terms no less favorable to BioNTech Zhuhai than the terms offered by us to BioNTech Zhuhai.

Within five years following the effective date of the agreement, if BioNTech Zhuhai identifies a bispecific antibody in the field of inflammatory diseases and immunology that is not subject to our option and intends to license it to a third party, BioNTech Zhuhai must notify us and we have the right to notify BioNTech Zhuhai of our interest within a specified period. Upon our notice, the parties will negotiate in good faith on a non-exclusive basis for a certain period of time to reach a binding term sheet for a subsequent license agreement, and if we do not notify BioNTech Zhuhai or the parties fail to reach a binding term sheet or enter into a subsequent license agreement within a specified period, BioNTech Zhuhai is free to grant to any third party licenses or rights to such compounds.

Unless earlier terminated, the BioNTech Zhuhai Option Agreement will remain in effect for three years following the effective date of the agreement, subject to renewal upon mutual agreement. Each party may terminate in the event of the other party's material breach, subject to a customary cure period, or bankruptcy, or, in BioNTech Zhuhai's case, for our non-payment for a specified period.

Exclusive License Agreement

Pursuant to the BioNTech Zhuhai Option Agreement, we exercised an option to license a certain antibody candidate discovered and developed by BioNTech Zhuhai directed to TL1A and IL-23p19, the BBT003 program, and entered into an Exclusive License Agreement with BioNTech Zhuhai on September 28, 2025 (the "BioNTech Zhuhai License Agreement" and together with the BioNTech Zhuhai Assignment Agreement and the BioNTech Zhuhai Option Agreement, the "BioNTech Zhuhai Agreements"), pursuant to which BioNTech Zhuhai granted us an exclusive, royalty-bearing, sublicensable (subject to certain notice or consent rights of BioNTech Zhuhai) license under certain intellectual property rights controlled by BioNTech Zhuhai and its affiliates to develop, manufacture, and commercialize the licensed compounds and related products worldwide. We have provided written notice to BioNTech Zhuhai to exercise an option to license an additional antibody candidate discovered and developed by BioNTech Zhuhai directed to the BBT004 program.

We are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for at least one licensed product in each Major Market (the United States, Europe, Japan, and Greater China), and, if we obtain regulatory approval for a licensed product in any country in a Major Market, commercialize such licensed product, including obtaining pricing and reimbursement approval. In addition, we must obtain IND approval for at least one licensed product in any country worldwide on or before the two-year anniversary of October 9, 2025 and dose the first patient with a licensed product in a Phase 2 clinical trial on or before the four-year anniversary of October 9, 2025; in each case subject to our 12-month extension right.

We are subject to certain notice obligations to BioNTech Zhuhai if we develop a licensed product in the oncology field, which may prompt BioNTech Zhuhai to buy back the rights in such licensed product in the oncology field. Until May 7, 2028, BioNTech Zhuhai and its affiliates are restricted from developing any bispecific antibody that is not a licensed compound or licensed product and that is directed to TL1A and IL-23p19 as a primary mechanism of action in the I&I field.

Unless earlier terminated, the BioNTech Zhuhai License Agreement will expire on a licensed product-by-licensed product and country-by-country basis, upon the latest of patent expiration, regulatory exclusivity expiration, or termination, or ten years after such first commercial sale in such country (the "Royalty Term"), and we may terminate for any or no reason upon advance written notice to BioNTech Zhuhai. BioNTech Zhuhai may terminate if we or our sublicensees shelve development or pre-launch commercialization of a program for a certain time period without justification and we fail to cure such shelving event, or if we or our sublicensees challenge the patents licensed to us by BioNTech Zhuhai. In addition, either party may terminate for the other party's material breach or insolvency or as a result of certain force majeure circumstances, each subject to certain notice and/or cure periods. Upon termination (but not expiration), all licenses and all other rights granted to us terminate, and we are obligated to grant BioNTech Zhuhai a reversion license under certain intellectual property rights controlled by us and used in

connection with the licensed products, and transfer all regulatory materials and know-how within the reversion IP to BioNTech Zhuhai.

In September 2025, the Company entered into a Triparty Payment Agreement with BioNTech Zhuhai and Adimab LLC ("Adimab") under which BioNTech Zhuhai exercised its option for use of certain Adimab intellectual property for the purposes of development and commercialization of BBT003, and became obligated to pay for a sublicense under the development and commercialization license granted by Adimab to BioNTech Zhuhai with respect to such compounds.

For additional discussion around the obligations under the BioNTech Zhuhai Option Agreement and the BioNTech Zhuhai License Agreement, see the subsection titled "—Contractual Obligations and Commitments" and the sections titled "Business—Our Collaboration, License, and Services Agreements—BioNTech Zhuhai Agreements—Research Collaboration and Option Agreement" and "Business—Our Collaboration, License, and Services Agreements—BioNTech Zhuhai Agreements—Exclusive License Agreement" included elsewhere in this prospectus.

Components of Results of Operations

Revenue

We have not generated any revenue to date. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of, and commercialize any of, our product candidates and we do not know when, or if, that will occur. If our development efforts for our current or potential future product candidates are successful and result in regulatory approval or if we enter into additional license or collaboration agreements with third parties, we may generate revenue in the future from product sales, payments from such license or collaboration agreements, or any combination thereof. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with the development of our product candidates, and the ongoing research and development efforts for additional product candidates. These expenses include:

- payments to third parties in connection with the clinical development of our product candidates, including contract research organizations ("CROs") and consultants;
- the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to clinical development manufacturing organizations ("CDMOs") and consultants;
- employee related expenses, including salaries, bonuses, related benefits, and stock-based compensation expense for employees engaged in research and development functions;
- payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees, and for sponsored research arrangements with third parties;
- acquisition, license, and other development costs incurred related to the BioNTech Zhuhai Agreements; and
- other expenses, which include direct or allocated expenses for IT, travel, and training costs.

A significant portion of our research and development costs have been, and will continue to be, external costs. Because we are working on multiple research and development programs at one time, we track external costs on a program-by-program basis following a program's nomination as a product candidate. External costs that are not allocated to a product candidate, such as consulting fees, are classified as early program and indirect unallocated external research and development costs. We do not allocate employee costs or other indirect costs to specific

product candidates because these costs are deployed across multiple product candidates and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially in the foreseeable future as we advance our existing product candidates; continue to research and develop additional product candidates to expand our pipeline; maintain, expand, protect, and enforce our intellectual property portfolio; and hire additional personnel.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing, and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses.

Any changes in the outcome of any of these factors could significantly impact the costs, timing, and viability associated with the development of our product candidates and our ability to generate significant revenues from product sales.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, bonuses, related benefits, and stock-based compensation expense for personnel in executive, finance, and administrative functions. General and administrative expenses also include office costs, which include direct expenses for rent, supplies, services, and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, recruiting, and information technology costs, and tax, accounting, and audit services.

We anticipate that our general and administrative expenses will increase as we increase our headcount to support the growth of the company. We further expect that our general and administrative expenses will increase substantially following the completion of this offering, as we will incur substantially higher expenses relating to director and officer insurance premiums, legal, accounting, audit, regulatory, compliance, and investor and public relations services as a result of being a public company.

Other Income, Net

Other income, net consists primarily of interest earned on our cash and cash equivalents and marketable securities, research and development incentive income, the change in fair value of our preferred stock tranche right obligation, the accretion of discounts on marketable securities, and realized and unrealized gains on foreign currency transactions.

Income Taxes

Since our Inception, we have not recorded any income tax benefits in the United States for the net losses we have incurred or for the research and development tax credits earned in each period and interim period, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized. As of December 31, 2025, we had $13.3 million and $11.1 million of U.S. federal and state net operating loss carryforwards, respectively. The federal net operating loss carryforwards are not subject to expiration and the state net operating loss carryforwards begin to expire in 2044. These loss carryforwards are available to reduce future federal and state taxable income, if any. We recorded a current income tax provision of $2.2 million for the year ended December 31, 2025 related to income taxes at our Australian subsidiary where we generate taxable income under a transfer pricing arrangement.

Results of Operations

Comparison of the Six Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for the six months ended June 30, 2026 and 2025:

	Six Months Ended June 30,		
(in thousands)	**2026**	**2025**	**Change**
Operating expenses:			
Research and development	$ 20,646	$ 11,892	$ 8,754
General and administrative	3,413	3,556	(143)
Total operating expenses	24,059	15,448	8,611
Loss from operations	(24,059)	(15,448)	(8,611)
Other income (expense):			
Other income, net[(1)]	2,893	1,551	1,342
Total other income, net	2,893	1,551	1,342
Loss before income taxes	(21,166)	(13,897)	(7,269)
Income tax provision	1,194	850	344
Net loss	$ (22,360)	$ (14,747)	$ (7,613)

(1) Includes interest income, research and development incentive, change in fair value of preferred stock tranche right obligation, and other income, net. See Condensed Consolidated Statements of Operations and Comprehensive Loss in our condensed consolidated financial statements.

Research and Development Expenses

The breakdown of our research and development expenses is as follows:

	Six Months Ended June 30,		
(in thousands)	**2026**	**2025**	**Change**
External costs:			
BBT001	$ 6,636	$ 3,950	$ 2,686
BBT002	5,073	3,097	1,976
Early program costs	5,368	448	4,920
Other indirect or unallocated costs	141	659	(518)
Total external costs	17,218	8,154	9,064
Internal personnel costs	3,428	3,738	(310)
Total research and development expenses	$ 20,646	$ 11,892	$ 8,754

Research and development expenses increased to $20.6 million for the six months ended June 30, 2026 from $11.9 million for the six months ended June 30, 2025. The increase in research and development expenses was primarily attributable to:

- $4.7 million of increased costs associated with our lead programs, BBT001 and BBT002, which were primarily due to increases in clinical development costs of $5.4 million as these programs advanced through Phase 1b/2a clinical trials in the second half of 2025 and increases in manufacturing development costs of $0.3 million. These increases were partially offset by decreases of $0.5 million in upfront license fees, $0.2 million in preclinical development costs, and $0.1 million in other research and development costs;
- $4.9 million of increased costs associated with early programs, which were primarily due to increases of $4.8 million in manufacturing development costs associated with BBT003;

- $0.5 million of decreased costs associated with other indirect or unallocated research and development costs, which were primarily due to a reduction of $0.4 million in non-program-related upfront license fees; and
- $0.3 million of decreased personnel costs due to the recognition pattern of certain equity awards and increased headcount, including a decrease of $1.9 million in stock-based compensation expense, partially offset by increases of $1.5 million in salaries, bonuses, travel, and other personnel-related costs associated with expanding our research and development activities.

General and Administrative Expenses

General and administrative expenses decreased to $3.4 million for the six months ended June 30, 2026 from $3.6 million for the six months ended June 30, 2025. The decrease was driven primarily by a $0.8 million decrease in professional services and external general and administrative expenses, partially offset by a $0.7 million increase in general and administrative personnel costs.

Of the $0.8 million decrease in professional services and external general and administrative expenses, $2.0 million related to a decrease in stock-based compensation, partially offset by a $1.3 million increase in legal and professional services as we prepare to become a public company. Of the $0.7 million increase in general and administrative personnel costs, $0.6 million related to compensation and other benefits due to increased headcount and an increase of $0.1 million in stock-based compensation.

Comparison of the year ended December 31, 2025 to the period from March 14, 2024 (Inception) to December 31, 2024

The following table summarizes our results of operations for the year ended December 31, 2025 and the period from Inception to December 31, 2024:

(in thousands)	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024	Change
Operating expenses:			
Research and development	$ 38,096	$ 13,025	$ 25,071
General and administrative	5,910	855	5,055
Total operating expenses	44,006	13,880	30,126
Loss from operations	(44,006)	(13,880)	(30,126)
Other income (expense):			
Other income, net[(1)]	5,152	139	5,013
Total other income, net	5,152	139	5,013
Loss before income taxes	(38,854)	(13,741)	(25,113)
Income tax provision	2,233	—	2,233
Net loss	$ (41,087)	$ (13,741)	$ (27,346)

(1) Includes interest income, research and development incentive, change in fair value of preferred stock tranche right obligation, and other income, net. See Consolidated Statements of Operations and Comprehensive Loss in our consolidated financial statements.

Research and Development Expenses

The breakdown of our research and development expenses is as follows:

(in thousands)	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024	Change
External costs:			
BBT001	$ 15,519	$ 6,165	$ 9,354
BBT002	12,979	5,063	7,916
Other early program and indirect unallocated costs	3,064	626	2,438
Total external costs	31,562	11,854	19,708
Internal personnel costs	6,534	1,171	5,363
Total research and development expenses	$ 38,096	$ 13,025	$ 25,071

Research and development expenses increased to $38.1 million for the year ended December 31, 2025 from $13.0 million for the period from Inception to December 31, 2024. The increase in research and development expenses was primarily attributable to:

- $17.3 million of increased costs associated with our lead programs, BBT001 and BBT002, which were primarily due to increases in clinical development costs of $13.6 million for the advancement of these programs into Phase 1b/2a clinical trials during 2025, as well as increases in manufacturing development costs of $4.4 million, preclinical development costs of $2.2 million, and other research and development costs of $0.4 million, offset by a $3.4 million reduction in upfront license fees;
- $2.4 million of increased costs associated with early programs and other indirect research and development costs, which were primarily due to increases of $1.5 million in upfront license fees related to our BBT003 program and $0.8 million in other external research and development costs; and
- $5.4 million of increased personnel costs due to increased headcount and the issuance of stock-based awards, including increases of $2.8 million in salaries, bonuses, travel, and other personnel-related costs associated with expanding our research and development activities and $2.6 million in stock-based compensation.

General and Administrative Expenses

General and administrative expenses increased to $5.9 million for the year ended December 31, 2025 from $0.9 million for the period from Inception to December 31, 2024. The increase was driven primarily by a $3.9 million increase in professional services and other external general and administrative costs due to the issuance of stock-based awards and to support our growth and a $1.1 million increase in general and administrative personnel costs due to increased headcount.

Of the $3.9 million increase in professional services and external general and administrative costs, $2.6 million related to non-employee stock-based compensation, $0.5 million related to recruiting, $0.4 million related to legal and professional fees, and $0.4 million related to increased office, travel, and other general administrative expenses. Of the $1.1 million increase in general and administrative personnel costs, $0.9 million related to employee compensation and benefits and $0.2 million related to travel and other expenses.

Other Income, Net

Other income, net increased to $5.2 million for the year ended December 31, 2025 from $0.1 million for the period from Inception to December 31, 2024. The increase was driven primarily by $2.0 million of increased interest income and $3.3 million of research and development incentive credit, offset by a $0.5 million change in fair value of the preferred stock tranche right obligation.

Liquidity and Capital Resources

Sources of Liquidity

Since Inception, we have incurred net losses and negative cash flows from operations. As of June 30, 2026, we had an accumulated deficit of $77.2 million. For the six months ended June 30, 2026 and 2025, we had net losses of $22.4 million and $14.7 million, respectively, and we expect to incur substantial additional losses in future periods. For the year ended December 31, 2025 and the period from Inception to December 31, 2024, we had net losses of $41.1 million and $13.7 million, respectively, and we expect to incur substantial additional losses in future periods. We have historically financed our operations primarily through the sale of convertible preferred stock. From Inception through June 30, 2026, we have financed our operations with an aggregate of $136.1 million in gross cash proceeds from the sale of convertible preferred stock. In June 2024, we raised aggregate gross proceeds of approximately $5.1 million from the issuance and sale of our Series Seed Preferred Stock. In August 2024, we raised aggregate gross proceeds of approximately $9.0 million from the issuance and sale of our Series Seed Plus Preferred Stock. In February 2025, we raised aggregate gross proceeds of approximately $53.3 million from the issuance and sale of our Series A-1 Preferred Stock. In June 2025, we raised aggregate gross proceeds of approximately $35.6 million from the issuance and sale of our Series A-1 Preferred Stock. In October 2025, we raised aggregate gross proceeds of approximately $32.1 million from the issuance and sale of our Series A-2 Preferred Stock. In January 2026, we raised aggregate gross proceeds of approximately $1.0 million from the issuance and sale of our Series A-2 Preferred Stock.

As of June 30, 2026, we had cash and cash equivalents and marketable securities of $71.5 million. These amounts are not expected to be sufficient to fund our operations for at least 12 months from the date our financial statements were available to be issued. Therefore, there is substantial doubt about our ability to continue as a going concern, as more fully described in Note 1 to our consolidated financial statements, and our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2025 with respect to this uncertainty.

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of, and commercialize any of, our product candidates and we do not know when, or if, that will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Moreover, following the completion of this offering, we expect to incur additional costs associated with operating as a public company.

Future Funding Requirements

As of June 30, 2026, we had total cash and cash equivalents and marketable securities of $71.5 million. Based on our current plans, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into late 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will continue to require additional capital to develop our product candidates and to fund operations for the foreseeable future. We anticipate that we will need to raise substantial additional capital, for which the requirements will depend on many factors, including:

- the scope, progress, timing, results, and costs of developing and manufacturing our product candidates and their components, and conducting preclinical studies and clinical trials and other testing of our product candidates;
- the costs, timing, and outcome of regulatory review of any of our product candidates;

- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing and establish new strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation, tariffs, and fluctuating interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technologies and market developments; and
- the extent to which we acquire or invest in other businesses or products.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of our product candidates. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans.

We may seek to raise capital through public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements, or a combination of one or more of these or other funding sources. Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as needed would have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we raise additional funds by issuing equity securities, our stockholders may experience dilution and the terms of any financing may adversely affect the rights of our stockholders. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation, or asset sale transactions and, in the event of insolvency, debt holders would be repaid before holders of equity securities receive any distribution of our corporate assets. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or we may have to accept other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See the section titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash for each of the periods presented below:

(in thousands)	Six Months Ended June 30, 2026	Six Months Ended June 30, 2025	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024
Net cash used in operating activities	$ (20,137)	$ (19,040)	$ (39,804)	$ (4,634)
Net cash (used in) provided by investing activities	15,032	—	(39,728)	—
Net cash provided by financing activities	996	88,794	120,813	13,996
Net increase in cash and cash equivalents	$ (4,109)	$ 69,754	$ 41,281	$ 9,362

Operating Activities

Net cash used in operating activities during the six months ended June 30, 2026 of $20.1 million was primarily attributable to our net loss of $22.4 million. This was partially offset by net changes in operating assets and liabilities of $1.7 million and non-cash charges of $0.6 million. Net changes in operating assets and liabilities was largely driven by a $1.1 million decrease in other assets and a $1.2 million increase in accrued expenses and other current liabilities, offset by an increase of $0.3 million in prepaid expenses and other current assets and a decrease of $0.3 million in accounts payable. Non-cash charges are comprised of $0.7 million in stock-based compensation expense, offset by $0.1 million in accretion of discounts on marketable securities and unrealized gains on foreign currency transactions.

Net cash used in operating activities during the six months ended June 30, 2025 of $19.0 million was primarily attributable to our net loss of $14.7 million and changes in operating assets and liabilities of $9.3 million, largely driven by a decrease of $7.1 million in accrued expenses and other current liabilities and an increase of $2.3 million in prepaid expenses and other assets, partially offset by a $0.1 million increase in accounts payable. This was offset by non-cash charges, including $4.5 million for stock-based compensation expense and $0.5 million for changes in the fair value of our preferred stock tranche right obligation and $0.1 million in accretion of discounts on marketable securities and unrealized losses on foreign currency transactions.

Net cash used in operating activities during the year ended December 31, 2025 of $39.8 million was primarily attributable to our net loss of $41.1 million and net changes in operating assets and liabilities of $4.3 million, largely driven by a $4.6 million increase in prepaid expenses and other assets. This was offset by non-cash charges of $5.6 million, including $5.4 million for stock-based compensation expense and $0.5 million for changes in the fair value of our preferred stock tranche right obligation, offset by $0.3 million in accretion of discounts on marketable securities and unrealized gains on foreign currency transactions.

Net cash used in operating activities during the period from Inception to December 31, 2024 of $4.6 million was primarily attributable to our net loss of $13.7 million, offset by net changes in operating assets and liabilities of $8.9 million, largely driven by increases in accrued expenses and other current liabilities of $9.3 million, partially offset by increases in prepaid expenses and other current assets of $0.4 million. This was further offset by non-cash charges of $0.2 million for stock-based compensation expense.

For the periods presented, changes in prepaid expenses and other current assets, other assets, accounts payable and accrued expenses, and other current liabilities not described above were generally due to the growth in our business, the advancement of our clinical programs, and the timing of vendor invoicing and payments.

Investing Activities

Net cash provided by investing activities of $15.0 million during the six months ended June 30, 2026 was attributable to maturities of marketable securities of $30.0 million, offset by purchases of marketable securities of $15.0 million. There were no investing activities during the six months ended June 30, 2025.

Net cash used in investing activities of $39.7 million for the year ended December 31, 2025 was attributable to purchases of marketable securities of $47.2 million, offset by maturities of marketable securities of $7.5 million, respectively. There were no investing activities during the period from Inception to December 31, 2024.

Financing Activities

Net cash provided by financing activities of $1.0 million during the six months ended June 30, 2026 consisted of proceeds of $1.0 million from the sale of shares of Series A-2 convertible preferred stock, net of transaction costs.

Net cash provided by financing activities of $88.8 million during the six months ended June 30, 2025 consisted of $88.8 million from the sale of our Series A-1 convertible preferred stock, net of payments of issuance costs.

Net cash provided by financing activities of $120.8 million during the year ended December 31, 2025 primarily consisted of proceeds of $88.8 million and $32.0 million from the sales of our Series A-1 and Series A-2 convertible preferred stock, net of payments of issuance costs, respectively.

Net cash provided by financing activities of $14.0 million during the period from Inception to December 31, 2024 consisted of proceeds of $5.1 million and $8.9 million from the sales of our Series Seed and Series Seed Plus redeemable convertible preferred stock, net of payments of issuance costs, respectively.

Contractual Obligations and Commitments

BioNTech Zhuhai Agreements

Pursuant to the BioNTech Zhuhai Agreements, we are required to make certain milestone, royalty, and other payments, some of which are contingent on the achievement of certain specified events. For more information on the nature of the BioNTech Zhuhai Agreements, refer to the subsections titled "—BioNTech Zhuhai Agreements—BioNTech Zhuhai Assignment Agreement" and "—BioNTech Zhuhai Agreements—BioNTech Zhuhai Option Agreement and Exclusive License Agreement" above.

BioNTech Zhuhai Assignment Agreement

Under the BioNTech Zhuhai Assignment Agreement, we are obligated to (i) share a portion of a platform fee owed by BioNTech Zhuhai to BioNTech Zhuhai's upstream licensor Alloy Therapeutics, LLC ("Alloy") in the amount of $7,500 per program until May 2026, (ii) pay, for each program, a $50,000 annual fee for so long as the program remains active and the relevant rights have not been terminated or abandoned before the applicable anniversary date, and (iii) pay, when invoiced, product-specific milestone payments that flow through BioNTech Zhuhai's agreement with Alloy, with aggregate development milestone payments that could reach approximately $1.8 million per program and aggregate commercial milestone payments that could reach $11.0 million per program. In May 2026, BioNTech Zhuhai did not renew its license with Alloy. As a result, we were released from our obligation to pay the associated annual platform fee of $7,500 per Assigned Program. The remaining rights and obligations remain in full effect. Under the BioNTech Zhuhai Assignment Agreement, as of June 30, 2026, we have made cash payments to BioNTech Zhuhai totaling approximately $4.8 million, including approximately $0.2 million in 2024 and $4.6 million in 2025. No payments were made under the BioNTech Zhuhai Assignment Agreement during the six months ended June 30, 2026.

For more information, refer to the subsection titled "—BioNTech Zhuhai Agreements—BioNTech Zhuhai Assignment Agreement" above.

BioNTech Zhuhai Option Agreement

For each research program conducted under the BioNTech Zhuhai Option Agreement, we are obligated to pay BioNTech Zhuhai a one-time research fee of $0.5 million, subject to adjustment if we request additional research or development activities. If a compound becomes abandoned and BioNTech Zhuhai subsequently licenses such compound to a third party, BioNTech Zhuhai is obligated to pay us a revenue share equal to certain percentages of the licensing net proceeds, ranging from mid-single-digit to sub-teen percentages, with the applicable percentage dependent on the development stage of such compound at the time BioNTech Zhuhai licenses such compound,

subject to a minimum payment. Under the BioNTech Zhuhai Option Agreement, we have made cash payments to BioNTech Zhuhai totaling approximately $0.1 million during the six months ended June 30, 2026 and $1.0 million during the year ended December 31, 2025. For more information, refer to the subsection titled "—BioNTech Zhuhai Agreements—BioNTech Zhuhai Option Agreement and Exclusive License Agreement" above.

BioNTech Zhuhai License Agreement

Under the BioNTech Zhuhai License Agreement, we paid BioNTech Zhuhai a $1.0 million upfront payment in cash during the year ended December 31, 2025, and are obligated to pay them an annual license fee of $57,500 until the first commercial sale of the first licensed product, with aggregate development milestone payments that could reach $6.9 million, aggregate first commercial sale milestone payments that could reach $57.5 million, and additional aggregate sales milestones that could reach $217.5 million, with each milestone payment payable only once upon the first achievement of the applicable milestone event, as well as royalties in a low-single-digit percentage of net sales by us, our affiliates, or sublicensees on a licensed product-by-licensed product and country-by-country basis, subject to certain customary reductions. Our obligation to pay BioNTech Zhuhai royalties will commence on the first commercial sale of a licensed product in a given country and end, on a licensed product-by-licensed product and country-by-country basis, upon the latest of patent expiration, regulatory exclusivity expiration, or termination, or ten years after such first commercial sale in such country (the "Royalty Term"). For more information, refer to the subsection titled "—BioNTech Zhuhai Agreements—BioNTech Zhuhai Option Agreement and Exclusive License Agreement" above.

Pursuant to a certain payment agreement entered into among BioNTech Zhuhai, its upstream licensor Adimab, LLC ("Adimab"), and us on September 29, 2025, the rights of which are sublicensed to us under the BioNTech Zhuhai License Agreement, we have paid a one-time fee of $0.5 million in 2025 directly to Adimab and are obligated to make payments directly to Adimab to satisfy certain payment obligations owed by BioNTech Zhuhai to Adimab, which include aggregate development milestone payments that could reach $3.0 million and marketing approval milestone payments that could reach $3.0 million, on a licensed product-by-licensed product basis, and royalties in a low-single-digit percentage of net sales of certain of the licensed products under the BioNTech Zhuhai License Agreement by us, our affiliates, or sublicensees, subject to certain customary reductions.

Value Appreciation Rights

We grant incentive awards to employees and consultants as value appreciation rights ("VARs"). The VARs are settled in cash or other consideration having a value equal to the difference between the grant-date price and the fair value of our common stock on the applicable payment date, multiplied by the number of VARs vested. The vesting of each VAR, based on the modified terms, is contingent upon a change in control of the Company prior to its expiration date. As of June 30, 2026 and December 31, 2025, all of the VARs were expected to be settled in cash. The VARs are liability-classified awards which are not recorded on the consolidated balance sheets as of June 30, 2026 and December 31, 2025 as the performance condition is not considered probable. As of June 30, 2026 and December 31, 2025, the intrinsic value of the VARs was $5.6 million and $2.7 million, respectively. Refer to "Critical Accounting Estimates and Judgments" below for further discussion regarding the cash requirements.

Other Planned Uses of Capital

We enter into contracts in the normal course of business with CROs, CDMOs, and other third parties for nonclinical, clinical, and manufacturing, and other development services. Payments due upon cancellation of contracts with CROs, CDMOs, and other third parties consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Quantitative and Qualitative Disclosures About Market Risk

Our business and financial results are affected by fluctuations in world financial markets, including the impacts of foreign currency exchange rates and inflation. We evaluate our exposure to such risks on an ongoing basis, and, if material, seek ways to manage these risks to an acceptable level, based on management's judgment of the appropriate trade-off between risk, opportunity, and cost.

Foreign Currency Risk

We operate in the United States, Australia, and China. Our expenses are generally denominated in U.S. dollars. We are subject to foreign currency transaction gains or losses on certain of our payments denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material and we have not had a formal hedging program with respect to foreign currency; however, we may consider doing so in the future.

Critical Accounting Estimates and Judgments

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as the related disclosures in the notes to the consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances. Actual results may differ materially from these estimates.

We consider an accounting estimate to be critical if it requires management to make assumptions that are highly uncertain at the time the estimate is made and if changes in the estimate or different estimates that reasonably could have been used would have had a material impact on our consolidated financial statements. While our significant accounting policies are described in Note 2 to our consolidated financial statements, we believe the following accounting estimates involve the most significant judgments and uncertainties material to the preparation of our consolidated financial statements.

Research and Development Expenses and Accruals

Research and development expenses consist primarily of costs incurred for the research and development of our product candidates, including payroll and personnel-related costs, stock-based compensation, external research and development costs, acquired in-process research and development ("IPR&D") costs, license fees, research fees, contract manufacturing costs, clinical and preclinical development costs, and consulting fees. We expense research and development costs as incurred.

A significant component of our research and development expenses is attributable to third-party service providers, including CROs, CDMOs, clinical trial sites, and other vendors supporting preclinical studies, clinical trials, and manufacturing development activities. We record accrued research and development expenses for estimated costs of services performed but not yet invoiced as of each balance sheet date. Non-refundable research and development advance payments are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or services are performed. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

These accruals are a critical accounting estimate because they are based on information that may not yet be fully available to us at the time we close our books. In estimating accrued research and development expenses, we assess the status of ongoing activities under our vendor agreements and apply judgments about the level of effort or percentage of completion of the services provided. Significant inputs into these estimates may include patient

enrollment, patient visits, screening and dosing activity, site initiation and close-out activity, trial monitoring progress, manufacturing progress, achievement of contractual milestones, and other information communicated by our vendors and internal project managers.

We adjust our estimates as additional information becomes available and record any such adjustments in the period in which the facts that give rise to the adjustment become known. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the fees invoiced may vary from our estimates. Changes in these estimates could result in increases or decreases to research and development expense and accrued liabilities in the period in which the changes are identified. To date, we have not recorded any material adjustments to our accrued or prepaid research and development expenses.

For clinical trial accruals, the most significant judgments generally relate to the number of patients enrolled, the timing and extent of services performed by clinical sites and CROs, and changes in trial protocols or scope of work. If actual timing of patient enrollment, site activity, or vendor performance differs from our estimates, the amount of accrued research and development expense recorded in any period could differ materially from the amounts ultimately paid.

Asset Acquisition and Acquired In-Process Research and Development Expenses

We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire IPR&D assets with no alternative future use is recognized as expense on the acquisition date.

We will recognize additional research and development expenses in the future or capitalize such amounts for completed technology if and when it becomes probable we will be obligated to make contingent milestone payments under the terms of the agreements by which we acquired the IPR&D assets.

Contingent consideration in an asset acquisition is measured and recognized when payment becomes probable and reasonably estimable. Subsequent changes in the accrued amount of contingent consideration are measured and recognized at the end of each reporting period and upon settlement as an adjustment to the cost basis of the acquired asset or group of assets, or, if related to IPR&D with no alternative future use, charged to expense.

We determined the acquisition of the assigned programs under the BioNTech Zhuhai Assignment Agreement was an asset acquisition related to IPR&D assets with no alternative future use. As such, we recorded $1.0 million and $4.0 million during the year ended December 31, 2025 and the period from Inception to December 31, 2024, respectively, of IPR&D expense, which is a component of research and development expense in the consolidated statements of operations and comprehensive loss. We further concluded that the arrangement did not qualify as a business combination because the assets acquired did not include the elements of a business.

Stock-Based Compensation

We grant stock-based awards to employees, non-employee directors, and non-employees, including stock options, RSUs and restricted stock, based on the fair value of the awards on the grant date and recognize the related compensation expense over the requisite service period. For awards with only service-based vesting conditions, we generally recognize expense on a straight-line basis over the vesting period. For awards with performance-based vesting conditions, we recognize compensation expense when achievement of the performance condition becomes probable over the requisite service period using the attribution method applicable to the award.

The fair value of stock options is estimated on the date of grant using the Black-Scholes option-pricing model, which requires the use of subjective assumptions, including:

- expected volatility of our common stock,
- expected term of the award,

- risk-free interest rate,
- expected dividend yield, and
- the fair value of the underlying common stock on the grant date.

We also grant incentive awards to employees and consultants as VARs. The VARs are settled in cash or other consideration having a value equal to the difference between the grant-date price and the fair value of our common stock on the applicable payment date, multiplied by the number of VARs vested. The VARs contain both service-based and performance-based vesting conditions. Based on the modified terms, upon a change in control of the Company, any VARs that have achieved the respective service-based and other performance-based conditions, if applicable, vest and become payable. To the extent the service-based vesting condition has not been fully met at the time of a change in control for the Company, such VARs will continue to vest in accordance with the applicable service vesting conditions. The VARs are liability-classified awards that we record at fair value on our consolidated balance sheet when deemed probable, with changes in fair value recognized in earnings. As of December 31, 2025, we have determined that the performance conditions for the VARs are not probable. We recognize compensation expense for the VARs when the achievement of the performance condition(s) becomes probable and over the requisite service period using the attribution method applicable to the award. Prior to our initial public offering, we have elected to measure the VARs at their intrinsic value. Subsequent to our initial public offering, we will measure the VARs at their fair value using a Monte Carlo simulation model.

In October 2026, we cancelled 701,797 VARs which were payable upon a liquidity event, defined as a change in control or public listing, and we granted RSUs covering up to 701,797 shares of common stock issuable pursuant to the Liquidity Event RSU Settlement, which will vest upon both a performance condition (which will be satisfied in connection with this offering) and a service condition, with the amount eligible to vest calculated based on the volume-weighted average price of our common stock in the 20-day trading period immediately following a public listing. Based on the initial public offering price of $16.00 per share, we estimate that 621,192 shares will be eligible to vest, with a grant date fair value of $10.0 million.

Changes in the assumptions used in the Black-Scholes model, Monte Carlo simulation model, or changes in the estimated fair value of our common stock could materially affect the amount of stock-based compensation expense recognized in our consolidated statements of operations and comprehensive loss and VAR-related liabilities on our consolidated balance sheets. In addition, because the estimated fair value of our common stock may increase over time as we advance our business and approach an initial public offering or other liquidity event, stock-based compensation expense for future grants may be higher than that recognized for historical grants.

Determination of Fair Value of Common Stock

As there has been no public market for our common stock to date, the historical estimated fair value of our common stock has been determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock, as well as additional factors that may have changed since the date of the most recent valuation through the date of grant.

In accordance with the guidance outlined in the American Institute of Certified Public Accountants' *Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the "Practice Aid"), a third-party valuation firm prepared valuations of our common stock using a market approach to estimate our common stock value, using either the option-pricing method ("OPM"), or the hybrid method, both of which used a market approach to estimate our enterprise value. The market approaches used were either the recent transactions method or the market adjusted equity value method.

In accordance with the Practice Aid, the OPM method was the most appropriate method for determining the fair value of our common stock prior to April 30, 2026 and we determined the hybrid method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors for valuations as of April 30, 2026 and going forward. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has

value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a valuation methodology that combines the probability-weighted expected return method ("PWERM") and the OPM, where the equity value in one or more of the scenarios is allocated between our equity securities using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of our future values, assuming various outcomes, including an initial public offering. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability-weighted to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates which resulted in valuations of our common stock of $2.41 per share as of February 12, 2025, $2.90 per share as of June 27, 2025, $4.81 per share as of October 31, 2025, $7.68 per share as of April 30, 2026, $8.04 per share as of June 19, 2026, and $13.57 per share as of September 15, 2026. The third-party valuations associated with dates prior to June 19, 2026 were performed retrospectively.

Given the absence of a public market for our common stock to date, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date. The factors included, but were not limited to:

- our operating results and financial performance;
- the progress of our research and development efforts, including the status of preclinical studies and clinical trials for our product candidates;
- the lack of marketability of our equity as a private company;
- the prices of our preferred stock sold to new and existing investors, and the rights, preferences, and privileges of our preferred stock as compared to those of our common stock;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into strategic alliance and license agreements;
- the valuation of publicly-traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event, such as an initial public offering ("IPO") or a sale of our company, given prevailing market conditions;
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry; and
- the third-party valuations described above.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, and the stage of development of our product candidates. If our board of directors had made different assumptions, our stock-based compensation expense, net loss allocable to common stockholders and net loss per share allocable to common stockholders could have been significantly different.

Once a public trading market for our common stock has been established in connection with the consummation of this offering, it will no longer be necessary for our board of directors, or a committee thereof, to estimate the fair

value of our common stock in connection with our accounting for granted stock options and other awards, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

The following table summarizes by grant date the number of shares subject to stock option awards granted under our 2024 Plan from January 1, 2025 through the date of this prospectus, the per share exercise price of the awards and the estimated fair value of our common stock, and the per share estimated fair value of the awards on each grant date:

Grant Date	Type of Award	Number of Shares Subject to Awards Granted	Per Share Exercise Price of Awards Granted	Fair Value of Common Stock on Grant Date	Per Share Estimated Fair Value of Awards on Grant Date[1]
May 6, 2025	Stock Option	93,142	$1.84	$2.41 [2]	$2.18
August 16, 2025	Stock Option	567,682	$1.84	$2.90 [2]	$2.57
October 6, 2025	Stock Option	12,059	$1.84	$2.90 [2]	$2.48
April 30, 2026	Stock Option	552,957	$4.81	$7.68 [3]	$6.41
July 10, 2026	Stock Option	268,093	$8.04	$8.04	$6.67
September 18, 2026	Stock Option	1,353,356	$13.57	$13.57	$11.45

(1) The estimated fair value per share of the awards represents our measurement of the weighted-average fair value of option grants using the Black-Scholes model.
(2) At the time of the stock option grants from May 6, 2025 through October 6, 2025, our Board determined that the fair value of our common stock of $1.84 per share reasonably reflected the fair value of our common stock as of the grant date based on information known to us on the date of grant. However, as described below, the fair values of our common stock as of the dates of these grants were adjusted in connection with retrospective fair value assessments for accounting purposes.
(3) At the time of the stock option grants on April 30, 2026, our Board determined that the fair value of our common stock of $4.81 per share reasonably reflected the fair value of our common stock as of the grant date based on information known to us on the date of grant. However, as described below, the fair value of our common stock as of the date of these grants was adjusted in connection with a retrospective fair value assessment for accounting purposes.

In the course of preparing for this offering, in June 2026, we performed a retrospective fair value assessment solely for accounting and financial reporting purposes, and concluded that (i) the fair value of our common stock underlying stock options we granted on May 6, 2025 was $2.41 per share for accounting purposes, (ii) the fair value of our common stock underlying stock options we granted on August 16, 2025 and October 6, 2025 was $2.90 per share for accounting purposes, and (iii) the fair value of our common stock underlying stock options we granted on April 30, 2026 was $7.68 per share for accounting purposes. We applied the fair values of our common stock from our retrospective fair value assessments to determine the fair value of these awards and calculate stock-based compensation expense for accounting purposes. These reassessed values were based, in part, upon third-party valuations of the fair value of our common stock prepared on a retrospective basis solely for accounting and financial reporting purposes as of February 12, 2025, June 27, 2025, and April 30, 2026. The third-party valuations were prepared using either an OPM or a hybrid method, both of which used market approaches to determine our enterprise value, as further described above. The fair values increased primarily due to the model factoring in the likelihood of an IPO scenario.

Internal Controls and Procedures

In connection with the preparation of our financial statements for the year ended December 31, 2025 and the period from Inception to December 31, 2024, we concluded that there were material weaknesses in our internal control over financial reporting. For further information, see the section titled “Risk Factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.”

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time that those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Unless we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act, we will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.235 billion or more, (ii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years, or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

- we may present only two years of audited financial statements, plus unaudited condensed financial statements for any interim period, and related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- we may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we may not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (1) the market value of our stock held by non-affiliates is less than $250.0 million or (2) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Pronouncements

A description of recently issued and recently adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements and our unaudited condensed consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company developing next-generation, long-acting precision bispecific antibodies designed to redefine standards of care in immunology and inflammation ("I&I") and fundamentally improve patient quality of life. Although monoclonal antibodies have transformed the I&I treatment landscape, many patients remain underserved, continuing to experience incomplete responses or residual disease activity. We believe that next-generation therapeutic approaches, particularly bispecific and multi-target biologics that simultaneously modulate complementary and synergistic inflammatory pathways, are necessary to expand responder populations, address the significant unmet medical need, and unify treatment across overlapping disease biology.

Our vision is to deliver transformative medicines for I&I patients across every stage of disease. We use third-party, advanced antibody engineering to create long-acting bispecific antibodies that combine clinically and commercially validated biologic pathways into a single molecule formulated for high-concentration subcutaneous ("SubQ") delivery. Our goal is to improve durability, convenience, and clinical differentiation beyond the current capabilities of existing monotherapies, which we refer to as breaking the therapeutic ceiling. We believe our product candidates have the potential to address unmet medical need across I&I, spanning dermatology, respiratory, gastroenterology, and autoimmune diseases ("AID"), and capture a substantial part of the rapidly growing global I&I market, which is projected to exceed $200 billion by 2030.

Since our inception on March 14, 2024 ("Inception"), we have acquired assets from BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"), that became our lead product candidates, BBT001 and BBT002, secured regulatory clearances to initiate clinical trials for these product candidates across multiple geographical regions, advanced them from preclinical to clinical development, completed dosing and safety follow ups of intravenous ("IV") formulations of these product candidates in healthy volunteers, initiated enrollment and dosing of patients for proof-of-concept ("PoC") readouts, developed high-concentration SubQ formulations of both product candidates, initiated healthy volunteer and PoC substudies of such SubQ formulations, and initiated SubQ dosing of BBT001 in patients. We have also identified two additional promising product candidates, BBT003 and BBT004, in collaboration with our partner BioNTech Zhuhai, and we plan to advance BBT003 into clinical development by the end of 2026. We believe this track record reflects our distinctive ability to move with urgency and precision across discovery, development, and operations.

Our lead product candidate, **BBT001,** a next-generation, long-acting bispecific antibody targeting two clinically and commercially validated pathways, interleukin-4 receptor alpha ("IL-4Rα") and interleukin-31 ("IL-31"), is designed to simultaneously address core Type 2 inflammation and chronic itch, the two defining burdens of atopic dermatitis ("AD") and other inflammatory skin diseases. BBT001 has been intentionally engineered using validated half-life extension ("HLE") technology with the goal of enabling extended dosing intervals relative to conventional antibody therapies. We are currently evaluating BBT001 for the treatment of moderate-to-severe AD in a global Phase 1 clinical trial in the United States, Australia, Europe, and New Zealand ("Global BBT001 Study") and in a Phase 1a/1b clinical trial in China ("China AD Study"). We have also initiated a Phase 2a clinical trial of BBT001 for the treatment of chronic spontaneous urticaria ("CSU") in China ("China CSU Study").

In preliminary results from the single-ascending-dose ("SAD") and multiple-ascending-dose ("MAD") healthy volunteer portions of our Global BBT001 Study, BBT001 demonstrated strong pharmacokinetic ("PK") results with an estimated half-life of 33 days and rapid and sustained pharmacodynamic ("PD") activity, including thymus and activation-regulated chemokine ("TARC") biomarker suppression. BBT001 also demonstrated favorable tolerability results and low immunogenicity, supporting the potential for quarterly maintenance dosing.

In July 2026, we reported positive topline PoC results from our Global BBT001 Study of patients with moderate-to-severe AD who have received neither biologics targeting the same pathways as our product candidate nor Janus kinase ("JAK") inhibitors (we refer to these patients as "bio-naïve") treated with four weeks of an IV formulation of BBT001 in New Zealand and the United States ("4-week PoC bio-naïve AD data"). We consider clinical studies and substudies that enroll and dose patients (as opposed to healthy volunteers) as PoC studies.

As of the June 8, 2026 data cutoff date, all 17 enrolled patients were evaluable for preliminary safety and clinical response, with a median follow-up of 71 days after the first dose and a range of 33 to 165 days. The topline results that support PoC of BBT001 as a potential treatment for moderate-to-severe AD patients include:

- ***Fast-onset, statistically significant and clinically meaningful improvement in Eczema Area and Severity Index ("EASI")***. BBT001 produced a highly statistically significant placebo-adjusted EASI reduction beginning at Week 1. The placebo-adjusted EASI reduction deepened through Week 6 and remained sustained throughout the course of treatment for patients followed. At Week 6, the placebo-adjusted proportion of patients treated with BBT001 who achieved more than 50% improvement from baseline EASI ("EASI-50") and more than 75% improvement from baseline EASI ("EASI-75") was 82% and 64%, respectively.
- ***Rapid and progressively greater itch relief***. BBT001 reduced Peak Pruritus Numerical Rating Scale ("PP-NRS") scores as early as Day 1, with improvements deepening throughout treatment and remaining sustained for eight weeks after the last dose.
- ***Robust and durable suppression of Type 2 inflammatory biomarkers***. BBT001 produced early and substantial reductions in key biomarkers, including TARC and immunoglobulin E ("IgE"), that were sustained for eight weeks after the last dose, demonstrating durable inhibition of Type 2 inflammation.
- ***Favorable safety findings***. BBT001 was observed to be well tolerated, with no cases of conjunctivitis reported, consistent with prior findings in healthy volunteers.
- ***Extended half-life supporting infrequent dosing.*** BBT001 demonstrated an extended half-life in patients with AD, consistent with prior observations in healthy volunteers. Based on preclinical and clinical trial results to date, including PK, receptor occupancy, depth of response, and duration of response, we believe a quarterly maintenance dosing regimen will be possible.
- ***Low immunogenicity***. BBT001 demonstrated a low incidence of treatment-emergent anti-drug antibodies ("ADA") that has been low titer with no apparent evidence of neutralizing activity, consistent with prior findings in healthy volunteers.

We expect several additional upcoming clinical data readouts for BBT001 throughout the first half of 2027, including topline PoC results of: (i) bio-naïve patients with moderate-to-severe AD treated with 12 weeks of an IV formulation of BBT001 ("12-week PoC bio-naïve AD data"); (ii) patients with moderate-to-severe AD who have previously received either biologics targeting the same pathways as our product candidate or JAK inhibitors (we refer to these patients as "bio-experienced") treated with 12 weeks of an IV formulation of BBT001 ("12-week PoC bio-experienced AD data"); and (iii) patients with CSU treated with 14 weeks of an IV formulation of BBT001 ("14-week PoC CSU data"). We recently announced the dosing of our first patient in a 12-week PoC substudy of a SubQ formulation of BBT001 in bio-naïve patients with moderate-to-severe AD as part of our Global BBT001 Study (the "12-week SubQ AD PoC Substudy") and plan to initiate study start-up activities for our Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT001 to treat patients with moderate-to-severe AD ("Phase 2b AD Study") by the end of 2026. Our Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

Our second lead product candidate, **BBT002**, a next-generation, long-acting bispecific antibody targeting two clinically and commercially validated pathways, IL-4Rα and interleukin-5 ("IL-5"), is designed to simultaneously address both central pillars of Type 2 inflammation, the interleukin-4 ("IL-4") and interleukin-13 ("IL-13") axis and the IL-5 and eosinophil ("EOS") axis, in a single molecule. BBT002 has also been engineered using the same HLE technology as BBT001 with the goal of enabling extended dosing intervals relative to conventional antibody therapies. We believe BBT002 has the potential to address a number of Type 2 inflammatory disorders across respiratory and allergic diseases. We are currently evaluating BBT002 for: (i) the treatment of chronic obstructive pulmonary disease ("COPD") in our global Phase 1 clinical trial in the United States, Australia, Europe, Georgia, and New Zealand ("Global BBT002 Study"); and (ii) our Phase 1/2a clinical trial for COPD in China ("China COPD Study"). We are also evaluating BBT002 for the treatment of chronic rhinosinusitis with nasal polyps ("CRSwNP") in a Phase 2a clinical trial in China ("China CRSwNP Study").

In preliminary results from the SAD and MAD healthy volunteer portions of our Global BBT002 Study, BBT002 demonstrated strong PK results with an estimated half-life of approximately 29 days, dose-dependent, rapid, complete, and sustained dual biomarker effects, including reduction of TARC and EOS depletion for more than eight weeks, favorable safety and tolerability data, and low immunogenicity, supporting the potential for quarterly maintenance dosing. We expect several upcoming clinical data readouts for BBT002, including topline PoC results of patients with COPD treated with four weeks of an IV formulation of BBT002 ("4-week PoC COPD data") in the first half of 2027 and patients with CRSwNP treated with 12 weeks of an IV formulation of BBT002 ("12-week PoC CRSwNP data") in the first half of 2027. In addition, we have initiated our global Phase 2a study of a SubQ formulation of BBT002 in patients with asthma ("Phase 2a Asthma Study"), and plan to initiate study start-up activities for a Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT002 in patients with one of the respiratory indications in 2027.

We are also advancing two preclinical product candidates: **BBT003**, a next-generation, long-acting bispecific antibody targeting Tumor Necrosis Factor-like ligand 1A ("TL1A") and the p19 subunit of interleukin-23 ("IL-23p19") for inflammatory bowel diseases ("IBD"), including Crohn's disease ("CD") and ulcerative colitis ("UC"), for which we plan to enter the clinic by the end of 2026, and **BBT004**, a next-generation, long-acting dual B-cell depletion bispecific antibody for autoantibody-driven AID.

Each of our programs is designed to be a "pipeline-in-a-molecule" with the potential for broad applicability across multiple indications. We have, or can obtain under commercially reasonable terms, worldwide rights to all of our programs and are initially pursuing the indications summarized in Figure 1 below. Our programs and key upcoming catalysts, including multiple anticipated PoC data readouts, are summarized in Figure 1 below. Clinical development is a complex and challenging process with uncertain outcomes and is subject to a number of risks. See the section titled "Risk Factors—Risks Related to Research, Development, Regulatory Approval and Commercialization" for more information on risks that can cause delays in completing a trial or reaching a milestone on time.

Figure 1: Our Pipeline and Key Upcoming Catalysts



Our Strengths

We believe that our company and our differentiated programs possess the following attributes that will help us successfully advance and develop new investigational therapies:

- ***Compelling Early Data Supporting our Multi-Target Approach***. Our preclinical and clinical data provide early evidence of the key features we believe are required for differentiated bispecific antibodies in I&I diseases, including multi-target activity, durable pathway inhibition, and favorable immunogenicity. In our

in vitro and *in vivo* experiments comparing BBT001 to either Dupixent ("anti-IL-4Rα"), a dupilumab analogue or a nemolizumab analogue ("anti-IL-31Rα"), BBT001 demonstrated greater anti-inflammatory activity than each of the therapies tested, as well as better itch control compared to Dupixent. Similarly, in our *in vivo* experiments in both COPD and asthma mouse models, BBT002 demonstrated greater anti-inflammatory activity and improved lung function compared to Dupixent and Tezspire ("anti-TSLP"). In preliminary results from the SAD and MAD healthy volunteer portions of our Global BBT001 Study and Global BBT002 Study and the preliminary 4-week PoC bio-naïve AD data from our Global BBT001 Study, BBT001 and BBT002 each demonstrated extended half-lives, sustained target-relevant PD activity, and low titer ADA with no apparent impact on safety or PK.

- ***Broad and Deep Pipeline with Worldwide Rights***. We have four bispecific programs targeting multiple large I&I indications, spanning dermatology, respiratory, gastroenterology, and AID. We currently have two clinical programs and plan to advance a third program into clinical development by the end of 2026. We have, or can obtain under commercially reasonable terms, worldwide rights to all of our programs. In addition, pursuant to the BioNTech Zhuhai Option Agreement, BioNTech Zhuhai has agreed to develop novel antibodies directed to certain target combinations that are nominated by us, and we have the exclusive option to license those novel antibodies. See the section titled "Our Collaboration, License, and Services Agreements—BioNTech Zhuhai Agreements."

- ***Clinically Validated Bispecific Antibody Platform Architecture***. BBT001 and BBT002 share the same bispecific antibody construct utilizing a fully human immunoglobulin G1 ("IgG1") scaffold containing crystallizable fragment ("Fc")-silencing mutations, together with two humanized variable heavy-chain domains of heavy-chain-only antibodies ("VHH") in a 2+2 antigen binding format. This underlying antibody construct has been clinically validated through pumitamig, a bispecific antibody discovered at BioNTech Zhuhai that has been studied in more than 2,000 patients treated in third-party clinical trials to date, including seven ongoing global Phase 3 clinical trials with registrational potential. Although pumitamig shares the same bispecific antibody architecture as our two lead product candidates, the molecules are distinct, have different targets, are being developed for different disease areas and may not offer the same features or benefits. Our earlier-stage candidates, BBT003 and BBT004, also leverage the IgG1 antibody engineering capabilities of BioNTech Zhuhai, but utilize a 1+1 bispecific antibody format tailored to their respective targets.

- ***Clinically and Commercially Validated Pathways with Complementarity and Synergy***. All of the pathways for our product candidates are clinically validated and most underlie today's commercially successful I&I biologics (e.g., Dupixent (IL-4Rα), Nemluvio (IL-31Rα), Nucala (IL-5), and Skyrizi (IL-23p19)), which together generate tens of billions of dollars in annual revenue. By focusing on targets and mechanisms of action that are orthogonal and complementary, we believe our bispecific antibodies have the potential for synergistic efficacy and improved clinical outcomes relative to conventional single targeting biologics. As an example, we believe our lead product candidate BBT001 in AD has the potential to address both Type 2 inflammation and itch by concurrently targeting IL-4Rα and IL-31 in a single convenient treatment, which could deliver meaningfully greater benefit than any individually approved therapy.

- ***Reduced Immunogenicity and Extended Half-Life.*** We incorporate third-party, advanced antibody engineering designed to optimize half-life and other key molecular properties, with the goal of extending dosing intervals relative to currently approved biologic therapies. We design our product candidates using the fully human IgG1-based bispecific formats, including humanized VHH-based architecture for BBT001 and BBT002 and fully human IgG1-based 1+1 formats for BBT003 and BBT004, with the goal of reducing immunogenicity risk while preserving familiar antibody pharmacology. BBT001 and BBT002 have also been engineered to increase the binding affinity to the neonatal Fc receptor ("FcRn") and leverage the body's natural antibody recycling mechanisms. Based on preclinical and clinical trial results to date, including PK, receptor occupancy, depth of response, and duration of response, we believe a quarterly maintenance dosing regimen will be possible for BBT001 and BBT002.

- ***Significant Commercial Opportunity in the Large and Fast-Growing I&I Market, Including Dermatology, Respiratory, Gastroenterology, and AID***. We are pursuing areas of high unmet needs in high-value I&I indications, including AD, CSU, COPD, CRSwNP, asthma, and IBD, where large established biologic markets exist with significant growth, but where single-targeting approaches face limitations on efficacy and dosing convenience, creating a clear opportunity for our bispecific candidates to redefine the standards of care.

- ***Broad Expansion Potential Across I&I through "Pipeline-in-a-Molecule" Design***. Each of our programs is designed to be a "pipeline-in-a-molecule," with potential to expand into a broad range of target indications across I&I disease segments. Although we are initially focused on well-defined target indications with high unmet need, we believe that our product candidates target pathways that underlie multiple indications. For example, we believe BBT001 has significant potential across multiple dermatology indications beyond AD, including CSU, prurigo nodularis ("PN"), alopecia areata ("AA"), bullous pemphigoid ("BP"), and chronic pruritus of unknown origin ("CPUO"), whereas BBT002 has significant potential across multiple respiratory indications beyond COPD, including CRSwNP and asthma, and other I&I indications, including CSU, eosinophilic esophagitis ("EoE"), and food allergy.

- ***Demonstrated Operational Efficiency and Speed of Execution***. Since our Inception, we have acquired assets from BioNTech Zhuhai, prior to the acquisition of Biotheus by BioNTech, that became our lead product candidates, BBT001 and BBT002, secured regulatory clearances to initiate clinical trials for these product candidates across multiple geographical regions, advanced them from preclinical to clinical development, completed dosing and safety follow-ups of IV formulations of these product candidates in healthy volunteers, initiated enrollment and dosing of patients for PoC readouts, developed high-concentration SubQ formulations of both product candidates, initiated healthy volunteer and PoC substudies of such SubQ formulations, and initiated SubQ dosing of BBT001 in patients. We have also identified two additional promising product candidates, BBT003 and BBT004, in collaboration with our partner BioNTech Zhuhai. We plan to advance BBT003 into clinical development by the end of 2026. We believe this track record reflects our distinctive ability to move with urgency and precision across discovery, development, and operations.

- ***Experienced Leadership Team***. Our management team has deep and complementary expertise across antibody discovery, clinical development, regulatory affairs, business development, and company building. Members of our leadership team and many of our employees have previously worked together at BioNTech Zhuhai, bringing experience across the discovery, development, and strategic partnering of innovative biologic medicines. This shared history has helped establish a highly integrated organization focused on efficient execution and streamlined decision-making.

Our Strategy

Our vision is to deliver transformative medicines for I&I patients across every stage of disease. We believe our pipeline of bispecific antibodies, designed to simultaneously target multiple clinically and commercially validated pathways, has the potential to redefine the standards of care and bring about the next era of I&I therapeutics. The key elements of our strategy include:

- ***Advance a Portfolio of Bispecific Antibodies Targeting High-Value I&I Indications by Synergistically Combining Multiple Clinically and Commercially Validated Biologic Targets***. Our portfolio is designed for value creation, speed and scale in the fast-growing I&I market, spanning dermatology, respiratory, gastroenterology, and AID. We use our antibody expertise and regulatory and operational experience to leverage a clinically validated antibody structure developed by BioNTech Zhuhai and multiple clinically and commercially validated biologic targets to advance next-generation bispecific antibodies that we believe will meaningfully address areas of high unmet medical need in I&I.

- ***Continue to Advance Our Lead Product Candidate, BBT001, through Ongoing Clinical Development in AD and CSU and Pivotal Development Activities in AD***. We are currently evaluating BBT001 for the treatment of moderate-to-severe AD in our Global BBT001 Study and China AD Study and reported

positive topline 4-week PoC bio-naïve AD data from our Global BBT001 Study in July 2026. We also expect several additional upcoming clinical data readouts for BBT001 throughout the first half of 2027, including 12-week PoC bio-naïve AD data and 12-week PoC bio-experienced AD data. We also initiated the China CSU Study, which has the potential to establish clinical PoC for BBT001 beyond AD, and for which we expect to report 14-week PoC CSU data in the first half of 2027. We recently announced the dosing of our first patient in the 12-week SubQ AD PoC Substudy and plan to initiate study start-up activities for our Phase 2b AD Study of a SubQ formulation of BBT001 by the end of 2026. Our Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

- ***Continue to Advance our Second Lead Product Candidate, BBT002, through Clinical Development in COPD, CRSwNP, and Asthma***. We are currently evaluating BBT002 for the treatment of COPD in our Global BBT002 Study and China COPD Study and for CRSwNP in our China CRSwNP Study. In preliminary results from the SAD and MAD healthy volunteer portions of our Global BBT002 Study, BBT002 demonstrated potentially strong PK results with an estimated half-life of 29 days, rapid and sustained dual biomarker effects, including reduction of TARC and EOS depletion for more than eight weeks after a single dose, favorable safety and tolerability data, and low immunogenicity, supporting the potential for quarterly maintenance dosing. BBT002 is designed as a "pipeline-in-a-molecule" for Type 2 inflammatory disorders across respiratory and allergic diseases. We expect several upcoming clinical data readouts for BBT002, including topline 4-week PoC COPD data and 12-week PoC CRSwNP data in the first half of 2027. In addition, we have initiated our global Phase 2a Asthma Study and plan to initiate study start-up activities for a Phase 2b dose-ranging study of a SubQ formulation of BBT002 in patients with one of the respiratory indications in 2027.

- ***Expand Late-Stage Clinical Development Plans and Activities of BBT001 and BBT002 Beyond AD, CSU, COPD, and CRSwNP into Additional I&I Target Indications to Unlock Their Full "Pipeline-in-a-Molecule" Potential***. Beyond AD and CSU, we believe BBT001 has significant potential across multiple dermatology indications. Subject to receiving positive data in our ongoing clinical trials for AD and CSU, we plan to expand BBT001 clinical development into additional target indications including PN, AA, BP, and CPUO. BBT001's dual targeting of IL-4Rα and IL-31 is designed to be particularly well suited to these indications because it has the potential to simultaneously address the Type 2 inflammatory cascade and the chronic itch pathway. Subject to obtaining positive data in our ongoing clinical trials for multiple respiratory diseases including COPD, CRSwNP, and asthma, we plan to expand BBT002 clinical development into additional target indications including CSU, EoE, and food allergy. BBT002's dual targeting of IL-4Rα and IL-5 is designed to simultaneously address two central and non-overlapping drivers of Type 2 inflammatory disease and concurrently improve lung function and reduce risk of exacerbations.

- ***Advance BBT003 and BBT004 into Clinical Development in Gastroenterology and AID Indications, where Simultaneous Targeting of Established Pathways May Improve Patient Outcomes***. We plan to develop BBT003 for IBD, including UC and CD, where its multi-targeting approach is designed to target TL1A and IL-23p19, key inflammatory pathways involved in disease pathogenesis. We currently plan to initiate a Phase 1 study for BBT003 by the end of 2026. We are also advancing BBT004 for autoantibody-driven AID, where dual B-cell targeting may enable differentiated outcomes.

- ***Build Corporate Infrastructure Required for Growth, Including Capabilities to Support Late-Stage Clinical Development, Regulatory Execution, and Future Commercialization***. As our lead product candidates advance, we intend to scale our corporate infrastructure to support a growth-stage biotechnology company, including capabilities across clinical development, clinical operations, manufacturing, quality, regulatory affairs, medical affairs, market access, and commercial planning. We believe these investments will position us to efficiently execute pivotal trials and prepare for potential product launches. We also plan to build targeted commercial capabilities in select indications and geographies where we believe an internal model can create the greatest long-term value. We believe this operating model of internal capability building can optimize execution, preserve capital efficiency, and maximize long-term portfolio value.

- ***Pursue Strategic Partnerships and Opportunities Where Appropriate to Maximize Long-Term Value***. We believe the significant global commercial opportunity associated with our pipeline, together with the scale of resources required for late-stage development, global regulatory execution, manufacturing, and commercialization, may create compelling opportunities for strategic partnerships or other similar opportunities. We intend to evaluate collaborations, licensing arrangements, and co-development partnerships that could accelerate development, expand access to key markets, leverage complementary capabilities, reduce execution risk, and enhance capital efficiency. We believe such arrangements allow us to maximize the long-term value of our programs while enabling us to remain focused on advancing our pipeline and executing our corporate strategy.

Our Team, Corporate Progress, and Investors

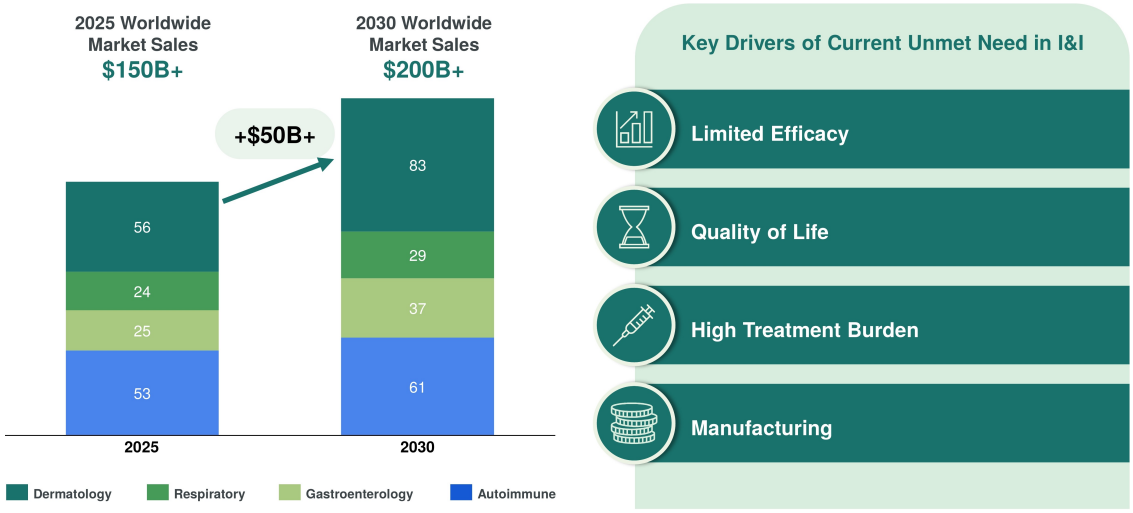
Members of our leadership team and many of our employees have previously worked together at BioNTech, bringing experience across the discovery, development, and strategic partnering of innovative biologic medicines. This shared history has helped establish a highly integrated organization focused on efficient execution and streamlined decision-making. We are led by our co-founder and Chief Executive Officer, Shanshan Xu, M.D., Ph.D., M.B.A., who previously served as Head of Global External Innovations at BioNTech, where she and her team sourced and executed 13 strategic partnerships and acquisitions, including the identification of the asset now known as pumitamig for an initial strategic partnership, followed by BioNTech's subsequent acquisition of BioNTech Zhuhai (then known as Biotheus). Our co-founder and Chief Development Officer, Thang Ho, Ph.D., who previously served as Clinical Pharmacology and Pharmacometrics Lead at BioNTech, oversees an integrated team spanning preclinical research, translational medicine, toxicology, and clinical pharmacology. Our Chief Financial Officer, Jonathan I. Lieber, M.B.A. also serves part-time as Chief Financial Officer of Rallybio Corporation, a publicly-traded clinical-stage biotechnology company, and previously served as Chief Financial Officer of two other publicly-traded companies, Applied Genetic Technologies Corporation and Histogenics Corporation.

Since our Inception, we have acquired assets from BioNTech Zhuhai, prior to the acquisition of Biotheus by BioNTech, that became our lead product candidates, BBT001 and BBT002, secured regulatory clearances to initiate clinical trials for these product candidates across multiple geographical regions, advanced them from preclinical to clinical development, completed dosing and safety follow ups of IV formulations of these product candidates in healthy volunteers, initiated enrollment and dosing of patients for PoC readouts, developed high-concentration SubQ formulations of both product candidates, initiated healthy volunteer and PoC substudies of such SubQ formulations, and initiated SubQ dosing of BBT001 in patients. In addition to our operational execution across multiple programs, as of June 30, 2026, we have raised $136.1 million in gross proceeds through multiple private financings with leading healthcare investors, including ATHOS, BVF Partners, Dawn Biopharma (a platform controlled by KKR), INCE Capital, RA Capital, and Salvia. The investors listed above are included solely to identify certain significant stockholders. The inclusion of any investor name above should not be construed as an endorsement by such investors of our company, business, or prospects, and such investors have not been involved in the preparation of this prospectus. Prospective investors should not rely on the past investment decisions of our investors, as our investors may have different risk tolerances and acquired their shares in prior offerings at prices lower than the price offered to the public in this offering, see "Certain Relationships and Related Party Transactions—Convertible Preferred Stock Financings" for more information.

Industry Background and Market Opportunity

The global I&I market, which already exceeds $150 billion and is projected to exceed $200 billion by 2030, is growing rapidly with an estimated 6% compound annual growth rate ("CAGR") between 2025 and 2030. The market growth is mainly driven by persistent unmet need. Across I&I, patients still face limited efficacy, high treatment burden, and delivery inconvenience, and major effects on quality of life, and there is increasing demand for biologics and their ability to redefine disease control.

Figure 2: Expected I&I Market Growth



Source: Evaluate Pharma as of July 2026

Biologics in Immunology and Inflammation ("I&I")

Biologics have reshaped the I&I treatment landscape by shifting treatment away from broad immunosuppression toward targeted, pathway-based therapies. Biologics accounted for approximately 37% of total drug revenue generated in AD in 2025 and are a major driver of growth within AD. Across immune-mediated inflammatory diseases, biologics have demonstrated clinically meaningful improvements in safety and efficacy and are now established components of the standard of care for many patients. Approved biologics include IL-4- and IL-13-directed agents (e.g., Dupixent, Ebglyss) that target inflammation, as well as IL-31 pathway targeted therapies (e.g., Nemluvio) that address chronic itch. Multiple other I&I diseases share overlapping Type 2 inflammatory pathways, which has supported cross-indication biologic development.

A similar case is evident in respiratory disease, where biologics have transformed the management of severe asthma and are increasingly used in COPD and CRSwNP. Biologics have also become foundational therapies in gastroenterology, where anti-TNF, anti-integrin, and IL-23 targeted agents are widely used in IBD. Biologics, such as TNF inhibitors (e.g., Humira, Enbrel), have also improved treatment paradigms and clinical outcomes in autoimmune I&I indications, such as rheumatoid arthritis and psoriatic arthritis. The success of biologics across these diverse I&I indications demonstrates the broad applicability of targeted immune modulation and highlights the potential for continued expansion into additional patient populations and disease settings.

Despite the growing success of biologics in I&I to date, overall penetration of biologics remains concentrated in higher-severity populations, presenting a potential opportunity for market expansion and broader adoption across earlier disease stages. Furthermore, while current biologics have redefined disease control, some patients across dermatology, respiratory, gastroenterology, and AID may experience incomplete responses or residual disease activity. Currently approved biologics have important limitations that are shaping the next phase of the I&I treatment landscape including:

- ***Limited Efficacy for Many Patients***: Although single-pathway biologics improve disease management for many patients, they may not address all aspects of disease biology in every patient population. Disease pathogenesis is often driven by multiple overlapping inflammatory pathways, and inhibition of a single target may not fully address the underlying biology in all patients. Many patients continue to experience incomplete responses and/or secondary loss of response, which we refer to as a therapeutic ceiling of the existing therapies, resulting in unmet medical need.

- ***Chronic I&I Diseases Have a Profound Impact on Patient Quality of Life****:* Despite advances in treatment, many patients continue to struggle with persistent symptoms such as fatigue, itch, pain, respiratory exacerbations, gastrointestinal issues, and sleep disruption, as well as anxiety and depression, impaired social functioning, reduced productivity, and the ongoing burden of unpredictable disease flares, all leading to a diminished ability to fully participate in everyday life.

- ***High Treatment Burden***: Chronic injections, administration complexity, access requirements, and ongoing patient monitoring needs contribute to high patient burden for biologic therapies, which can result in limited patient adherence.

The challenges experienced by patients present opportunities to develop next-generation therapeutic approaches, particularly bispecific and multi-target biologics, that are designed to simultaneously modulate complementary and synergistic inflammatory pathways.

Key Challenges of Other Approaches

Because disease pathogenesis is often driven by multiple overlapping inflammatory pathways, inhibition of a single target may not fully address the underlying biology in all patients. Therefore, I&I patients may require concurrent treatments or in some instances, co-formulation of two separate monoclonal antibodies. However, these approaches introduce several scientific, regulatory, manufacturing, and patient-experience challenges such as:

- ***Complex Pharmacology and Dose Optimization***: Co-formulated and concurrently administered antibodies remain independent molecular entities and may exhibit different PK profiles, tissue distribution, receptor occupancy, dosing intervals, and exposure requirements. As a result, optimizing one component may lead to over- or under-dosing of the other, and dose-ratio optimization may need to be revisited in specific patient populations such as pediatrics.

- ***More Challenging Regulatory and Clinical Development Pathway***: Regulatory agencies may require demonstration of the contribution of each individual component to safety and efficacy, potentially necessitating additional trial arms, larger pivotal trials, or separate registrational programs. Development may be further complicated by the limited precedent for novel I&I antibody combinations in pivotal trials.

- ***Increased Delivery Burden for Patients***: Combining two biologics can create practical administration challenges, including larger injection volumes, use of multiple injectors or syringes, or multiple injections per dosing visit. These challenges can be particularly pronounced during loading phases and may negatively impact patient convenience, adherence, and overall treatment experience.

- ***Higher Manufacturing Complexity and Cost of Goods***: Each antibody requires its own manufacturing process, analytical characterization, formulation development, stability testing, and supply chain management. Maintaining and coordinating two biologic products generally increases operational complexity and manufacturing costs.

- ***Formulation and SubQ Volume Limitations***: Achieving a practical co-formulation can be difficult when both antibodies require high doses, as viscosity, concentration, and injection-volume constraints may limit formulation flexibility. These challenges can restrict the ability to deliver the therapy in a low-volume, patient-friendly SubQ format.

- ***Greater Commercial and Lifecycle Management Complexity***: Co-formulated and concurrently administered products can introduce additional challenges related to inventory management, reimbursement, labeling, pricing strategy, and lifecycle management. Payers may also place greater emphasis on understanding the contribution and value of each individual component within the combination or may refuse to cover a second treatment.

Bispecific antibodies may address many of these challenges by incorporating multiple mechanisms of action into a single molecule.

Key Benefits of Bispecific Antibodies

Bispecific antibodies are increasingly recognized for their potential to become an important future standard of care in I&I by offering a compelling platform to address complex disease biology. By incorporating multiple mechanisms of action into a single molecule, bispecific antibodies can simultaneously modulate complementary and synergistic inflammatory pathways, providing meaningful differentiation from single-target therapies and supporting the potential for differentiated outcomes across a range of I&I indications.

Key advantages include:

- ***Simultaneous Multi-Pathway Modulation and Simplified Pharmacology***: Because a bispecific antibody is a single molecular entity, it can engage multiple complementary targets simultaneously while maintaining an identical PK profile, tissue distribution, and dosing interval across both mechanisms, thereby eliminating the need to balance competing exposure requirements to achieve the optimal pharmacological effects on both targets. Additionally, with both mechanisms in one molecule, the dose selection and optimization, including in special populations such as pediatrics, can be conducted within a unified framework.
- ***More Straightforward Regulatory and Clinical Development Pathway***: A bispecific antibody is developed and evaluated as a single molecule, avoiding the requirement to demonstrate the independent contribution of each component of co-formulated antibodies through additional trial arms, larger pivotal trials, or separate registrational programs, allowing for a simplified trial design, and potentially streamlined regulatory process and shortened development timelines.
- ***Reduced Delivery Burden and Convenient Dosing for Patients and Providers***: Consolidating two biological mechanisms into one molecule enables delivery through a single injection, thereby reducing overall treatment complexity and reducing burden of administering the therapy. The reduced burden of administration during both loading and maintenance phases improves patient convenience and overall treatment experience, which can improve adherence.
- ***Streamlined Manufacturing, Off-the-Shelf Accessibility, and Lower Cost of Goods***: A bispecific antibody requires only one manufacturing process, one set of analytical methods, one formulation development program, one stability testing program, and one supply chain, thereby reducing operational complexity and manufacturing costs. Compared with cell therapies or combinations of two or more monoclonal antibodies, which can present significant manufacturing and logistical complexity, bispecific antibodies offer a more readily deployable, single, off-the-shelf approach.
- ***Greater Formulation Flexibility and SubQ Compatibility***: Engineering a single molecule to carry dual specificity reduces the total protein load relative to combining two full-dose antibodies, easing viscosity, concentration, and injection-volume constraints. This expanded formulation flexibility increases the feasibility of delivering the therapy in a low-volume, patient-friendly SubQ format.
- ***Simplified Commercial and Lifecycle Management with Compelling Market Opportunity***: An approved bispecific antibody enters the market as a single product with a unified label, pricing strategy, reimbursement pathway, and inventory profile, reducing commercial complexity and enabling cleaner lifecycle management.

As bispecific antibodies are evaluated across earlier lines of treatment and broader patient populations, they may address an increasing portion of the global I&I market and present differentiated commercial opportunities for well-positioned programs.

Our Approach: Rationally Combining Validated Pathways into Long-Acting Bispecific Antibodies

Our approach is to develop long-acting bispecific antibodies for I&I diseases by rationally combining clinically and commercially validated biologic pathways into a single optimized molecule. Many I&I diseases are driven by complex and heterogeneous inflammatory pathways, which can limit the efficacy of single-target therapies and contribute to incomplete responses, persistent symptoms, and treatment burden. We select target pairs based on non-

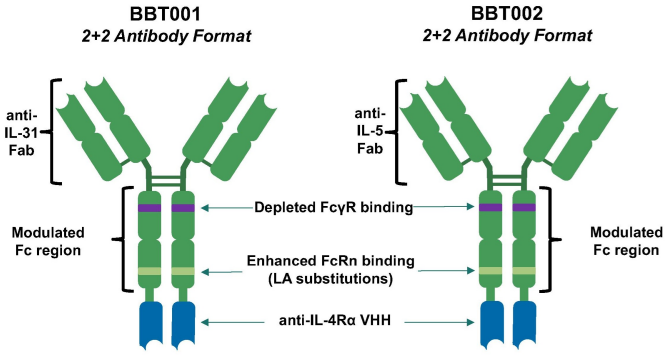
redundant biology, potential for mechanistic synergy, and commercial opportunity, and use third-party, advanced antibody engineering designed to optimize half-life, dual-target engagement, immunogenicity, manufacturability, and SubQ administration. We believe this approach has the potential to generate differentiated product candidates that address limitations of existing therapies and support multi-indication development opportunities across large I&I markets.

Clinically Validated Bispecific Antibody Platform

Our bispecific antibody candidates are based on a platform originating from BioNTech Zhuhai, a biopharmaceutical company with expertise in the discovery and development of next-generation antibodies, including bispecific antibodies designed to engage multiple pathways. See the section titled "Our Collaboration, License, and Services Agreements—BioNTech Zhuhai Agreements." The underlying antibody construct has been clinically validated through BNT327/PM8002, now known as pumitamig, a bispecific antibody discovered at BioNTech Zhuhai that has been studied in more than 2,000 patients treated in third-party clinical trials to date, including seven ongoing global Phase 3 clinical trials. Pumitamig and the BioNTech Zhuhai platform have also been the subject of significant strategic transactions. Pumitamig was initially the focus of an exclusive global license and collaboration agreement between BioNTech Zhuhai (then known as Biotheus) and BioNTech in 2023. In 2024, BioNTech acquired BioNTech Zhuhai (then known as Biotheus) for $800.0 million upfront and up to $150.0 million in potential milestone payments. In 2025, BioNTech and Bristol Myers Squibb entered into a global strategic partnership to co-develop and co-commercialize pumitamig with a total potential transaction value of up to $11.1 billion. We are applying this construct format from BioNTech Zhuhai, which has been clinically validated and manufactured at scale, to rationally selected I&I target combinations where we believe dual-pathway blockade has the potential to create differentiated medicines.

Our lead clinical product candidates, BBT001 and BBT002, share the same underlying bispecific construct format as pumitamig: a fully human IgG1 scaffold containing Fc-silencing mutations, together with two humanized VHH domains in a tetravalent 2+2 antigen binding format. Although pumitamig shares the same bispecific antibody architecture as our two lead product candidates, the molecules are distinct, have different targets, are being developed for different disease areas, and may not offer the same features or benefits. This construct format is designed to provide a number of benefits: (i) bivalent binding to each target; (ii) an IgG1-based structure for balanced immunogenicity and target-mediated drug disposition ("TMDD") risks and familiar pharmacology; and (iii) established CMC, analytical characterization, and scalable manufacturability.

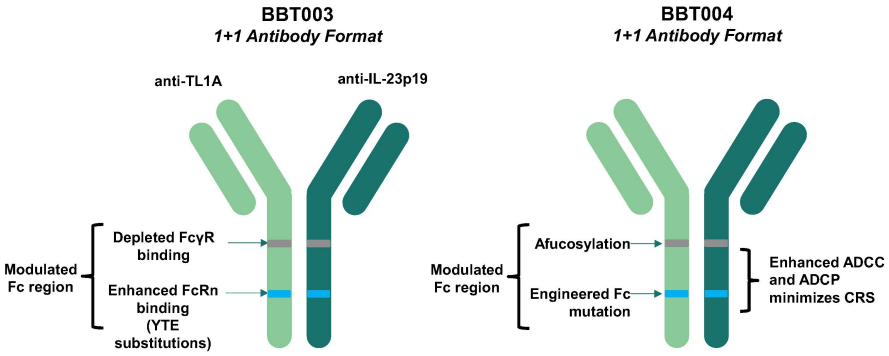
Figure 3: Our 2+2 Bispecific Antibody Constructs



Our earlier-stage candidates, BBT003 and BBT004, also leverage the IgG1 antibody engineering capabilities of BioNTech Zhuhai, but use 1+1 bispecific formats tailored to their respective targets and are designed to reduce immunogenicity risks. BBT003 shares the same Fc-silencing mutations as BBT001 and BBT002, but uses a YTE

substitution, an established Fc engineering approach designed to enhance FcRn-mediated antibody recycling and extend serum half-life. BBT004 has an Fc mutation and afucosylation to enhance ADCC and ADCP.

Figure 4: Our 1+1 Bispecific Antibody Constructs



Together these programs demonstrate the modularity of our pipeline and our ability to apply fit-for-purpose bispecific architecture to rationally selected I&I target combinations.

Clinically and Commercially Validated Targets

We leverage our team's deep experience in biologics to identify clinically and commercially validated pathways that are known biologic drivers of disease and have also demonstrated significant commercial potential in large I&I markets. We expect our focus on validated targets will continue to allow us to move quickly and efficiently into and through the clinic, as evidenced by the significant progress we have made since our Inception.

Importantly, similar to pumitamig, our product candidates combine two complementary, validated mechanisms into one single molecule. Each product candidate is designed to target orthogonal and non-redundant pathways, which we believe can result in mechanistic synergy to improve patient outcomes beyond what may be achieved by targeting either pathway alone. BBT001 targets both IL-4Rα and IL-31 pathways, which are clinically and commercially validated by approved biologics such as Dupixent and Nemluvio, respectively. The simultaneous blockade of IL-4Rα and IL-31 is designed to address both core Type 2 inflammation and chronic itch in a single bispecific molecule for a number of inflammatory skin diseases. By combining these mechanisms, BBT001 is designed to more comprehensively interrupt the inflammation-itch-scratch cycle that perpetuates disease activity in AD and other inflammatory skin diseases, with the potential to improve the depth and speed of clinical response, reduce residual itch, enhance quality of life, and support a differentiated dosing profile.

BBT002 targets both IL-4Rα and IL-5 pathways, which are clinically and commercially validated by approved biologics such as Dupixent and Nucala, respectively. The simultaneous blockade of IL-4Rα and IL-5 is designed to address two central and non-overlapping drivers of Type 2 inflammatory disease in a single bispecific molecule. IL-4Rα blockade is designed to inhibit the IL-4/IL-13 axis, which contributes to Type 2 inflammation, mucus production, and airway remodeling, while IL-5 blockade is designed to inhibit EOS-mediated inflammation, a key driver of exacerbations in severe asthma, COPD, and other Type 2 inflammatory respiratory diseases. By combining pathways validated by approved biologics, BBT002 is designed to provide broader Type 2 disease control than single-pathway approaches.

BBT003 and BBT004 extend this approach to additional I&I target combinations. BBT003 targets TL1A and IL-23p19, pathways that are evaluated and validated by anti-TL1A antibodies in late-stage clinical development, such as Sanofi/Teva's duvakitug, and approved IL-23p19 inhibitors, such as Skyrizi, respectively. BBT003 is designed to provide broader control of intestinal inflammation by combining TL1A's potential anti-inflammatory and anti-fibrotic activity with the commercially validated IL-23 pathway. BBT004 is designed to target two validated B-cell lineage targets to support deeper and more durable B-cell depletion across AID than single-target approaches.

Advanced Antibody Engineering

Our approach is to translate rational dual-pathway biology into product candidates with attributes we believe are important for chronic I&I treatment. In addition to selecting validated, complementary targets, we design and direct BioNTech Zhuhai to engineer our bispecific antibodies to optimize key properties, including:

- ***Durable and Simultaneous Dual-Target Engagement***: We apply tetravalent 2+2 bispecific architectures for BBT001 and BBT002 designed for balanced, high-avidity binding to each target and 1+1 bispecific architectures for BBT003 and BBT004 tailored to their respective mechanisms of action;
- ***Half-Life Extension Technology***: We apply Fc engineering designed to extend dosing intervals to many of our product candidates. We select the appropriate HLE approach for each product candidate on a molecule-by-molecule basis, taking into account antibody format, target biology, and observed PK and PD. BBT001 and BBT002 use LA (M428L/N434A) substitutions that have been shown by third parties to increase the binding affinity of the immunoglobulin G ("IgG") Fc region to the FcRn by approximately six-fold. BBT003 uses a YTE (M252Y/S254T/T256E) substitution, another established Fc engineering approach developed by third parties, that is designed to enhance FcRn-mediated antibody recycling and extend serum half-life. The YTE substitution can also slightly reduce FcγR binding, to decrease immune effector functions like antibody-dependent cellular cytotoxicity ("ADCC"). Typically, antibodies in circulation are taken up by cells and either degraded or recycled back into circulation through an FcRn-mediated process. By enhancing FcRn binding, our HLE substitutions are designed to reduce lysosomal degradation, increase antibody recycling, and prolong serum exposure. We believe selecting HLE approaches on a candidate-by-candidate basis enables us to optimize the PK profile, stability, melting temperature, and manufacturability for each molecule, and supports our goal of developing long-acting bispecific antibodies with dosing profiles appropriate for chronic I&I diseases;
- ***Low Immunogenicity***: We design our product candidates using the fully human IgG1-based bispecific formats, including humanized VHH-based architecture for BBT001 and BBT002 and fully human IgG1-based 1+1 formats for BBT003 and BBT004, with the goal of reducing immunogenicity risk while preserving familiar antibody pharmacology. This approach is supported by clinical precedent from the BioNTech Zhuhai-designed construct and early clinical data from BBT001 and BBT002, where observed ADA has been low titer with no apparent impact on safety or PK parameters as of the data cutoff date;
- ***Fit-for-Purpose Fc Engineering***: We engineer the Fc region of our product candidates to align immune effector function with each program's intended mechanism of action. For BBT001, BBT002, and BBT003, we use Fc-silencing mutations designed to reduce FcγR binding and minimize undesired immune-cell activation, including ADCC, antibody-dependent cellular phagocytosis ("ADCP"), and complement activity, consistent with mechanisms focused on pathway blockade. For BBT004, we use Fc-enhancing modifications designed to support ADCC and ADCP, consistent with its intended B-cell depletion approach;
- ***Manufacturability***: Our product candidates use IgG1-based bispecific formats designed to leverage familiar antibody pharmacology, established CMC workflows, and analytical characterization pathways. BBT001 and BBT002 apply the same underlying 2+2 construct format as pumitamig. We believe this precedent, together with our modular IgG1-based approach, supports efficient development and scalable manufacturing across our portfolio; and
- ***SubQ Delivery***: We have developed high-concentration SubQ formulations for BBT001, BBT002, and BBT003 designed to enable convenient self-administration. Our SubQ formulations are designed to deliver therapeutically effective doses in low injection volumes suitable for autoinjector, pre-filled syringe, or on-body device delivery.

Together, we believe these attributes position our product candidates to deliver durable pathway inhibition or B-cell depletion with convenient administration across I&I.

Broad Expansion Potential Across I&I Indications

We focus on establishing clinical PoC in well-defined initial indications with high unmet need to efficiently demonstrate clinical activity. From this foundation, we are positioned to expand each asset into a broader set of indications where the underlying biology is shared.

Our product candidates are designed as "pipeline-in-a-molecule" opportunities, targeting pathways that underlie multiple indications across I&I. Beyond AD, we believe BBT001 has significant potential across multiple dermatology indications including CSU, PN, AA, BP, and CPUO. Similarly, we see meaningful opportunities for BBT002 in COPD, CRSwNP, and asthma as well as CSU and EoE.

Our earlier-stage programs further extend this pipeline-in-a-molecule strategy: BBT003 is initially focused on IBD, including CD and UC, with potential expansion opportunities in AID and fibrosis, while BBT004 is focused on autoantibody-driven AID.

Our Pipeline

Our pipeline is focused on four bispecific antibody programs for the treatment of a broad range of I&I indications, as shown in Figure 5 below. Each of our product candidates is designed to engage multiple validated, orthogonal, and complementary targets known to be key biologic drivers of disease, with the goal of delivering differentiated and potentially superior clinical outcomes in each indication we pursue. In addition, our proprietary bispecific antibodies incorporate validated third-party HLE technologies. We believe these technologies, together with third-party advanced antibody engineering techniques, represent clinically and commercially validated approaches demonstrated across multiple third-party approved and late-stage biologics programs. We expect a number of key upcoming catalysts, including multiple anticipated PoC data readouts, which are also summarized in Figure 5 below. Clinical development is a complex and challenging process with uncertain outcomes and is subject to a number of risks. See the section titled "Risk Factors – Risks Related to Research, Development, Regulatory Approval and Commercialization" for more information on risks that can cause delays in completing a trial or reaching a milestone on time.

Figure 5: Our Pipeline and Key Upcoming Catalysts



BBT001 Program: Pipeline-in-a-Molecule for Type 2 Inflammatory Disorders in Dermatology

Overview

Our lead product candidate, BBT001, is a next-generation, long-acting bispecific antibody targeting both IL-4Rα and IL-31 for a range of Type 2 inflammatory disorders in dermatology. IL-4Rα and IL-31 are two clinically

and commercially validated targets with Dupixent (anti-IL-4Rα) and Nemluvio (anti-IL-31Rα) generating $17.8 billion and $452 million, respectively, in global sales in 2025, which represented Nemluvio's first full year on the market. Galderma estimates that Nemluvio will generate $4 billion in peak sales.

By simultaneously targeting IL-4Rα, which mediates central drivers of inflammation, and IL-31, a key cytokine associated with pruritus, BBT001 is designed to address both inflammatory and itch-related pathways that contribute to disease burden in AD and related conditions. We are initially developing BBT001 for the treatment of AD and CSU, with an initial target market that is expected to grow to more than $35 billion by 2030, with potential to expand into PN, AA, BP, and CPUO to capture a large share of inflammatory dermatology market that we estimate will exceed $45 billion by 2030.

We are currently evaluating BBT001 for the treatment of moderate-to-severe AD in a global Phase 1 clinical trial in the United States, Australia, Europe, and New Zealand ("Global BBT001 Study") and a Phase 1a/1b clinical trial in China ("China AD Study"). We have also initiated a Phase 2a clinical trial of BBT001 for the treatment of chronic spontaneous urticaria ("CSU") in China ("China CSU Study").

In July 2026, we reported positive topline PoC results from our Global BBT001 Study of patients with moderate-to-severe AD who have received neither biologics targeting the same pathways as our product candidate nor JAK inhibitors (we refer to these patients as "bio-naïve") treated with four weeks of an IV formulation of BBT001 in New Zealand and the United States ("4-week PoC bio-naïve AD data").

We expect several additional upcoming clinical data readouts for BBT001 throughout the first half of 2027, including topline PoC results of bio-naïve patients with moderate-to-severe AD treated with 12 weeks of an IV formulation of BBT001 ("12-week PoC bio-naïve AD data"), patients with moderate-to-severe AD who have previously received either biologics targeting the same pathways as our product candidate or JAK inhibitors (we refer to these patients as "bio-experienced") treated with 12 weeks of an IV formulation of BBT001 ("12-week PoC bio-experienced AD data"); and patients with CSU treated with 14 weeks of an IV formulation of BBT001 ("14-week PoC CSU data"). We recently announced the dosing of our first patient in the 12-week SubQ AD PoC Substudy and plan to initiate study start-up activities for our Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT001 in patients with moderate-to-severe AD by the end of 2026 ("Phase 2b AD Study"). The Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

Dermatology Background

Dermatological diseases such as AD, psoriasis, CSU, PN, and others affect hundreds of millions of people worldwide. Biologics have transformed the treatment paradigm across many indications in dermatology – validating Type 2 inflammation as a druggable pathway, establishing new safety and efficacy benchmarks, and effectively displacing broad immunosuppressants in many patients. Today, dermatology biologics represent a multi-billion dollar global market, with Dupixent alone generating approximately $17.8 billion in sales in 2025 across multiple indications. Despite this commercial success, biologic patient penetration in many indications remains relatively low, highlighting a large remaining opportunity for next-generation therapies that can improve outcomes while expanding the addressable patient population.

AD has emerged as one of the most important biologic markets in dermatology. GrandView Research projects that the global AD market will reach $29 billion in 2030. However, current biologic use is largely concentrated in patients with moderate-to-severe disease, limiting treatment to a relatively small portion of the overall disease population. Estimates indicate that a limited proportion of the approximately 53 million AD patients across major markets receive biologics, and many patients who are treated with current biologic therapies remain uncontrolled. Single-target approaches like Dupixent, while transformative, do not fully resolve disease in many patients, leaving substantial room for improvement in efficacy, durability, and treatment burden.

The evolution of the psoriasis market provides a useful precedent. Over the past two decades, successive generations of biologics transformed psoriasis from a market primarily treated with topical agents and broad systemic therapies into one of the largest biologic categories in dermatology. As efficacy improved from early tumor necrosis factor ("TNF") inhibitors to highly selective interleukin-17 ("IL-17") and interleukin-23 ("IL-23")

inhibitors, biologic utilization expanded significantly, treatment was initiated earlier in the disease course, and the overall market grew well beyond initial expectations. Importantly, market growth was driven not only by share shifts among therapies but also by expansion of the treated population itself. AD appears to be following a similar trajectory, albeit at an earlier stage of development.

The opportunity expands beyond AD. Adjacent dermatologic indications such as CSU and PN remain early in their biologic adoption curves and continue to exhibit substantial unmet need despite recent therapeutic advances. These settings are particularly well suited for next-generation approaches, including bispecifics and multi-target biologics, which could address non-overlapping drivers such as Type 2 inflammation and autoimmune itch pathways simultaneously. As in AD and more broadly in I&I, the opportunity is not only to improve efficacy but also to expand responder populations and shift biologic treatment paradigms earlier, positioning these indications as significant opportunities for the next wave of innovation.

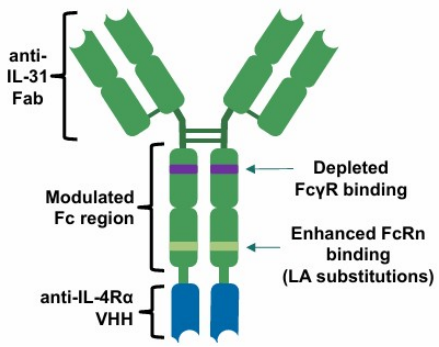
Our Solution for Type 2 Inflammatory Skin Diseases: BBT001

Overview

Our lead product candidate, BBT001, a next-generation, long-acting bispecific antibody targeting two clinically and commercially validated pathways, IL-4Rα and IL-31, is designed to simultaneously address core Type 2 inflammation and chronic itch, two defining drivers of AD and other inflammatory skin diseases.

We are currently evaluating BBT001 for the treatment of moderate-to-severe AD in our Global BBT001 Study and China AD Study and reported positive topline 4-week PoC bio-naïve AD data from our Global BBT001 Study in July 2026. We expect several additional upcoming clinical data readouts for BBT001 throughout the first half of 2027, including 12-week PoC bio-naïve AD data, 12-week PoC bio-experienced AD data and 14-week PoC CSU data. We recently announced the dosing of our first patient in the 12-week SubQ AD PoC Substudy and plan to initiate study start-up activities for our Phase 2b AD Study of a SubQ formulation of BBT001 by the end of 2026. Our Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

Figure 6: BBT001 is a Bispecific IgG1 Antibody that Targets IL-4Rα and IL-31 in a 2+2 Format



BBT001 is designed to combine the benefits of two clinically and commercially validated targets and overcome some of the challenges of prior biologics:

- The core structural framework is a fully human IgG1 antibody that specifically targets IL-31, labeled above as anti-IL-31 Fab. The IL-31 pathway is commercially validated through the success of Nemluvio, which targets IL-31Rα.
- Two VHH fragments are fused to the IgG1 antibody and are designed to target IL-4Rα, labeled above as anti-IL-4Rα VHHs. The IL-4Rα pathway is commercially validated through the success of Dupixent.

- The Fc region of the IgG1 antibody has been modulated in two ways:
  - Depleting FcγR binding to reduce ADCC and complement dependent cytotoxicity ("CDC") effects; and
  - Enhancing FcRn binding through LA (M428L/N434A) substitutions which are designed to reduce lysosomal degradation, increase antibody recycling, and prolong serum exposure.

Our goal is to develop BBT001 to be a first line therapy for moderate-to-severe AD and other Type 2 inflammatory skin diseases. BBT001 is designed to:

- ***Address Core Type 2 Inflammation and Chronic Itch***: By simultaneously blocking IL-4Rα (inhibiting IL-4 and IL-13 signaling) and IL-31 (the key pruritogenic cytokine), BBT001 is designed to break the vicious itch-scratch cycle that perpetuates disease in AD and related conditions. Both targets are orthogonal and commercially validated.
- ***Achieve Faster Onset and Break the Therapeutic Ceiling***: We believe dual targeting of both the inflammatory and pruritogenic pathways has the potential to provide faster onset and greater reduction of itch and skin lesions compared to capabilities of single-target approaches due to the complementarity of the targets.
- ***Enable Extended Dosing Intervals***: Fc modifications using an LA (M428L/N434A) substitution are designed to increase FcRn affinity and extend drug half-life. BBT001 has demonstrated a half-life of approximately 33 days in humans, supporting the potential for quarterly maintenance dosing.
- ***Provide High-Concentration SubQ Delivery***: We have developed a high-concentration SubQ formulation of BBT001 to enable commercial presentation in a low-volume injection designed for convenient at-home administration. We have initiated healthy volunteer and PoC substudies of a SubQ formulation of BBT001 and recently announced the dosing of our first patient in the 12-week SubQ AD PoC Substudy.

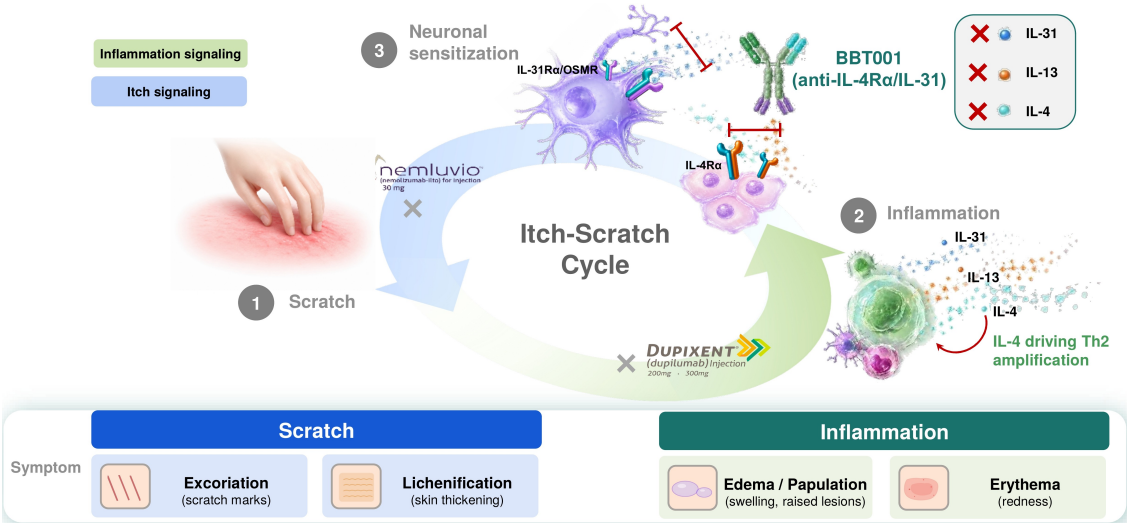
Scientific Rationale

We aim to address the underlying pathophysiology of AD by targeting two interconnected processes, Type 2 inflammation and chronic itch, in one single treatment. By simultaneously blocking IL-4Rα and IL-31, BBT001 is designed to break the vicious itch-scratch cycle, which is illustrated below. Scratching behavior (annotated by grey circle 1 in Figure 7 below) damages skin epithelial cells, causing them to release alarmins that act on T-helper 2 ("Th2") cells, in particular, the Th2 subset. Activated Th2 cells release key Type 2 cytokines, including IL-4, IL-13 and IL-31, causing type 2 inflammation (annotated by grey circle 2 in Figure 7 below).

IL-4 specifically promotes the differentiation of naïve CD4+ T cells into Th2 cells, which then secrete even more IL-4 and IL-13, creating a self-perpetuating "loop" of inflammation. IL-4 and IL-13 also decrease the expression of filaggrin, a protein essential for maintaining the skin barrier. This leads to transepidermal water loss and increased susceptibility to irritants, further fueling the inflammatory cycle.

IL-4 and IL-13 activate shared IL-4Rα signaling complexes on sensory nerve cell surfaces that drive immune activation and inflammatory cell recruitment. This leads to amplifying itch responses, neuronal sensitization, and resulting damage to the epidermal barriers. IL-31 also binds to IL-31Rα on sensory nerve cell surfaces, allowing transmission of itch sensations and leading to increased neuronal sensitization (annotated by grey circle 3 in Figure 7), producing persistent itch and scratching. Combined, these Type 2 cytokines activate the vicious itch-scratch cycle in AD.

Figure 7: Two Powerful Mechanisms in One Molecule to Break the Vicious Itch-Scratch Cycle



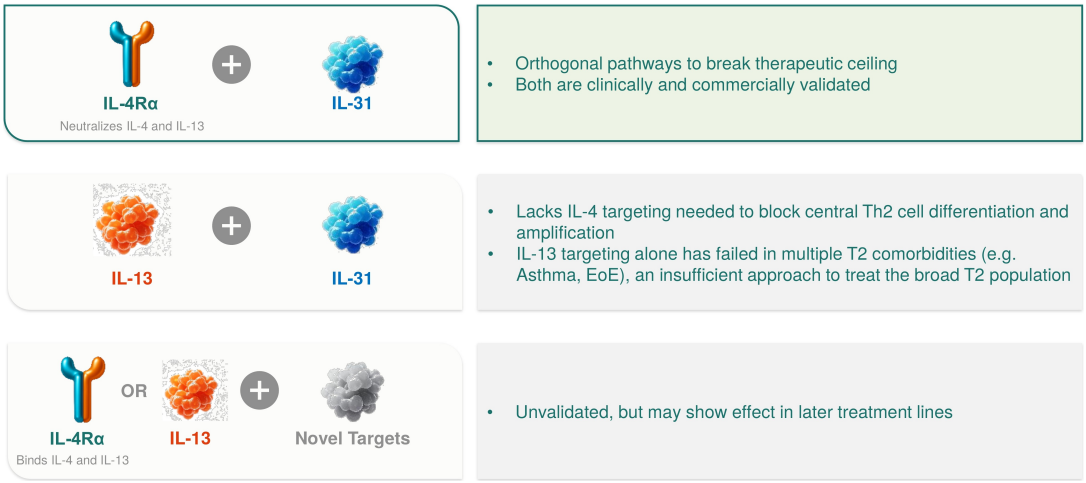
The rationale for simultaneously targeting IL-4Rα and IL-31 is rooted in the complementary and synergistic biology of these pathways in AD:

- IL-4Rα is the shared receptor subunit for both IL-4 and IL-13. Inhibition of IL-4Rα blocks IL-4 and IL-13 activity and reduces inflammation, IgE production, and improves epithelial barrier function. Dupixent's clinical and commercial success has validated IL-4Rα as a therapeutic target in AD and other Type 2 inflammatory diseases. Critically, published third-party data demonstrate that Dupixent treatment does not reduce IL-31 levels, indicating that the IL-31-mediated itch pathway remains active under IL-4Rα blockade alone.
- IL-31 is a pruritogenic cytokine also produced by Th2 cells that signals through the IL-31 receptor alpha/oncostatin M receptor beta ("IL-31Rα/OSMRβ") heterodimer located on sensory neurons. IL-31 is the key mediator of chronic itch in AD, and IL-31 levels are significantly elevated in AD patients compared with healthy controls. Nemluvio, which targets IL-31Rα, was recently approved for PN and AD, validating IL-31 as a therapeutic target. Published third-party data of Nemluvio indicate that targeting the IL-31 pathway results in rapid reduction of itchiness, thereby reducing scratching.

Additionally, we believe that combination therapies that target only IL-13 and IL-31 will not be sufficient, as such combinations lack the IL-4 targeting needed to block central Th2 cell differentiation and amplification. Anti-IL-13-based therapies have failed in multiple type 2 comorbidities such as asthma and EoE. Therefore, we designed BBT001 to target IL-4Rα, which can block both IL-4 and IL-13 activity. Pairing either IL-4Rα or IL-13 with a novel target would introduce biological risk as the target would not be validated, therefore, we believe our combination is the most rational pairing to deliver deeper response and break the therapeutic ceiling of existing monotherapies.

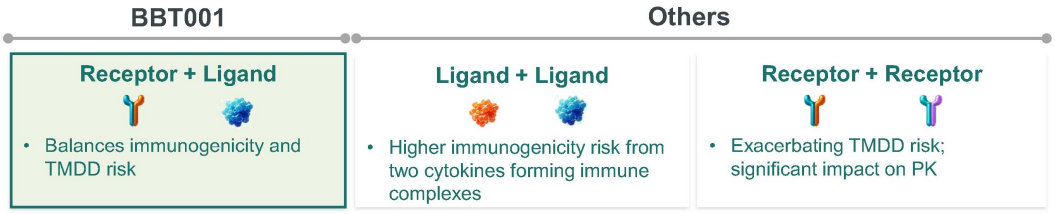
By combining both mechanisms in a single molecule, BBT001 is designed to break the therapeutic ceiling of single-target approaches in inflammatory skin disorders. Targeting only inflammation can leave a major itch pathway active. Targeting itch alone can leave the core inflammatory process insufficiently controlled. BBT001 is designed to interrupt both sides of the cycle in one molecule: IL-4Rα addresses IL-4 and IL-13 signaling, while direct IL-31 neutralization addresses neuronal itch signaling. We believe this combination can translate into faster symptom relief and deeper, more durable disease control, which we refer to as breaking the therapeutic ceiling.

Figure 8: Rational Target Pairing Combines Validated Biology to Break the Therapeutic Ceiling



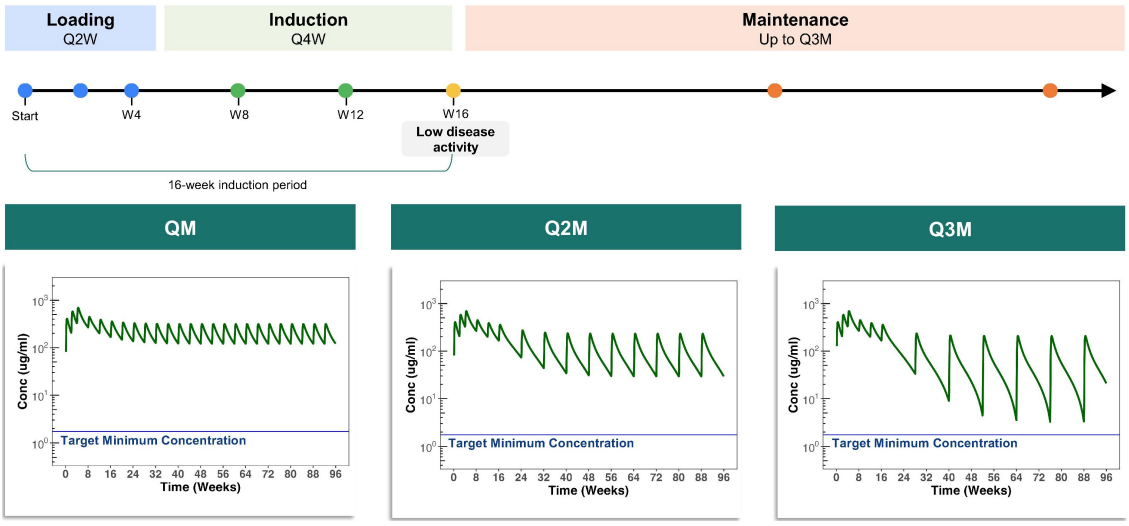
In selecting the target pair for BBT001, we sought to balance the distinct development risks associated with receptor and ligand targeting. Receptor binding can drive TMDD through internalization and clearance. In bispecific antibodies that targets two receptors, either arm may independently contribute to this process, potentially increasing nonlinear clearance and reducing systemic exposure. Although BBT001 may have TMDD through its IL-4Rα-targeting arm, our data indicate this effect is saturable and can be overcome at clinically relevant doses, enabling sustained exposure and long apparent half-life. Conversely, targeting two soluble ligands may increase the potential for multivalent immune-complex formation. Pairing IL-4Rα with the soluble IL-31 as bispecific targets avoids adding a second source of receptor-mediated clearance while limiting the potential for immune-complex formation associated with dual-ligand targeting. We believe this receptor-ligand target pairing provides a favorable balance among TMDD, immunogenicity risk and sustained systemic exposure.

Figure 9: Receptor-Ligand Pairing Can Improve PK and Half-Life



Based on clinical trial results to date, including PK, receptor occupancy, depth of response, and duration of response, we believe a quarterly maintenance dosing regimen could be possible. Using PK data of the SAD and MAD healthy volunteer substudies of our Global BBT001 Study, we conducted simulations using a three-compartment population PK model with TMDD to model potential exposure levels for maintenance dosing every one, two, or three months, as shown in Figure 10 below, to determine whether the PK concentration could be maintained above the target minimum concentration. Actual results in any future clinical trial may differ from the simulated results.

Figure 10: Simulations of Potential Exposure Levels



Simulations were generated using a population PK model incorporating target-mediated drug disposition (TMMD). The model adequately characterized BBT001 PK profiles in healthy volunteers and was used to simulate alternative dosing regimens. The target minimum concentration was defined based on the IC90 from the CCL2 release assay and a concentration approximately 10-fold above that required to achieve 90% IL-4Rα saturation. Actual results in any future clinical trial may differ from the simulated results.

BBT001 for the Treatment of Atopic Dermatitis ("AD")

Overview

We are currently evaluating BBT001 for the treatment of AD in our Global BBT001 Study and China AD Study and reported topline 4-week PoC bio-naïve AD data from our Global BBT001 Study in July 2026. We expect several additional upcoming clinical data readouts for BBT001 throughout the first half of 2027, including 12-week PoC bio-naïve AD data and 12-week PoC bio-experienced AD data. We recently announced the dosing of our first patient in the 12-week SubQ AD PoC Substudy and plan to initiate study start-up activities for our Phase 2b AD Study of a SubQ formulation of BBT001 by the end of 2026. The Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

Disease Background and Market Opportunity

AD, commonly referred to as eczema, is a chronic, relapsing inflammatory skin disease characterized by intense pruritus (itch), eczematous lesions, skin barrier dysfunction, and recurrent flares. The disease frequently begins in childhood but may persist into adulthood or newly arise later in life. AD is one of the most common inflammatory skin diseases in the world, affecting approximately 129 million adults and children globally. Recent epidemiology studies suggest adult prevalence of approximately 4.9% in the United States, 4.4% across key European markets, and 2.1% in Japan, while pediatric prevalence is generally higher, often ranging from approximately 10% to 20% depending on geography and methodology. In the United States alone, recent estimates suggest roughly 20 million adults and 9 million children are affected.

AD can substantially diminish patient quality of life, with persistent itch representing one of the most burdensome and debilitating symptoms of the disease. Chronic itch can drive a relentless itch-scratch cycle that exacerbates skin inflammation, worsens disease severity, and contributes to skin damage and recurrent flares. Importantly, uncontrolled itch frequently leads to sleep disruption, causing patients to have difficulty falling asleep, experience repeated nighttime awakenings, and obtain poor-quality restorative sleep. The cumulative effects of chronic itch and sleep loss can impair concentration, reduce productivity, contribute to fatigue, negatively affect

emotional well-being, and increase the risk of anxiety and depression. Together, these challenges can interfere with work, school, social interactions, and daily activities, resulting in a substantial and persistent burden on patients and a diminished ability to fully participate in everyday life.

AD is primarily driven by Type 2 inflammation, with key cytokine pathways including IL-4, IL-13, and IL-31 activated. IL-4 and IL-13 contribute to immune dysregulation, skin barrier impairment, inflammation, and increased susceptibility to infection, while IL-31 is strongly associated with chronic itch and the itch-scratch cycle that can worsen lesions and perpetuate disease activity. Additional immune pathways may also be relevant in subsets of patients, helping explain heterogeneity in treatment response. The commercial success of targeted biologics such as Dupixent, Ebglyss, and Nemluvio has validated AD as a major immunology market while highlighting continued unmet need for faster onset, deeper responses, better itch control, durability, and dosing convenience.

The AD market has expanded rapidly over the past decade as biologics and oral targeted therapies moved treatment beyond topical steroids and broad immunosuppressants. Dupixent established the category as a multi-billion-dollar global market, yet penetration remains low given the increasing awareness, growing patient population, under-treatment of moderate disease, and ongoing switching among inadequately controlled patients.

Important clinical outcomes used to assess treatment benefit include:

- Eczema Area and Severity Index (“EASI”) changes from baseline and response rates, particularly proportion of patients achieving EASI-50, EASI-75, EASI-90, and EASI-100—which measure percentage improvement in disease severity.
- Investigator Global Assessment (“IGA”) and validated IGA for AD (“vIGA-AD”) scores of 0 or 1 reflect clear or almost clear skin, respectively.
- The Peak Pruritus Numerical Rating Scale (“PP-NRS”) is a key measure of itch reduction and is highly relevant given the significant burden of chronic pruritus.
- Additional endpoints often include the amount of body surface area (“BSA”) affected by the skin condition, sleep improvement, flare reduction, durability of response, steroid-sparing effect, and overall safety and tolerability.

Current AD Treatment Options and Limitations

AD treatment is typically guided by disease severity, BSA involvement, itch burden, quality-of-life impairment, and prior treatment history.

- Mild disease is commonly managed with moisturizers, trigger avoidance, skin care measures, and topical therapies such as corticosteroids, topical calcineurin inhibitors, topical phosphodiesterase-4 inhibitors, and newer topical Janus kinase (“JAK”) inhibitors.
- For the 40% to 50% of AD patients with moderate-to-severe disease, or those inadequately controlled on topical therapy, treatment often escalates to systemic options including biologics and oral targeted agents. Traditional systemic immunosuppressants such as cyclosporine, methotrexate, azathioprine, and mycophenolate have historically been used, although long-term use may be limited by safety, monitoring, and tolerability considerations.

The modern AD treatment landscape has been transformed by targeted therapies. Mono-targeting biologics such as Dupixent (anti-IL-4Rα), Ebglyss (anti-IL-13), and Nemluvio (anti-IL-31Rα) offer differentiated mechanisms that target key drivers of disease, including inflammation and itch. Oral JAK inhibitors such as Rinvoq and Cibinqo can provide rapid onset and strong efficacy, particularly for itch, but may carry broader safety considerations depending on patient population and label restrictions. Treatment decisions increasingly balance efficacy, speed of response, safety, convenience, dosing frequency, route of administration, and patient preference. Despite these advances, many patients remain inadequately controlled or cycle through therapies due to incomplete response, persistent itch, relapse, or adherence challenges.

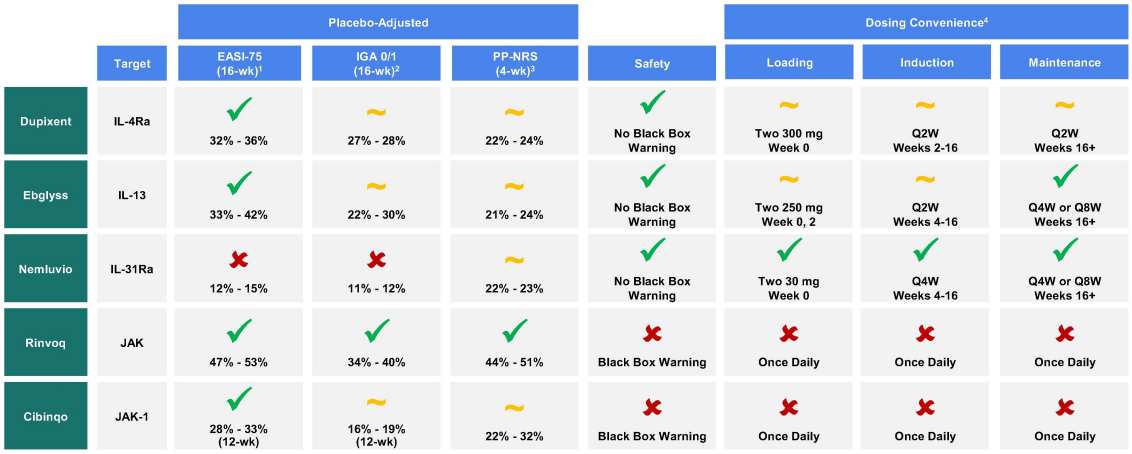
Dupixent, an IL-4Rα inhibitor that blocks IL-4 and IL-13 signaling, is the current favored standard-of-care biologic for moderate-to-severe AD and has established the category as a large global market. It has demonstrated robust efficacy across key endpoints, including EASI-75/90 and IGA 0/1, with a well-characterized safety profile and broad label across age groups. The reported placebo-adjusted percentage of EASI reduction from baseline results from Dupixent's Phase 3 SOLO 1 and 2 studies for Weeks 2, 4, and 6 were 24%, 35% and 37%, respectively. In adults, dosing is generally a 600 mg loading dose followed by 300 mg every two weeks, with weight-based dosing in pediatric patients. Despite Dupixent's efficacy, approximately 60% of patients remain uncontrolled and do not achieve clear, almost clear, or near-complete skin clearance. The frequent dosing requirement has also been associated with injection site reactions and side effects including conjunctivitis.

Ebglyss is a monoclonal antibody targeting IL-13, a central cytokine in Type 2 inflammation. It has demonstrated strong efficacy in AD, including high rates of skin clearance. The reported placebo-adjusted percentage of EASI reduction from baseline results from Ebglyss's Phase 3 studies for Weeks 2, 4 and 6 were 17%, 26%, and 32%, respectively. Like Dupixent, it also has improved dosing flexibility relative to earlier biologics, with maintenance dosing options extending beyond every two weeks in some regimens. As with Dupixent, Ebglyss side effects can include conjunctivitis and injection site reactions.

Nemluvio is a monoclonal antibody targeting IL-31Rα, a key driver of pruritus in AD. It has demonstrated rapid and meaningful reductions in itch, as measured by PP-NRS, and provides a differentiated mechanism focused on symptomatic relief. However, as the IL-31 pathway primarily addresses itch rather than the broader inflammatory cascade, Nemluvio is often viewed as complementary rather than comprehensive, and may be used in combination or in patients where pruritus is a dominant clinical feature. Nemluvio's skin clearance rates are generally lower than Dupixent and Ebglyss, with reported placebo-adjusted percentage of EASI reduction from baseline results from Nemluvio's ARCADIA 1 and 2 studies for Weeks 2, 4, and 8 at 16%, 21%, and 23%, respectively, due to its differentiated mechanism.

Rinvoq and Cibinqo are oral JAK inhibitors that provide a systemic approach to inhibiting multiple cytokine signaling pathways involved in AD pathogenesis. These agents have demonstrated rapid onset of action and strong efficacy across both skin clearance and itch endpoints, often exceeding biologics in early response kinetics. For example, the reported placebo-adjusted percentage of EASI reduction from baseline results from Rinvoq's Measure Up 1 and 2 studies for Weeks 2, 4, and 8 were 46%, 54%, and 46%, respectively. However, their use may be limited by safety considerations, including boxed warnings and burdensome lab monitoring requirements, which can restrict use in certain patient populations and influence physician and payer adoption. As a result, JAK inhibitors are often positioned for patients with more severe disease or those who have failed biologic therapies.

Figure 11: Current AD Treatment Options and Limitations



1. EASI-75 (16-wk) indicates the percentage of study participants with a placebo-adjusted 16-week EASI-75 change from baseline ("CFB") included in the applicable drug label, with green checks indicating greater than 30% and red crosses indicating less than 20%.

2. IGA 0/1 (16-wk) indicates the percentage of study participants with a placebo-adjusted 16-week IGA score of either zero or one included in the applicable drug label, with green checks indicating greater than 30% and red crosses indicating less than 15%.
3. PP-NRS (4-wk) indicates the percentage of study participants with a placebo-adjusted 4-week PP-NRS CFB, with green checks indicating greater than 40% and red crosses indicating less than 15%.
4. Dosing Convenience shows the maintenance dosing, with green check indicating dosing at every four weeks or longer and red crosses indicating daily dosing.

Current single-targeting biologics, such as monoclonal antibodies, have transformed the treatment landscape for AD, but several important limitations remain:

- ***Limited Efficacy Due to Narrow Mechanistic Targeting***. Although therapies targeting IL-4Rα, IL-13, or IL-31 have improved outcomes for patients with AD, many patients do not achieve optimal skin clearance or experience only partial responses, which we refer to as a therapeutic ceiling. The proportion of patients who experienced 50% or greater improvement or reduction ("EASI-50") reported in Dupixent's SOLO-1 and SOLO-2 studies and the respective Phase 2b studies for Ebglyss, Nemluvio, and Rinvoq ranged 17% to 66% in Weeks 2 through 6 (or Week 8, if no data was published for Week 6) and those who experienced 75% or greater improvement or reduction ("EASI-75") in Dupixent's SOLO-1 and SOLO-2 studies, Ebglyss's Advocate 1 and 2 studies, the Phase 2b study for Nemluvio, and Rinvoq's Measure Up 1 and 2 studies ranged from 3% to 56% in Weeks 2 through 6 (or Week 8, if no data was published for Week 6), where no more than 27% of patients dosed with a biologic achieved EASI-75 during such weeks. These limitations likely reflect the complex and heterogeneous nature of disease biology, where inhibition of a single inflammatory pathway may be insufficient to address the multiple drivers of disease, including inflammation, barrier dysfunction, immune activation, and pruritus. We believe that innovative therapeutic approaches such as dual or triple targeting of both the inflammatory and pruritogenic pathways has the potential to break the current therapeutic ceiling by providing faster onset, deeper response, and more sustained response. For example, Sanofi's lunsekimig, a bispecific targeting IL-13 and TSLP, achieved an estimated placebo-adjusted EASI-75 of 10-15% and 5-30% at Weeks 4 and 16, respectively, in its Phase 2b VELVET study, whereas Pfizer's tilrekimig, a trispecific targeting IL-4, IL-13 and TSLP, achieved a placebo-adjusted EASI-75 of approximately 10% and 43-52% at Weeks 4 and 16, respectively, in its Phase 2 study.

- ***Persistent Itch and Delayed Onset***. Chronic pruritus remains one of the most burdensome symptoms for patients. Although some therapies improve itch, onset can be variable and, in certain cases, slower than desired. Agents focused on inflammatory pathways may not fully or rapidly address itch, while itch-specific therapies may not sufficiently control the broader inflammatory disease. As an example, the placebo-adjusted PP-NRS reduction from baseline reported in Dupixent's SOLO-1 and SOLO-2 studies, Ebglyss's Advocate 1 and 2 studies, the Phase 2b study for Nemluvio, and Rinvoq's Measure Up 1 and 2 studies ranged from 13% to 48% in Weeks 2 through 6, where no biologic achieved greater than 27% reduction during such weeks. Although Nemluvio's Arcadia 1 and 2 reported a deepening change in PP-NRS through week 12, the placebo-adjusted PP-NRS did not exceed 30% during a 12-week measurement period.

- ***Durability and Disease Control***. Many patients experience fluctuations in disease control over time, including breakthrough flares or waning response, necessitating treatment adjustments or switching between therapies. This underscores the need for more durable and consistent disease suppression.

- ***Injection Burden and Convenience***. Most biologics require relatively frequent dosing, commonly every two to four weeks, with some expanding to every eight weeks, which can impact patient adherence and long-term persistence. This burden is particularly relevant in chronic diseases requiring lifelong management.

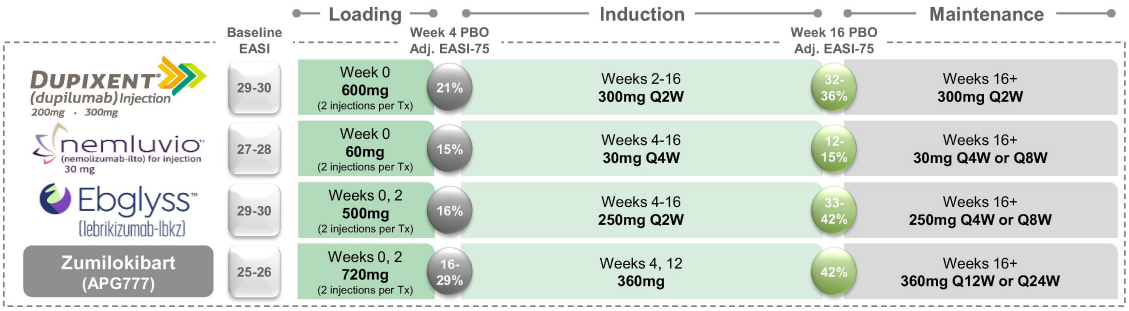
With BBT001, we aim to address many of these limitations. BBT001's mechanistic combination of the IL-4Rα and IL-31 pathways is designed to break the therapeutic ceiling of single-target approaches in inflammatory skin disorders. We aim for a very rapid onset of action, especially in itch control, similar to the JAK inhibitors, and seek increased depth and duration of response, necessary for chronic I&I conditions, and are targeting a once-every three-

month SubQ administration. Based on preclinical and clinical trial results to date, including PK, receptor occupancy, depth of response, and duration of response, we believe a quarterly maintenance dosing regimen will be possible.

AD biologics commonly use loading doses followed by an induction period with more frequent dosing early in treatment, followed by less frequent maintenance dosing. The approved dosing regimen from the corresponding FDA labels and the reported baseline EASI and placebo-adjusted EASI-75 scores for Week 4 and Week 16 for Phase 3 studies for Dupixent, Nemluvio, and Ebglyss, the three approved AD biologics, are shown in Figure 12 below along with the expected dosing regimen and the baseline EASI and the estimated placebo-adjusted EASI-75 scores for Week 4 and Week 16 from zumilokibart, a late clinical-stage bispecific antibody previously developed by Apogee before its acquisition by AbbVie. No head-to-head clinical trials have been performed comparing Dupixent, Ebglyss, Nemluvio and zumilokibart, and comparing results across differential trials should be interpreted with caution. Study designs and protocols for the studies referenced were different, and as a result, results may not be comparable.

Dupixent's dose regimen is comprised of a loading dose of two injections of 300 mg (total of 600 mg) at Week 0 followed by a 300 mg dose every other week thereafter. There is no decrease in dosing intervals in the long-term maintenance stage for Dupixent, but Nemluvio and Ebglyss have a 16-week induction period. Nemluvio's dose regimen is comprised of a loading dose of two injections of two 30 mg (total of 60 mg) at Week 0 followed by a 30 mg induction dose every fourth week starting Weeks 4 through 16, and a maintenance dose of 30 mg either every month or every two months thereafter depending on disease progression. Ebglyss's dose regimen is comprised of loading doses of two injections of 250 mg (total of 500 mg) at each of Weeks 0 and 2 with a 250 mg induction dose every other week starting Weeks 4 through 16, and a maintenance dose of 250 mg either every month or every two months thereafter depending on disease progression. The Week 4 and Week 16 placebo-adjusted EASI-75 scores for Dupixent, Nemluvio and Ebglyss ranged from 15 to 21% and 12 to 42%, respectively. Part A of the Phase 2 APEX trial of zumilokibart included a loading dose of two injections of 720 mg (total of 1440 mg) at each of Weeks 0 and 2 with a 360 mg induction dose at Week 4 and 12, and is expected to permit a maintenance dose of 360 mg every three or six months thereafter depending on disease progression. Zumilokibart's placebo-adjusted EASI-75 scores from the Phase 2 APEX study were similar to the approved therapies with Week 4 at 16-29% and Week 16 at 42%, respectively. Our 4-week study is designed to have two loading doses at Week 0 and 2, similar to Ebglyss and zumilokibart, with one induction dose at Week 4. Our 12-week PoC substudies extend dosing in the induction phase.

Figure 12: Loading, Induction and Maintenance Dosing of Standard of Care Biologics



There have been no head-to-head clinical trials between the product candidates listed above. Study designs and protocols for each were different, and as a result, results may not be comparable between the product candidates. Dose regimens of Dupixent, Nemluvio and Ebglyss are collected from approved FDA Label. The dose regimen of Zumilokibart is from Phase 2 APEX Part A. Baseline EASI represents the score for the active treatment arm in the referenced studies. EASI: Eczema Area and Severity Index; EASI-75: 75% or greater improvement/reduction in EASI score; Tx: treatment; Dupixent: SOLO-1 and SOLO-2 Studies; Ebglyss: Advocate 1 and Advocate 2 Studies; Nemluvio: Week 4 data of Ph2b (NCT03100344), Week 16 data of ARCADIA 1 and ARCADIA 2 Studies; Zumilokibart: Phase 2 APEX Part A and Part B mid dose.

Overview of BBT001 Clinical Development Program in AD

Our BBT001 clinical development program in AD is designed to evaluate clinical activity, safety, PK, PD, and immunogenicity, inform dose selection, and support the intended commercial product profile. We completed dosing and safety follow ups of IV formulations of BBT001 in healthy volunteers in our Global BBT001 Study and China AD Study. Building on these data, we are evaluating BBT001 across multiple PoC substudies of our Global BBT001 Study and China AD Study in bio-naïve and bio-experienced patients with moderate-to-severe AD in the United States, Australia, China, Europe, and New Zealand to assess clinical activity and inform future Phase 2b and pivotal

trial development. We have also initiated healthy volunteer and PoC substudies of a SubQ formulation of BBT001 as part of our Global BBT001 Study and recently announced the dosing of our first patient in the 12-week SubQ AD PoC Substudy.

4-Week Phase 1 Substudy of Bio-Naïve Patients with Moderate-to-Severe AD:

In July 2026, we reported positive topline PoC results from our Global BBT001 Study of patients with moderate-to-severe AD who have received neither biologics targeting the same pathways as our product candidate nor JAK inhibitors (we refer to these patients as "bio-naïve") treated with four weeks of an IV formulation of BBT001 in New Zealand and the United States ("4-week PoC bio-naïve AD data").

This randomized, double-blinded, placebo-controlled PoC substudy within our Global BBT001 Study is being conducted across sites in the United States and New Zealand. Key eligibility criteria include diagnosis with moderate-to-severe AD with confirmed history of at least one year, an EASI score of at least 16, an average PP-NRS score of at least 4, atopic lesions involving at least 10% BSA, and a vIGA-AD score of at least 3.

Figure 13: 4-week PoC Study in Bio-Naïve AD Patients



The mean age of enrolled patients was 31.1 years for the BBT001 group and 31.8 for the placebo group. The average duration of diagnosed disease was close to three decades, and 10 of the 17 patients had additional Type 2 comorbidities. Overall, patients receiving BBT001 had higher baseline EASI, BSA, weekly PP-NRS and vIGA scores compared to the placebo group with a mean EASI of 34.6 compared to 29.1 for the placebo group, mean BSA of 63% compared to 48%, mean weekly PP-NRS 7.3 compared to 6.3 and mean vIGA of 3.4 compared to 3.2.

Figure 14: Key Baseline Patient Characteristics

	BBT001 (N=12)	Placebo (N=5)
Age, yrs (mean, SD)	31.1 (11.39)	31.8 (12.11)
Weight, kg (mean, SD)	82.16 (14.00)	76.35 (21.09)
BMI, kg/m²(mean, SD)	27.66 (5.79)	25.34 (6.09)
Duration AD Diagnosis, yrs (mean, SD)*	28.14 (9.25)	30.5 (10.61)
Type 2 Comorbidity (N, %)**	8 (66.7%)	2 (40.0%)
Sex (N, %)		
Female	3 (25%)	1 (20%)
Male	9 (75%)	4 (80%)
Race (N, %)		
Caucasian	3 (25%)	2 (40%)
Asian	0 (0%)	2 (40%)
Black	2 (16.7%)	1 (20%)
Others***	7 (58.3%)	0 (0%)
EASI (mean, SD)	34.64 (11.38)	29.06 (14.00)
BSA, % (mean, SD)	62.58 (19.87)	47.60 (25.10)
Weekly PP-NRS (mean, SD)	7.34 (0.87)	6.33 (1.55)
vIGA (mean, SD)	3.42 (0.51)	3.20 (0.45)

* Duration of AD diagnosis of N=9 for BBT001 and N=2 for placebo.
** Type 2 Comorbidity includes asthma, allergy, hay fever, and urticaria.
*** Others included: Native Hawaiian or Pacific Islanders, multiple, other not specified, and unknown.

Seventeen adult bio-naïve participants with moderate-to-severe AD were randomized 2 to 1 and assigned to receive three repeat doses of BBT001 by IV administration at 450 mg or placebo. Patients were dosed on Day 1, 15, and 29 and are returning for several follow-ups through Day 169 to evaluate safety and tolerability of BBT001. The dosing regimen was designed to mimic the loading and initial induction phases of treatment for AD.

The primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including elimination half-life ("$t_{1/2}$"), and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB in TARC and IgE, and other clinical activity, such as CFB in EASI, proportion of patients achieving EASI-50 and EASI-75, and CFB in PP-NRS.

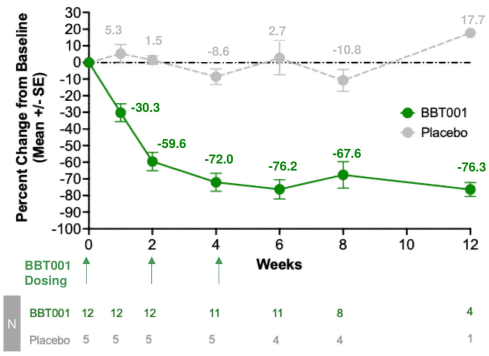
As of the June 8, 2026 data cutoff date, all 17 enrolled patients were evaluable for preliminary safety and clinical response, with a median follow-up of 71 days after the first dose and a range of 33 to 165 days.

Key highlights include:

- ***Fast-onset, statistically significant and clinically meaningful improvement in Eczema Area and Severity Index ("EASI").*** BBT001 produced a highly statistically significant placebo-adjusted EASI reduction beginning at Week 1 with a placebo-adjusted CFB in EASI of 35.6% (95% confidence interval ("CI") [-50.96, -13.69] and p-value of 0.0012). A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of 0.0012 means that there is a 0.12% probability that the difference between the placebo group and the BBT001 treatment group is purely due to chance. A p-value below 0.05 is generally considered statistically significant. The placebo-adjusted EASI reduction continued to deepen at Weeks 2, 4 and 6 for patients followed with placebo-adjusted CFB reductions of 61.1%, 63.5% and 79.0%, each of which had a p-value below 0.0001.

Figure 15: BBT001 EASI Reduction

Eczema Area and Severity Index (EASI) Score Change



Placebo-Adjusted Percentage of EASI Change*

Visit	Placebo-adjusted Change (%)	95% CI	p-value
Week 1	-35.56	(-50.96, -13.59)	0.0012
Week 2	-61.10	(-81.24, -43.87)	<0.0001
Week 4	-63.46	(-80.75, -43.27)	<0.0001
Week 6	-78.95	(-94.62, -57.14)	<0.0001

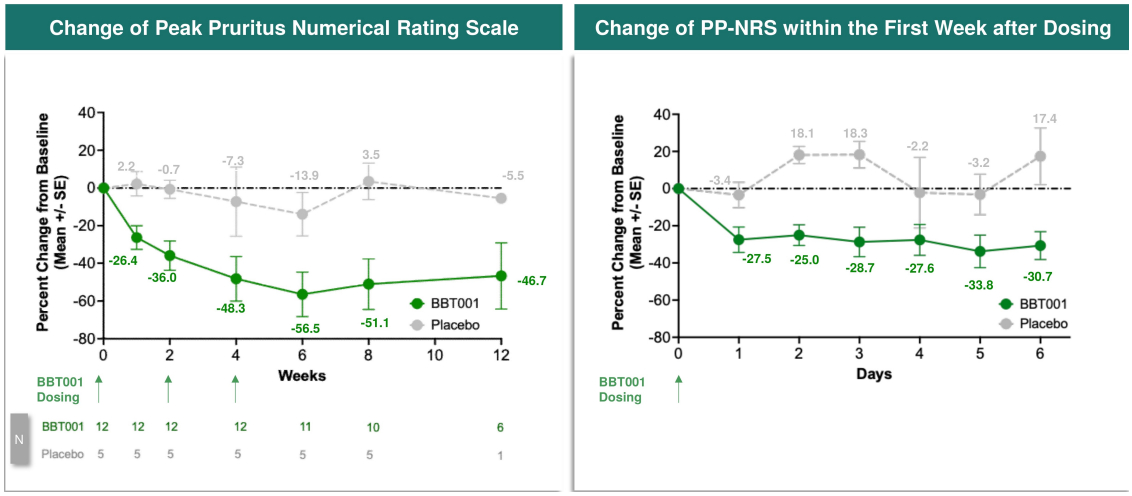
The p-values were derived from a mixed model for repeated measures. SE means standard error; CI means confidence interval.

* Placebo-adjusted changes shown are observed between-group differences. Least Squares mean method was used to compare the difference between BBT001 versus placebo group.

Additionally, the placebo-adjusted proportion of AD patients treated with BBT001 achieving more than 50% improvement from baseline EASI ("EASI-50") at Week 2 was 75%, growing to 91% at Week 4, and remaining sustained at 82% two weeks after the last dose at Week 6. BBT001's placebo-adjusted EASI-75 response demonstrated that patients not only experienced early response that was sustained, but the response also deepened over time with an increasing number and proportion of patients who achieved placebo-adjusted EASI-75 at subsequent follow up visits. Two (17%) of the 12 patients at Week 2 and five (45%) of the 11 patients who had received their last dose at Week 4, and seven (64%) of the 11 patients who had their Week 6 follow-up visit achieved EASI-75, demonstrating that the progression to substantial clearance increased in the two weeks following the last dose.

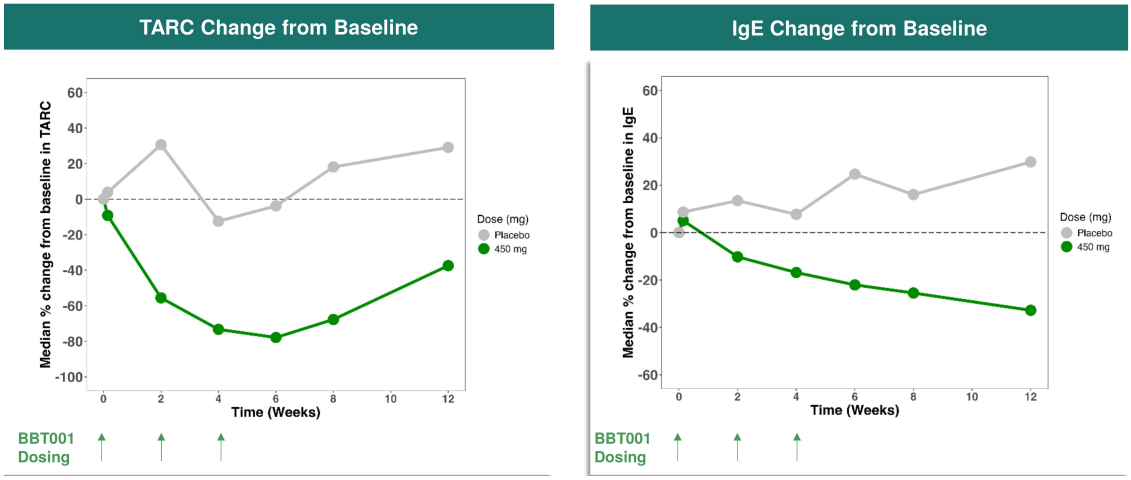
- ***Rapid and progressively greater itch relief.*** BBT001 delivered rapid itch control, as measured by reduced PP-NRS scores, as early as Day 1 (see the right side of Figure 16), with improvements deepening throughout the treatment period and remaining sustained for eight weeks after the last dose (see left side of Figure 16). Delivery of rapid itch relief within 24 hours after the first dose is clinically important as itch dominates daily life, disrupting sleep, concentration and work and driving scratching that further damages the skin.

Figure 16: BBT001 PP-NRS Reduction



- ***Robust and durable suppression of Type 2 inflammatory biomarkers***. BBT001 produced early and substantial reductions in key Type 2 biomarkers, including TARC and IgE, that were sustained for eight weeks after the last dose, demonstrating durable inhibition of Type 2 inflammation.

Figure 17: BBT001 TARC and IgE Reductions



- ***Favorable safety findings***. BBT001 was observed to be well tolerated, with no cases of conjunctivitis reported, consistent with prior findings in healthy volunteers. Treatment-emergent adverse events ("TEAE") were reported in 50% of BBT001-treated subjects compared to 60% of placebo subjects. Only one Grade 3 TEAE that was determined to be probably treatment related ("TRAE") was reported. It was resolved within a few hours.

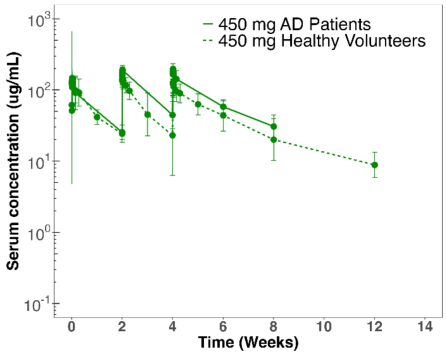
Figure 18: BBT001 Well Tolerated in Bio-Naïve AD Patients

Participants (%)	AD Patients MAD	
	BBT001 (N=12)	Placebo (N=5)
With ≥ 1 TEAE	6 (50.0%)	3 (60.0%)
With ≥ 1 Grade 3 TEAE*	1 (8.3%)	0 (0.0%)
With ≥ 1 TRAE	4 (33.3%)	0 (0.0%)
With ≥ 1 Grade 3 TRAE*	1 (8.3%)	0 (0.0%)

*Grade 3 TEAE/TRAE: IRR

- ***Extended half-life supporting infrequent dosing***. BBT001 demonstrated an extended half-life of approximately 33 days in patients with AD, consistent with prior observations in healthy volunteers**.**

Figure 19: BBT001 PK from the 4-week PoC Bio-naïve AD and MAD Healthy Volunteer Portions of Global BBT001 Study



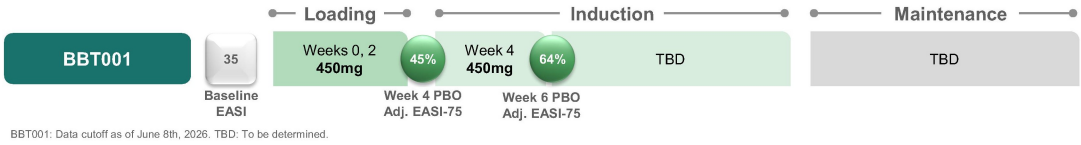
- ***Low immunogenicity***. BBT001 demonstrated a low incidence of treatment-emergent anti-drug antibodies of 2.1% in AD patients, that has been low titer and predominantly transient, with no apparent impact on PK or safety. There was no evidence of neutralizing activity, consistent with prior findings in healthy volunteers.

The consistency across lesions measured by EASI scores, itch measured by CFB in PP-NRS, sustained reductions in key Type 2 biomarkers, statistical significance, the early separation from placebo that continued deepening through treatment, and the persistence after last dosing gives us substantial confidence in the potential clinical impact of BBT001.

Additionally, based on clinical trial results to date, including PK, receptor occupancy, depth of response, and duration of response, we believe a quarterly maintenance dosing regimen could be possible. We designed our 4-week substudy to include two loading doses at Week 0 and Week 2, similar to Ebglyss's Advocate 1 and Advocate 2 studies and zumilokibart's Phase 2 APEX study, with one single induction dose at Week 4 to see the impact of a shortened induction period. Despite having enrolled patients with a higher baseline disease burden (mean baseline EASI of 35), and shorter treatment duration (only up to Week 4), BBT001 achieved a 64% placebo-adjusted EASI-75 response at Week 6. Our 12-week PoC substudies will evaluate a longer induction period, and as we initiate study start-up activities for our upcoming Phase 2b dose-ranging clinical trial study of a SubQ formulation of BBT001 in AD patients, we plan to evaluate different dose levels, loading and induction strategies, and dosing

intervals to identify the optimal induction and maintenance regimens to balance dosing with efficacy with an appropriate margin across patients.

Figure 20: Potential Loading, Induction and Maintenance Dosing Regimen of BBT001



Healthy Volunteer Data:

Both our Global BBT001 Study and China AD Study use master protocols that comprise both healthy volunteer and patient, or PoC, cohorts. The healthy volunteer portions of these studies are comprised of:

1) Phase 1 SAD and MAD cohorts of the IV formulation of BBT001 and a Phase 1 SubQ bridging cohort as part of our Global BBT001 Study; and

2) Phase 1a SAD cohorts of the IV formulation of BBT001 as part of our China AD Study.

We reported preliminary results from the SAD and MAD healthy volunteer portions of European Academy of Dermatology and Venereology ("EADV") Congress 2025 and the American Academy of Dermatology ("AAD") 2026 Annual Meeting, respectively. We have also completed dosing and safety follow ups from the SAD healthy volunteer portion of our China AD Study.

Healthy Volunteers Portions of Global BBT001 Study in Australia

The healthy volunteer portions of our randomized, double-blinded, placebo-controlled Phase 1 Global BBT001 Study are being conducted primarily in Caucasian populations at a single site in Australia.

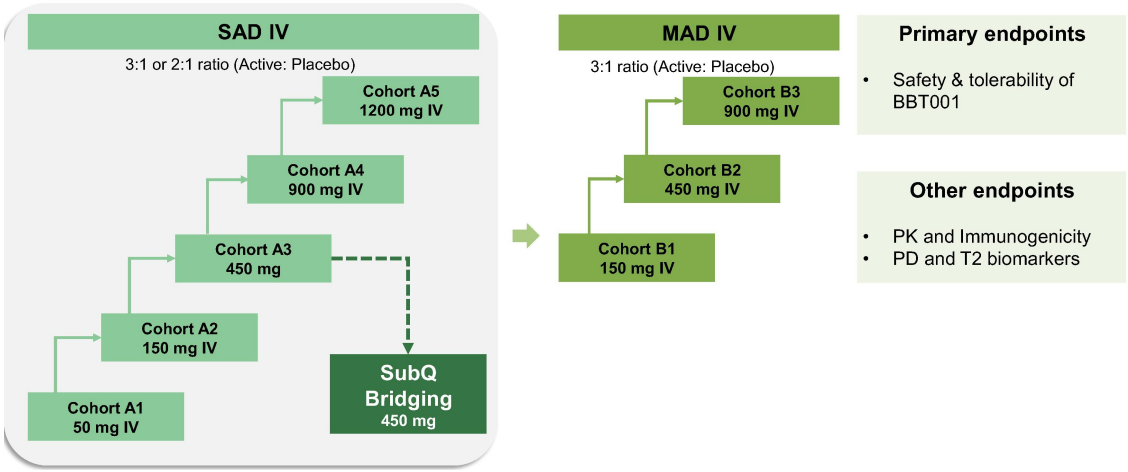
The primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of adverse events ("AEs"). The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including IL-4Rα receptor occupancy and phosphorylated signal transducer and activator of transcription 6 ("pSTAT6"), and CFB of Type 2 biomarkers, such as TARC as evidence of functional pathway inhibition and PD effects.

For the single-ascending-dose ("SAD") portion, 38 healthy volunteers were assigned to receive a single dose of BBT001 by IV administration in five sequential ascending dose cohorts (50, 150, 450, 900, or 1200 mg). The six participants in cohort A1 were randomized in a 2:1 ratio (active:placebo) with the remaining cohorts A2 through A5 randomized in a 3:1 ratio. Participants were dosed on Day 1 and returned for several follow-ups through Day 141.

For the multiple-ascending-dose ("MAD") portion, 24 healthy volunteers were assigned to receive three repeat doses of BBT001 by IV administration once every two weeks in three sequential ascending dose cohorts (150, 450, or 900 mg). The eight participants for each cohort were randomized in a 3:1 ratio (active:placebo). Participants were dosed on Day 1, 15, and 29 and returned for several follow-ups through Day 169.

For the SubQ bridging portion, 40 adult participants are being assigned to receive a single dose of 450 mg of BBT001 by SubQ administration. Patients in each cohort are randomized in a 3:1 ratio (active:placebo). Participants are dosed on Day 1 and return for several follow-ups through Day 141.

Figure 21: Study Design of Healthy Volunteer Portions of Global BBT001 Study



In September 2025 and March 2026, we presented preliminary results from the SAD and MAD healthy volunteer portions of our Global BBT001 Study in posters at the EADV Congress 2025 and the AAD 2026 Annual Meeting, respectively. When we prepared the poster for the MAD data, we also performed an updated interim analysis of the SAD data using the same data cutoff date of December 5, 2025.

Key preliminary results demonstrate that BBT001 met all primary endpoints as of the December 5, 2025 data cutoff date.

The preliminary results for the SAD and MAD healthy volunteers portions of our Global BBT001 Study, as of the data cutoff date of December 5, 2025, are summarized below:

- ***Safety and Tolerability****:* BBT001 was observed to be well tolerated across all dose levels evaluated for both the SAD and MAD healthy volunteer portions of our Global BBT001 Study. Treatment-emergent adverse events ("TEAEs") were reported in 68% of BBT001-treated subjects compared to 60% of placebo subjects in SAD, and in 85% compared to 100%, respectively, in MAD. No Grade 3 treatment-related adverse events ("TRAEs") were reported in SAD, and no Grade 3 TEAEs or TRAEs were reported in MAD.

Figure 22: BBT001 is Well Tolerated in Healthy Volunteers

SAD

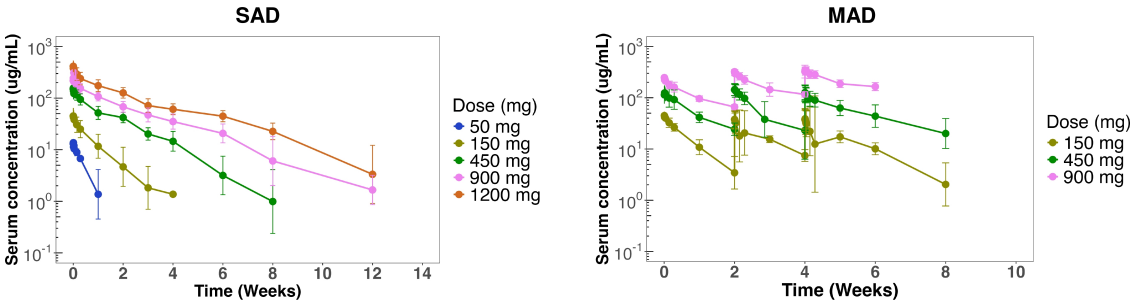
N (%)	Placebo (N =10)	Overall BBT001 (N=28)
≥ 1 TEAE	6 (60.0%)	19 (67.9%)
≥ 1 Grade 3 TEAE	1 (10.0%)	1 (3.6%)
≥ 1 TRAE	1 (10.0%)	6 (21.4%)
≥ 1 Grade 3 TRAE	0 (0.0%)	0 (0.0%)

MAD

N (%)	Placebo (N =6)	Overall BBT001 (N=20)
≥ 1 TEAE	6 (100%)	17 (85.0%)
≥ 1 Grade 3 TEAE	0 (0.0%)	0 (0.0%)
≥ 1 TRAE	1 (16.7%)	8 (40.0%)
≥ 1 Grade 3 TRAE	0 (0.0%)	0 (0.0%)

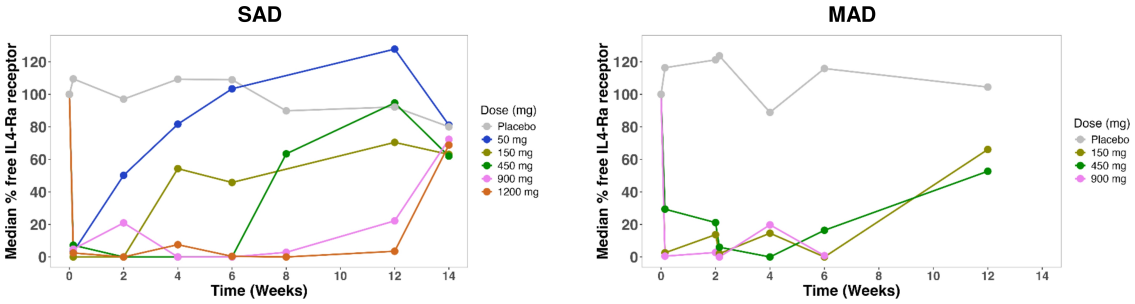
- ***Pharmacokinetics***: BBT001 demonstrated non-linear PKs. The estimated terminal half-life was approximately 33 days using population PK modeling. This half-life was consistent across the SAD and MAD portions.

Figure 23: BBT001 PK at Multiple Doses



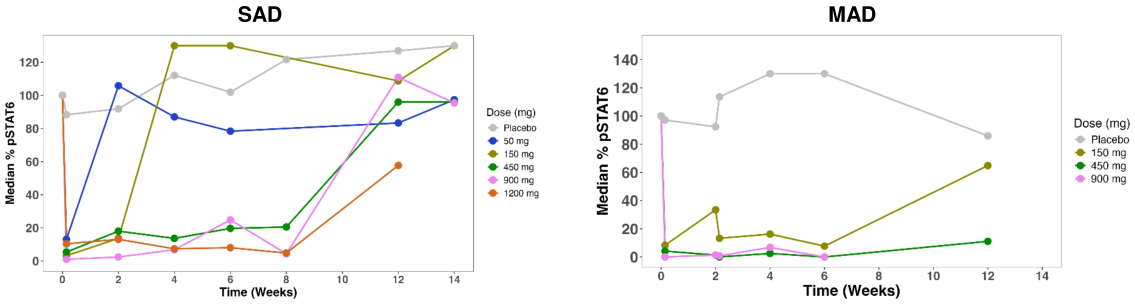
- ***Pharmacodynamics****:* BBT001 demonstrated rapid, complete, and sustained PD effects:
  - ***IL-4Rα Binding:*** Near-complete receptor occupancy was achieved rapidly and sustained for eight weeks or longer after dosing of single dose or multiple doses of BBT001 greater than 150 mg.

Figure 24: BBT001 IL-4Rα Binding at Multiple Doses



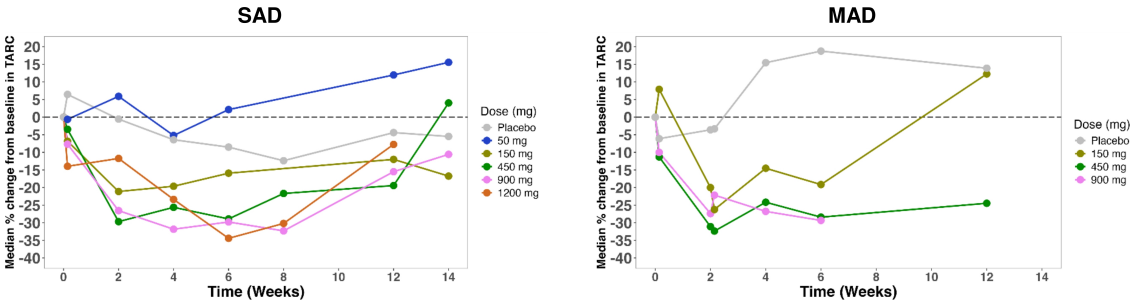
  - ***pSTAT6 Inhibition:*** Rapid, dose-dependent inhibition of IL-4-stimulated pSTAT6 was observed, sustained for eight weeks or longer after dosing of single dose or multiple doses of BBT001 at the dose greater than 150 mg.

Figure 25: BBT001 pSTAT6 Inhibition at Multiple Doses



  - ***TARC Reduction:*** BBT001 demonstrated dose-dependent, rapid, deep, and sustained TARC suppression. Potent TARC suppression was demonstrated to be sustained through Week 12 after a single dose of 150, 450, 900, and 1200 mg and through Week 12 after multiple doses at doses greater than 150 mg.

Figure 26: BBT001 TARC Reduction at Multiple Doses



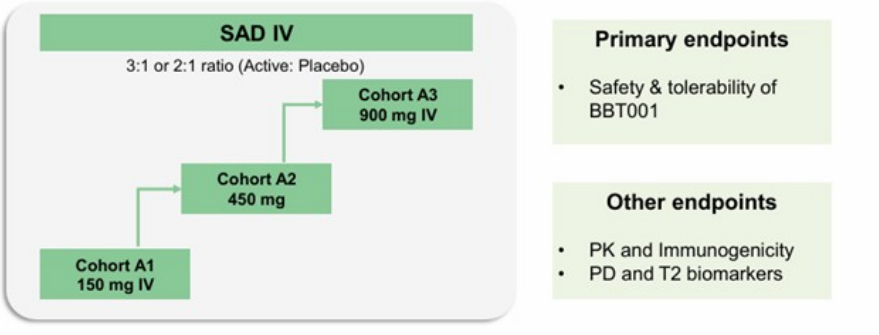
- ***Immunogenicity****:* BBT001 showed very low immunogenicity. In the SAD portion, approximately 21.4% of subjects had treatment-emergent ADA with only one subject having treatment emergent ADA at the therapeutic dose. In the MAD portion, only approximately 5% of samples and approximately 10% of subjects tested positive for treatment-emergent ADA, with all positive cases occurring at sub-therapeutic dose levels (150 mg). No treatment-emergent ADA was detected at therapeutic dose levels. ADA responses were low titer, with no apparent impact on PK or safety and no sign of neutralizing ADA.

Healthy Volunteers Portion of China AD Study

We are currently conducting a parallel double-blind, placebo-controlled first-in-human Phase 1a substudy in an Asian population in China as part of our China AD Study to evaluate BBT001 in 20 healthy volunteers who were assigned to receive a single dose of BBT001 by IV administration in three sequential ascending dose cohorts (150, 450 and 900 mg). The three participants in cohort A1 were randomized in a 2:1 ratio (active:placebo) with the remaining cohorts A2 and A3 randomized in a 3:1 ratio. Participants were dosed on Day 1 and returned for several follow-ups through Day 141 to evaluate safety and tolerability of BBT001.

Consistent with the Australia SAD and MAD healthy volunteer portions of our Global BBT001 Study, the primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including IL-4Rα receptor occupancy and pSTAT6, and CFB of Type 2 biomarkers, such as TARC.

Figure 27: Study Design of Healthy Volunteer Portion of China AD Study



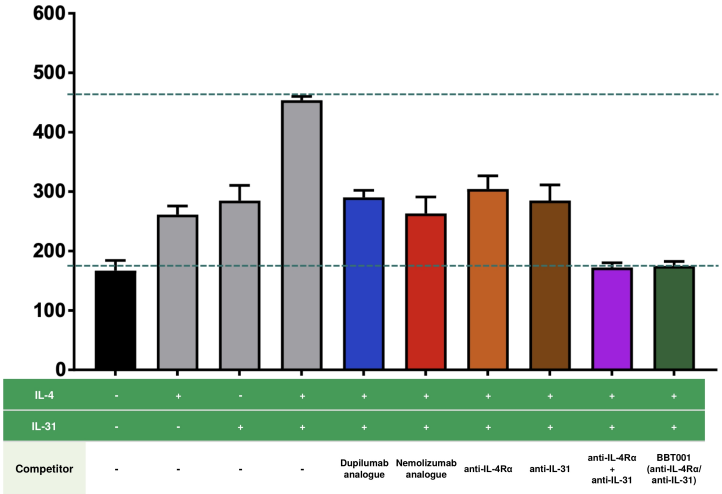
Interim results from the SAD healthy volunteer cohorts of our China AD Study as of September 20, 2025 demonstrated an extended half-life, potent and sustained inhibition of key biomarkers, and low immunogenicity, consistent with the results from preliminary and interim data from the Australia SAD and MAD healthy volunteer cohorts of our Global BBT001 Study as well as the preliminary 4-week PoC bio-naïve AD data from our Global BBT001 Study.

Our Preclinical Data

BBT001 has demonstrated compelling preclinical data supporting its potential in I&I indications:

- **Superior *in vitro* Activity**: In a head-to-head *in vitro* study of IL-4 and/or IL-31-induced *CCL2* expression in BEAS-2B (human bronchial epithelial) cells, BBT001 showed superior inhibitory effect compared to the dupilumab and nemolizumab analogues alone, suggesting that both arms were functionally potent and one arm did not limit the effect of the other.

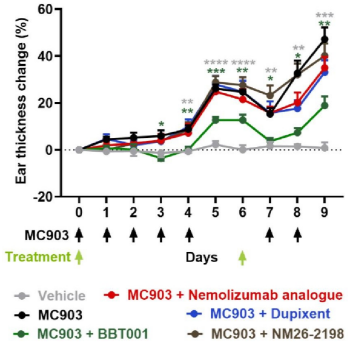
Figure 28: Effect on IL-4/IL-31-Induced CCL2 Expression in BEAS-2B Cells



Dupilumab analogue was expressed and purified in house based on the sequences from WHO INN PL 108.
Nemolizumab analogue was expressed and purified in house based on the sequences from patent WO2020157636, SEQ ID NO.5, SEQ ID NO.6.

- **Superior reduction of skin inflammation *in vivo***: In an MC903 (calcipotriene)-induced mouse AD model established in human IL-4/IL-4Rα/IL-31/IL-31Rα/OSMRβ knock-in C57 mice, BBT001 demonstrated statistically significantly more pronounced anti-inflammatory effects compared to Dupixent and a nemolizumab analogue with lower ear thickness changes.

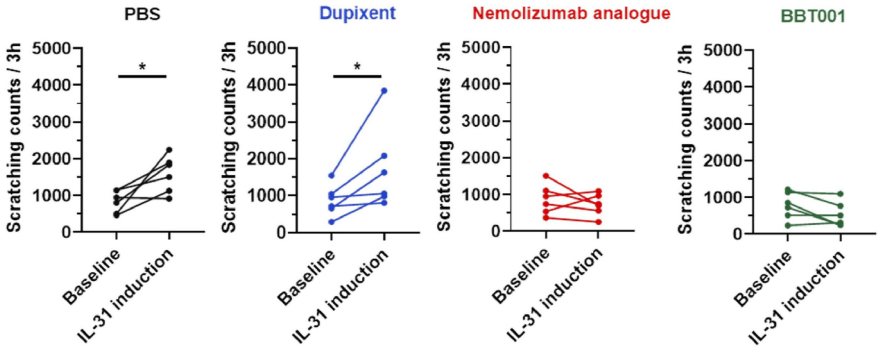
Figure 29: Anti-inflammatory Effect of BBT001 Compared to Dupixent and Nemolizumab Analogues



*p<0.05, **p<0.01 ****p<0.0001, versus MC903 only, two-way ANOVA

- **Reduction of Scratching**: In an IL-31-induced scratching established in human IL-4/IL-4Rα/IL-31/IL-31Rα/OSMRβ, BBT001 and a nemolizumab analogue, but not Dupixent, reduced IL-31-induced scratching behavior, suggesting that IL-31 blockade contributed independently to itch reduction beyond what IL-4Rα blockade alone achieved.

Figure 30: Reduction of Scratching of BBT001 Compared to Dupixent and a Nemolizumab Analogue



*p<0.05, paired t-test

- **Predicted Q3M Dosing**: Population PK modeling based on non-human primate ("NHP") data predicted a human half-life of approximately 29 days (subsequently supported by a finding of approximately 33 days in the SAD and MAD healthy volunteer portions of our Global BBT001 Study) and predicted that therapeutic drug concentrations with greater than 99% receptor occupancy can be maintained at doses of 150 mg or higher administered quarterly or once every three months ("Q3M"), well below the no observed adverse effect level ("NOAEL") of 200 mg/kg observed in a four-week long good laboratory practice ("GLP") toxicology study in NHPs.

Ongoing Clinical Development for BBT001 in AD

We are continuing to evaluate BBT001 in patients with moderate-to-severe AD in our Global BBT001 Study and China AD Study, including:

- a Phase 1b substudy of bio-naïve patients with moderate-to-severe AD in China who shall receive seven doses of an IV formulation of BBT001 over 12 weeks (as part of our China AD Study);
- a Phase 1 substudy of bio-experienced patients with moderate-to-severe AD in the United States, Australia, Europe, and New Zealand who shall receive five doses of an IV formulation of BBT001 over 12 weeks (as part of our Global BBT001 Study);
- a Phase 1b substudy of bio-experienced patients with moderate-to-severe AD in China who shall receive seven doses of an IV formulation of BBT001 over 12 weeks (as part of our China AD Study); and
- a Phase 1 substudy of bio-naïve patients with moderate-to-severe AD in the United States, Australia, Europe, and New Zealand who shall receive five doses of a SubQ formulation of BBT001 over 12 weeks (as part of our Global BBT001 Study).

12-week Phase 1b Substudy in Bio-Naïve Patients with Moderate-to-Severe AD in China

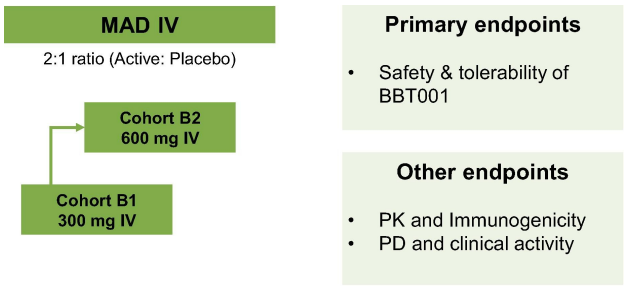
In the first half of 2027, we expect to report topline PoC results from our China AD Study of bio-naïve patients with moderate-to-severe AD treated with 12 weeks of an IV formulation of BBT001 in China ("12-week PoC bio-naïve AD data").

In this Phase 1b substudy, each patient shall receive seven repeat doses of either 300 or 600 mg of BBT001 by IV administration. The 300 mg dose cohort is currently fully enrolled, and we are currently enrolling for the 600 mg cohort.

Consistent with the 4-week PoC substudy within our Global BBT001 Study, the primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB in TARC and other clinical activity, such as

CFB in EASI, average weekly PP-NRS score, proportion of participants who achieve a vIGA-AD score of 0 or 1, and other endpoints.

Figure 31: Study Design of 12-week Phase 1b Substudy in Bio-naïve AD Patients in China



Global 12-week Phase 1 Substudy in Bio-Experienced Patients with Moderate-to-Severe AD

In this Phase 1 substudy of bio-experienced patients with moderate-to-severe AD treated with 12 weeks of an IV formulation of BBT001 (as part of our Global BBT001 Study), we are currently enrolling approximately 15 patients in the United States, Australia, Europe, and New Zealand. Each patient shall receive five repeat doses of 450 mg of BBT001 by IV administration. Patients are being randomized in a 2:1 ratio (active:placebo). Patients are dosed on Day 1, 15, 29, 57, and 85 and return for several follow-ups through Day 169 to evaluate safety and tolerability of BBT001.

Consistent with the 4-week PoC substudy of our Global BBT001 Study, the primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB in TARC and other clinical activity, such as CFB in EASI, average weekly PP-NRS score, proportion of participants who achieve a vIGA-AD score of 0 or 1, and other endpoints.

12-week PoC Phase 1b Substudy in Bio-Experienced Patients with Moderate-to-Severe AD in China

In this Phase 1b substudy of bio-experienced patients with moderate-to-severe AD treated with 12 weeks of an IV formulation of BBT001 (as part of our China AD Study), we are currently enrolling approximately 12 to 24 patients in China. Each patient shall receive seven repeat doses of either 300 or 600 mg of BBT001 by IV administration. Consistent with the 4-week PoC substudy of our Global BBT001 Study, the primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB in TARC and other clinical activity, such as CFB in EASI, average weekly PP-NRS score, proportion of participants who achieve a vIGA-AD score of 0 or 1, and other endpoints.

Global 12-week PoC Phase 1 Substudy in Bio-Naïve Patients with Moderate-to-Severe AD

In this Phase 1 substudy of bio-naïve patients with moderate-to-severe AD treated with 12 weeks of a SubQ formulation of BBT001 (as part of our Global BBT001 Study), we are currently enrolling up to 45 patients in the United States, Australia, Europe, and New Zealand. Each patient shall receive five repeat doses of either 360 or 720 mg of BBT001 by SubQ administration. Patients are being randomized in a 2:2:1 ratio (active:active:placebo). Consistent with the 4-week PoC substudy of our Global BBT001 Study, the primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB in TARC and other clinical activity, such as CFB in EASI, average weekly PP-NRS score, proportion of participants who achieve a vIGA-AD score of 0 or 1, and other endpoints. We recently announced the dosing of our first patient in this substudy.

BBT001 for the Treatment of Chronic Spontaneous Urticaria ("CSU")

Overview

We are concurrently conducting a Phase 2a PoC study of BBT001 of patients with CSU. We expect to report topline 14-week PoC CSU data in the first half of 2027.

Disease Background and Market Opportunity

CSU is a chronic inflammatory skin disease characterized by recurrent wheals (hives), angioedema (deep tissue swelling), and pruritus (itch), with itch representing a hallmark symptom and a major contributor to disease burden and impaired quality of life. Epidemiological studies suggest CSU affects approximately 0.5% to 1.0% of the global population at any given time, with prevalence estimates in the United States and Europe generally within this range.

CSU is a predominantly Type 2 inflammatory disease characterized by dysregulated mast cell and basophil activation, with IgE-mediated pathways playing a central role in disease pathogenesis. Clinical validation of Type 2 pathway inhibition has been established by the efficacy of anti-IgE therapy (Xolair) and more recently by the positive outcomes observed with IL-4Rα blockade (Dupixent), highlighting the importance of IL-4 and IL-13 signaling in CSU. Pruritus is the cardinal symptom of CSU and remains a major source of disease burden, sleep disturbance, and impaired quality of life. In the acute phase of CSU, itch is primarily driven by histamine released from activated mast cells, which explains the established role of H1-antihistamines as first-line therapy. However, a substantial proportion of patients remain symptomatic despite high-dose antihistamine treatment, suggesting the involvement of additional non-histaminergic pruritic pathways. Among these, IL-31, a clinically validated pruritogenic cytokine, has been demonstrated to act directly on sensory neurons to amplify itch signaling and neuroimmune crosstalk. Emerging evidence indicates that IL-31 contributes to chronic itch across multiple Type 2 inflammatory diseases including CSU, particularly in patients whose symptoms are incompletely controlled by antihistamines alone. Therefore, dual blockade of IL-4Rα and IL-31 by BBT001 may offer a complementary mechanism in CSU: IL-4Rα inhibition suppresses the upstream Type 2 inflammatory cascade, including IgE production and mast cell sensitization, while IL-31 blockade directly attenuates chronic itch signaling.

Current CSU Treatment Options and Limitations

CSU treatment follows a stepwise approach, beginning with second-generation H1-antihistamines and escalating to biologic therapy in patients with inadequate symptom control. While antihistamines can be effective for some patients, many remain symptomatic despite dose escalation. To date, there are only three approved therapeutics available for antihistamine-refractory CSU patients: Xolair (omalizumab), a once monthly SubQ anti-IgE biologic; Dupixent, a twice monthly SubQ IL-4Rα inhibitor; and Rhapsido (remibrutinib), a twice daily oral BTK inhibitor. Each of the approved therapeutics has its own limitations. Xolair contains a black box warning for anaphylaxis and carries burdensome in-office administration and monitoring requirements. Furthermore, approximately two-thirds of patients treated with Xolair do not experience complete symptom control. Although Dupixent was approved in 2025 for CSU, it has a more limited efficacy profile than Xolair. While Rhapsido has shown greater clinical efficacy in CSU than Dupixent, it is limited by safety and tolerability concerns. Rhapsido's label includes side effects such as nasopharyngitis, bleeding, headache, nausea, and abdominal pain. In severe, refractory cases, immunosuppressants such as cyclosporine may be used, although their long-term use can be limited by safety and tolerability concerns.

Clinical benefit in CSU is primarily assessed using the Urticaria Activity Score over seven days ("UAS7"), which captures both hive activity and itch severity, with complete disease control defined as UAS7=0. Additional measures include itch severity, angioedema activity, quality of life, sleep quality, and time to symptom control. Key treatment goals include rapid itch reduction, elimination of hives, sustained disease control, reduced flare frequency, and meaningful improvements in patient quality of life.

Current treatment options for CSU have improved disease management, but several important limitations remain:

- ***Incomplete Symptom Control***. A meaningful proportion of patients remain symptomatic despite optimized antihistamine therapy or escalation to biologics. Even with Xolair, not all patients achieve complete response (e.g., UAS7=0), and many experience only partial reductions in hives and itch.
- ***Heterogeneous Response and Non-Responders***. CSU is a biologically heterogeneous disease with both autoallergic and autoimmune drivers. As a result, single-mechanism therapies may not adequately address all underlying pathways, leading to variability in response and a subset of patients who do not respond to existing treatments.
- ***Relapse and Durability Challenges***. Disease control is often dependent on continued therapy, and relapse is common after discontinuation, particularly with biologic treatment. This underscores the need for therapies that provide more durable remission.
- ***Injection Burden and Treatment Convenience***. Biologic therapies such as Xolair are typically administered every four weeks, often in a clinical setting, which can create logistical challenges and impact patient adherence and persistence over time.
- ***Limited Options for Refractory Patients***. Patients who fail antihistamines and biologics have few effective and well-tolerated alternatives. Immunosuppressants such as cyclosporine may be used, but their long-term use is limited by safety concerns, monitoring requirements, and tolerability.
- ***Lack of Rapid and Complete Itch Control***. While antihistamines and biologics can reduce pruritus, onset may be variable and incomplete in some patients, and persistent itch remains a key driver of quality-of-life impairment.
- ***Chronic Disease Burden***. CSU often persists for years, requiring long-term management. Current therapies may control symptoms but do not consistently modify underlying disease biology to achieve sustained remission.

Phase 2a Study in CSU in China

We are currently conducting one Phase 2a study of BBT001 in bio-naïve adult patients with CSU in China. This Phase 2a study is a randomized, double-blind, placebo-controlled study to evaluate the safety and tolerability, PK, immunogenicity, PD, and clinical activity of 450 mg of BBT001 following eight doses of IV administration. Participants are being randomized in a 2:1 ratio. Participants are dosed on Day 1, 15, 29, 43, 57, 71, 85, and 99 and return for several follow-ups through Day 183.

The primary endpoints are safety and tolerability of BBT001, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT001, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are total IgE concentration, and clinical activity including UAS7, Itch Severity Score over seven days (“ISS7”), Hives Severity Score over seven days (“HSS7”), Urticaria Control Test (“UCT”) score, Angioedema Activity Score over seven days (“AAS7”) score, and other endpoints.

We expect to report topline data in the first half of 2027 from our ongoing 14-week study in CSU, which has the potential to establish clinical PoC for BBT001.

BBT001 Potential Program Expansion into Additional Target Indications

BBT001, designed as a pipeline-in-a-molecule, targets well-known pathways that underlie multiple indications in dermatology. In addition to AD and CSU, we believe there are expansion opportunities for developing BBT001 in a number of additional indications, including:

- ***Prurigo Nodularis ("PN")***: a chronic skin condition that causes extremely itchy, hard bumps to form on your skin;
- ***Alopecia Areata ("AA")***: an autoimmune condition where the immune system attacks hair follicles, causing hair to fall out in round patches;
- ***Bullous Pemphigoid ("BP")***: a rare, blistering skin disease that mostly affects older adults and causes large, fluid-filled blisters to form on the body; and
- ***Chronic Pruritus of Unknown Origin ("CPUO"):*** a condition defined by severe, non-stop skin itching lasting longer than six weeks without any clear cause.

Future Clinical Development Strategy

We plan to initiate study start-up activities for our Phase 2b AD Study by the end of 2026. The Phase 2b AD Study is expected to have an adaptive design with a standard-of-care biologic as an active control to select a recommended dose for our pivotal trial.

BBT002 Program: Pipeline-in-a-Molecule for Type 2 Inflammatory Disorders in Respiratory Disease

Overview

Our second lead product candidate, BBT002, is a bispecific antibody targeting both IL-4Rα and IL-5. IL-4Rα and IL-5 are two clinically and commercially validated targets with Dupixent and Nucala generating $17.8 billion and $2.6 billion, respectively, in global sales in 2025. By simultaneously targeting IL-4Rα, which affects IgE, mucus production, and airway remodeling, and IL-5, which affects EOS-mediated inflammation, BBT002 is designed to control the full spectrum of Type 2 inflammation and both improve lung function and reduce risk of exacerbations. We are initially developing BBT002 for the treatment of COPD, CRSwNP, and asthma, with potential to expand into other areas such as dermatology and gastroenterology, including for the treatment of CSU, EoE, and food allergy. We estimate that the largely untapped biologics respiratory market will exceed $60 billion in 2030 and believe that the broader type 2 inflammatory diseases addressable market for BBT002 will approach $85 billion by 2030.

We are currently evaluating BBT002 for the treatment of chronic obstructive pulmonary disease ("COPD") in our global Phase 1 clinical trial in the United States, Australia, Europe, Georgia, and New Zealand ("Global BBT002 Study") and our Phase 1/2a clinical trial for COPD in China ("China COPD Study"). We are also evaluating BBT002 for the treatment of chronic rhinosinusitis with nasal polyps ("CRSwNP") in a Phase 2a clinical trial in China ("China CRSwNP Study").

We expect several upcoming clinical data readouts for BBT002, including topline PoC results of patients with COPD treated with four weeks of an IV formulation of BBT002 ("4-week PoC COPD data") and patients with CRSwNP treated with 12 weeks of an IV formulation of BBT002 ("12-week PoC CRSwNP data") in the first half of 2027. In addition, we have initiated our global Phase 2a clinical trial of a SubQ formulation of BBT002 in patients with asthma ("Phase 2a Asthma Study") and plan to initiate study start-up activities for a Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT002 in patients with one of the respiratory indications in 2027.

Respiratory Disease Background

Biologics have transformed the treatment of respiratory diseases by shifting care from broad symptom management toward targeted, pathway-based therapy. Severe asthma was one of the earliest proof points for this paradigm, with biologics validating key inflammatory pathways, including IgE, IL-5, IL-4/IL-13, and TSLP. More

recently, the biologic opportunity has expanded beyond asthma into adjacent airway diseases such as CRSwNP and COPD, reflecting the shared role of Type 2 inflammation across multiple respiratory conditions.

Although the respiratory biologics market has an estimated market size of approximately $10 to $15 billion globally today, anchored by severe asthma and increasingly expanding into adjacent airway diseases, we estimate that the largely untapped biologics respiratory market will exceed $60 billion in 2030, with $30 billion attributed to asthma, $23 billion for COPD and $7 billion for CRSwNP. Leading products, including Dupixent, Nucala, Fasenra, and Tezspire, are each multi-billion-dollar franchises. Despite these options, significant unmet need remains. Current biologics are primarily used in severe or inadequately controlled patients, leaving overall penetration low relative to the large prevalence of respiratory disease. In asthma, many patients continue to experience exacerbations, impaired lung function, or persistent symptoms despite treatment. In CRSwNP, patients may continue to experience residual polyp burden, congestion, smell loss, or disease recurrence. In COPD, biologic use remains in the early stages and is generally limited to biomarker-defined Type 2 inflammatory subgroups within a highly heterogeneous disease. Together, these limitations highlight a large opportunity to improve depth of response, broaden eligible patient populations, and expand biologic use over time.

We believe the next wave of respiratory innovation will be defined by therapies designed to address multiple, complementary drivers of disease biology. Single-pathway biologics have established strong clinical and commercial validation, but many respiratory diseases involve overlapping inflammatory pathways that may not be fully controlled by inhibiting one target alone. Bispecific and other multi-target biologics have the potential to provide broader and more durable pathway inhibition, improve outcomes across heterogeneous patient populations, and further expand the respiratory biologics market. This evolution is consistent with the broader trajectory of I&I, where validated single-target therapies have created the foundation for next-generation approaches designed to deliver deeper disease control and greater patient benefit.

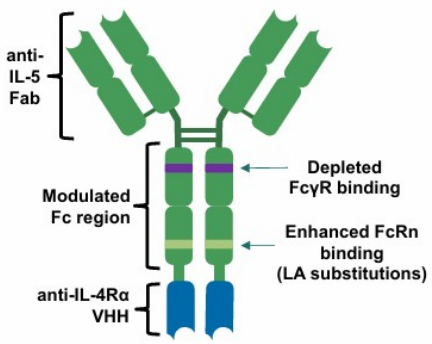
Our Solution for Type 2 Inflammatory Disorders in Respiratory Disease: BBT002

Overview

Our second lead product candidate, **BBT002**, is a next-generation, half-life extended bispecific IgG1 antibody that simultaneously targets IL-4Rα and IL-5 in a 2+2 format with differentiated attributes. BBT002 is designed to be the first molecule to address both central pillars of Type 2 inflammation—the IL-4/IL-13 axis and the IL-5/EOS axis—in a single treatment, creating a pipeline-in-a-molecule approach for respiratory and allergic diseases.

We are currently evaluating BBT002 for the treatment of COPD in our Global BBT002 Study and our China COPD Study. We are also evaluating BBT002 for the treatment of CRSwNP in our China CRSwNP Study. We expect several upcoming clinical data readouts for BBT002, including 4-week PoC COPD data in the first half of 2027 and 12-week PoC CRSwNP data in the first half of 2027. In addition, we have initiated our global Phase 2a Asthma Study and plan to initiate study start-up activities for a Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT002 in patients with one of the respiratory indications in 2027.

Figure 32: BBT002 is a Bispecific IgG1 Antibody that Targets IL-4Rα and IL-5 in a 2+2 Format



BBT002 is designed to combine the benefits of two clinically and commercially validated targets and overcome some of the challenges of prior biologics:

- The core structural framework is a fully human IgG1 antibody that specifically targets IL-5, labeled above as anti-IL-5 Fab. The IL-5 pathway is commercially validated through the success of Nucala, which targets IL-5.
- Two humanized single-domain heavy-chain variable fragments ("VHHs") are fused to the IgG1 antibody and are designed to target IL-4Rα, labeled above as anti-IL-4Rα VHH. The IL-4Rα pathway is commercially validated through the approval and commercial success of Dupixent.
- The Fc region of the IgG1 antibody has been modulated in two ways:
  - Depleting FcγR binding to reduce ADCC and CDC effects;
  - Enhancing FcRn binding through LA (M428L/N434A) substitutions which are designed to reduce lysosomal degradation, increase antibody recycling, and prolong serum exposure.

Our goal is to develop BBT002 to be a first line biologic for inadequately controlled COPD and other Type 2 inflammatory respiratory diseases. BBT002 is designed to:

- ***Address Core Type 2 Inflammation and EOS Differentiation and Inflammation***: By simultaneously blocking IL-4Rα (inhibiting IL-4 and IL-13 signaling, which affect IgE, mucus production, and airway remodeling) and IL-5 (inhibiting EOS-mediated inflammation), BBT002 is designed to control the full spectrum of Type 2 inflammation and both improve lung function and reduce risk of exacerbations. Both targets are orthogonal and commercially validated.
- ***Achieve Faster Onset and Break the Therapeutic Ceiling***: We believe dual targeting of both the Type 2 and EOS inflammatory pathways has the potential to provide faster onset and deeper response compared to single-target approaches due to the complementarity of the targets.
- ***Enable Extended Dosing Intervals***: Fc modifications using LA (M428L/N434A) substitutions increase FcRn affinity and extend drug half-life. BBT002 has demonstrated a half-life of approximately 29 days in humans, supporting the potential for quarterly maintenance dosing.
- ***Provide High-Concentration SubQ Delivery***: We have developed a high-concentration SubQ formulation to enable commercial presentation in a low-volume injection for convenient at-home administration.

Scientific Rationale

We believe that dual targeting IL-4Rα and IL-5 represents the most compelling and complementary strategy to maximize therapeutic potential.

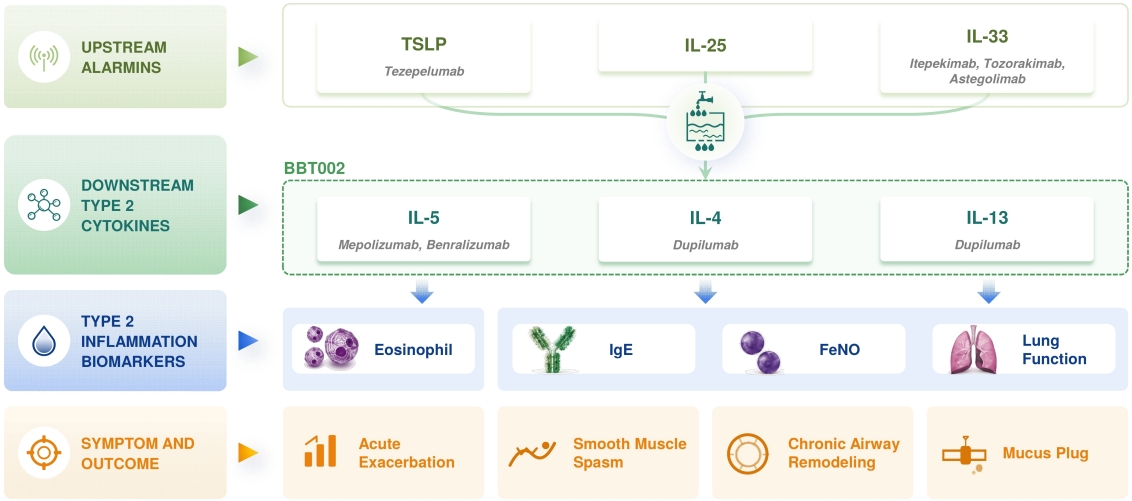
The rationale for simultaneously targeting IL-4Rα and IL-5 is based on the complementary and non-redundant roles of these pathways in Type 2 inflammatory disease:

- IL-4Rα modulates the IL-4/IL-13 axis, which drives multiple disease features including IgE class switching, mucus secretion, airway hyperresponsiveness and remodeling, and amplification of the Type 2 inflammatory response. Dupixent's approval in asthma, CRSwNP, EoE, and COPD has validated this pathway across multiple respiratory and allergic conditions.
- The IL-5 axis drives EOS differentiation in bone marrow, trafficking to tissue, and survival, leading to EOS-mediated inflammation that underlies acute exacerbations and tissue damage. IL-5 pathway biologics (Nucala, Fasenra) have demonstrated efficacy in reducing exacerbations in severe eosinophilic asthma and Nucala has also provided clinical validation for this pathway in COPD.

- Upstream alarmins such as TSLP, IL-25, and IL-33 are biologically overlapping and redundant – blocking one pathway may leave others active. In contrast, the IL-4/IL-13 and IL-5 pathways sit at a critical convergence point of Type 2 inflammation, with complementary and non-redundant biology.

In our view, neither axis alone is sufficient to control the full spectrum of Type 2 inflammation. Blocking IL-4 and IL-13 increases the forced expiratory volume in one second ("FEV_1"), reduces the fractional exhaled nitric oxide ("FeNO") and IgE but can paradoxically increase EOS, while blocking IL-5 alone depletes EOS, but has limited impact on FEV_1, FeNO, and IgE. Patients receiving anti-IL-5 therapies can continue to have elevated IgE and mucus-related symptoms. By combining both mechanisms, BBT002 is designed to achieve synergistic and more complete control of Type 2 inflammation.

Figure 33: BBT002 Targeting the Three Key Downstream Type 2 Cytokines



BBT002 for the Treatment of Chronic Obstructive Pulmonary Disease ("COPD")

Overview

We believe BBT002 has the potential to address a number of Type 2 inflammatory disorders across respiratory and allergic diseases. We are currently evaluating BBT002 for the treatment of COPD in the Global BBT002 Study and the China COPD Study. We recently reported positive preliminary results from our SAD and MAD healthy volunteer portions of our Global BBT002 Study and expect to report topline PoC results of patients with COPD treated with four weeks of an IV formulation of BBT002 ("4-week PoC COPD data") in the first half of 2027.

Disease Background and Market Opportunity

COPD is a progressive, chronic respiratory disease characterized by persistent airflow limitation and worsening respiratory symptoms, including shortness of breath (dyspnea), chronic cough, excess mucus production, wheezing, chest tightness, fatigue, reduced exercise tolerance, and recurrent respiratory infections. As the disease advances, many patients experience difficulty performing routine daily activities such as walking, climbing stairs, dressing, or sleeping, and recurrent exacerbations can lead to hospitalization, accelerated lung-function decline, and increased mortality. COPD is most commonly associated with cigarette smoking and environmental exposures, but disease biology is heterogeneous, with meaningful contributions from airway inflammation, mucus hypersecretion, small-airway remodeling, emphysema, impaired host defense, and recurrent injury-repair cycles. COPD affects approximately 400 million people globally and remains one of the leading causes of death worldwide.

Mechanistically, COPD has historically been viewed as a neutrophilic, macrophage-driven inflammatory disease, but a clinically important subset of patients has Type 2 inflammation, often identified by elevated blood

EOS. In these patients, IL-4/IL-13 signaling may contribute to mucus production, airway remodeling, and impaired epithelial barrier function, while IL-5 supports EOS survival, trafficking, and activation. This has created a biologic opportunity in eosinophilic or Type 2-high COPD, where targeted therapies may reduce exacerbations and improve lung function on top of inhaled maintenance therapy. The Global Initiative for Chronic Obstructive Lung Disease ("GOLD") has increasingly recognized blood EOS as a useful biomarker for Type 2 inflammation and treatment selection in COPD.

Commercially, COPD is a large, established respiratory market dominated by inhaled bronchodilators and inhaled corticosteroid combinations, but biologics are opening a new premium segment for patients with persistent exacerbations despite standard therapy. The overall COPD market is estimated at approximately $30 billion in 2025, with forecasts approaching $39 billion by 2030, while the COPD biologics segment remains early but is expected to grow meaningfully, particularly following the approval of Dupixent as an add-on maintenance treatment for select COPD patients with elevated Type 2 inflammation. Approximately 300,000 patients in the United States were deemed eligible for Dupixent's COPD indication at approval, highlighting a sizable initial biologic-addressable population despite broader global COPD prevalence. We estimate that by 2030, the COPD biologics market will approach $23 billion.

Current COPD Treatment Options and Limitations

Current treatment of COPD is centered on reducing symptoms, improving lung function, preventing exacerbations, and preserving quality of life. Foundational therapy typically begins with inhaled bronchodilators, including long-acting muscarinic antagonists ("LAMAs") and long-acting beta agonists ("LABAs"), used alone or in combination. Dual bronchodilator therapy ("LAMA/LABA") is a common maintenance standard for symptomatic patients, while escalation to triple therapy with inhaled corticosteroids ("ICS") plus LAMA/LABA is frequently used by patients with recurrent exacerbations, particularly those with elevated EOS levels or features of Type 2 inflammation. Common branded examples include Trelegy Ellipta, Breztri Aerosphere, and other inhaled maintenance combinations.

For patients with more advanced or exacerbation-prone disease, additional therapies may include phosphodiesterase-4 inhibitors such as Daliresp, chronic macrolide antibiotics in selected patients, pulmonary rehabilitation, supplemental oxygen for hypoxemic patients, and noninvasive ventilation in advanced disease. Smoking cessation remains the single most important intervention to slow disease progression, while vaccination and management of comorbidities are also core components of care. Despite these options, many patients continue to experience persistent symptoms, progressive lung-function decline, and recurrent exacerbations.

A newer treatment segment is emerging with biologic therapies for patients with Type 2 inflammatory COPD, particularly those with elevated EOS levels and continued exacerbations despite optimized inhaled therapy. Dupixent became the first broadly recognized biologic entrant in this segment, validating IL-4/IL-13 pathway targeting in select COPD patients. However, Dupixent can increase EOS levels which limits its use by patients with higher EOS counts.

IL-5 pathway biologics such as Nucala (anti-IL-5) have been clinically validated in COPD, with the strongest signals generally seen in patients with higher EOS counts and frequent exacerbations despite optimized inhaled triple therapy. Despite the broader biological complexity of COPD, smoking-related structural lung damage, and mixed inflammatory drivers beyond EOS alone, these programs have helped validate EOS as an actionable biomarker and established IL-5 as a relevant pathway in COPD.

Current treatment options for COPD have improved symptom management and reduced exacerbations for many patients, but substantial limitations remain:

- ***Progressive Disease Biology Despite Maintenance Therapy****:* Existing therapies can manage symptoms and reduce flare frequency, but they do not fully reverse structural lung damage such as emphysema, small-airway remodeling, or chronic mucus hypersecretion. Many patients continue to experience increased dyspnea, cough, mucus production, exercise intolerance, and impaired quality of life despite optimized inhaled bronchodilator or triple therapy. As a result, many patients continue to decline over time.

- ***Ongoing Exacerbations****:* A significant proportion of patients continue to experience moderate or severe exacerbations requiring steroids, antibiotics, emergency visits, or hospitalization. Exacerbations are clinically important because they accelerate lung-function decline, worsen mortality risk, and increase healthcare costs.
- ***Inhaler Complexity and Adherence Challenges***: COPD treatment often requires multiple inhalers, correct inhalation technique, and daily adherence. Real-world misuse of inhalers is common and may reduce treatment effectiveness, particularly in older patients with cognitive or physical limitations.
- ***Safety Limitations of Chronic Corticosteroid Exposure***: ICSs can reduce exacerbations in selected patients, especially those with elevated EOS levels, but chronic use may increase pneumonia risk and other steroid-related adverse effects in some populations.
- ***Limited Options for Biologically Defined Subgroups***. Only recently have biologics been developed and approved for COPD, primarily for patients with Type 2 eosinophilic inflammation. Many patients outside this phenotype still lack effective targeted therapies, and even within COPD, response can be variable.
- ***Heterogeneous Disease with One-Size-Fits-Many Treatment Algorithms***. COPD includes multiple overlapping biological endotypes (neutrophilic, eosinophilic, mixed inflammatory, emphysematous, chronic bronchitis). Current treatment algorithms often rely on symptoms and exacerbation history rather than precision biology, leading to suboptimal matching of therapy to patient subtype.
- ***Burden of Comorbidities***. COPD patients frequently have cardiovascular disease, metabolic disease, anxiety/depression, and other comorbidities that complicate treatment and worsen outcomes.

Overview of BBT002 Clinical Development Program in COPD

Our BBT002 clinical development program is designed to evaluate clinical activity, safety, PK, PD, and immunogenicity, inform dose selection, and support the intended commercial product profile. We completed dosing and safety follow ups of IV formulations of BBT002 in healthy volunteers in our Global BBT002 Study and China COPD Study, and are also conducting SubQ bridging work designed to support a patient-convenient SubQ presentation. We recently reported positive preliminary results from our SAD and MAD healthy volunteer portions of our Global BBT002 Study. Building on these data, we are evaluating BBT002 across multiple PoC substudies of the Global BBT002 Study and China COPD Study in patients with COPD in the United States, Australia, China, Europe, Georgia, and New Zealand to assess clinical activity and inform future Phase 2b and pivotal trial development.

Healthy Volunteer Data:

Both our Global BBT002 Study and China COPD Study use master protocols that comprise both healthy volunteer and patient, or PoC, cohorts. The healthy volunteer portions of these studies are comprised of:

1) Phase 1 SAD and MAD cohorts of the IV formulation of BBT002 and a Phase 1 SubQ bridging cohort as part of the Global BBT002 Study; and
2) Phase 1 SAD cohort of the IV formulation of BBT002 as part of the China COPD Study.

We reported preliminary results from the SAD and MAD healthy volunteer portions of our Global BBT002 Study at the American Thoracic Society (“ATS”) 2026 International Conference and the European Academy of Allergy & Clinical Immunology (“EAACI”) Annual Congress 2026, respectively. We have also completed dosing and safety follow ups from the SAD healthy volunteer portion of our China COPD Study.

Healthy Volunteers Portions of Global BBT002 Study in Australia

The healthy volunteer portions of our randomized, blinded, placebo-controlled Phase 1 Global BBT002 Study are being conducted primarily in Caucasian populations at a single site in Australia.

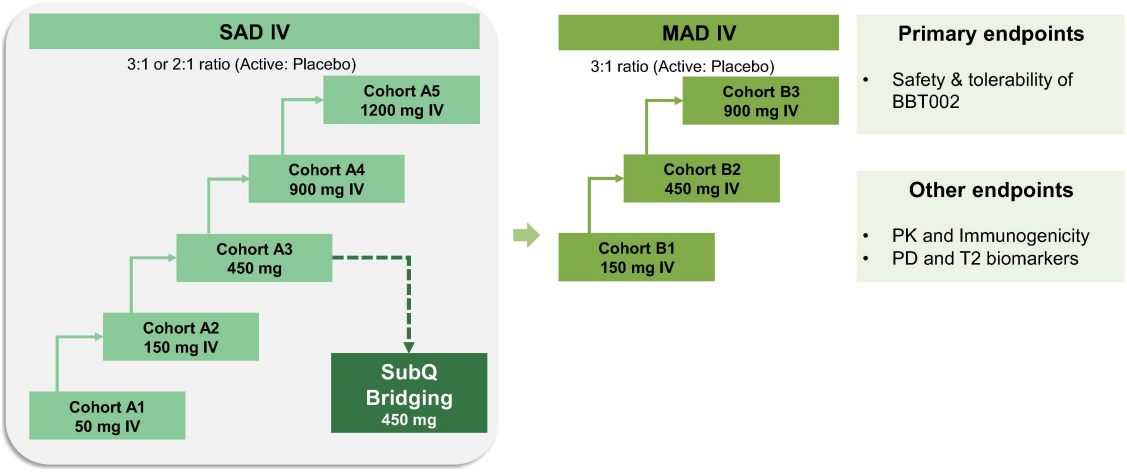
The primary endpoints are safety and tolerability of BBT002, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT002, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including IL-4Rα receptor occupancy and pSTAT6, and CFB of Type 2 biomarkers, such as TARC.

For the SAD portion, 41 healthy volunteers were assigned to receive a single dose of BBT002 by IV administration in five sequential ascending dose cohorts (50, 150, 450, 900, or 1200 mg). The six participants in cohort A1 were randomized in a 2:1 ratio (active:placebo) with the remaining cohorts A2 to A5 randomized in a 3:1 ratio. Participants were dosed on Day 1 and returned for several follow-ups through Day 141.

For the MAD portion, 26 healthy volunteers were assigned to receive three repeat doses of BBT002 by IV administration once every two weeks in three sequential ascending dose cohorts (150, 450, or 900 mg). The eight participants for each cohort were randomized in a 3:1 ratio (active:placebo). Participants were dosed on Day 1, 15, and 29 and returned for several follow-ups through Day 169.

For the SubQ bridging portion, up to 32 healthy volunteers are being assigned to receive a single dose of 450 mg of BBT002 by SubQ administration. Participants in each cohort are randomized in a 3:1 ratio (active:placebo). Participants are dosed on Day 1 and return for several follow-ups through Day 141.

Figure 34: Study Design of Healthy Volunteer Portions of Global BBT002 Study



In May and June 2026, we presented preliminary results from the SAD and MAD healthy volunteer portions of our Global BBT002 Study in oral presentations at the ATS 2026 International Conference and the EAACI Congress 2026, respectively.

Key preliminary results demonstrate that BBT002 met all primary endpoints as of the January 19, 2026 data cutoff date. The preliminary results for the SAD and MAD healthy volunteers portions of our Global BBT002 Study are summarized below:

- ***Safety***: BBT002 was observed to be well tolerated across all dose levels evaluated for both the SAD and MAD healthy volunteer portions of the Global BBT002 Study. TEAEs were reported in 80% of BBT002-treated subjects compared to 82% of placebo subjects in SAD, and in 70% compared to 83%, respectively,

in MAD. No Grade 3 TRAEs were reported in SAD, and no Grade 3 TEAEs or TRAEs were reported in MAD.

Figure 35: BBT002 is Well Tolerated in Healthy Volunteers

SAD

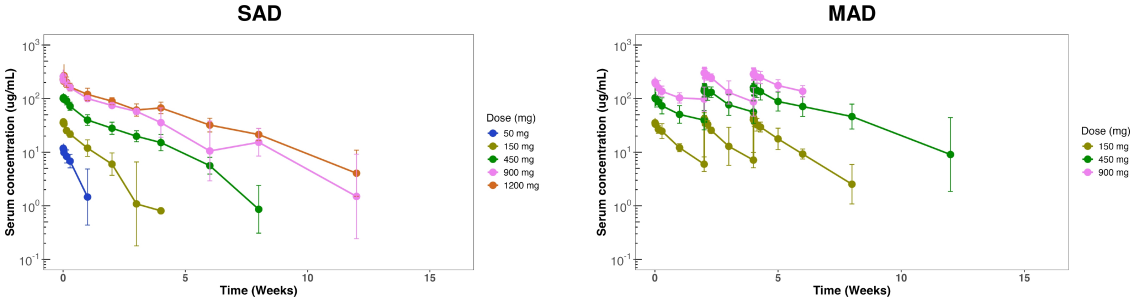
N (%)	Placebo (N =11)	Overall BBT002 (N=30)
≥ 1 TEAE	9 (81.8%)	24 (80.0%)
≥ 1 Grade 3 TEAE	0 (0.0%)	0 (0.0%)
≥ 1 TRAE	2 (18.2%)	8 (26.7%)
≥ 1 Grade 3 TRAE	0 (0.0%)	0 (0.0%)

MAD

N (%)	Placebo (N =6)	Overall BBT002 (N=20)
≥ 1 TEAE	5 (83.3%)	14 (70.0%)
≥ 1 Grade 3 TEAE	0 (0.0%)	0 (0.0%)
≥ 1 TRAE	0 (0.0%)	5 (25.0%)
≥ 1 Grade 3 TRAE	0 (0.0%)	0 (0.0%)

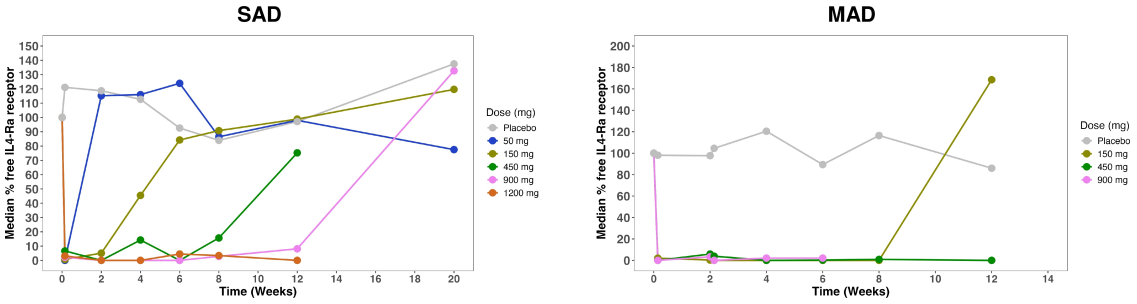
- ***Pharmacokinetics***: BBT002 demonstrated non-linear PK. The estimated half-life was approximately 29 days using population PK modeling for both SAD and MAD portions.

Figure 36: BBT002 PK at Multiple Doses



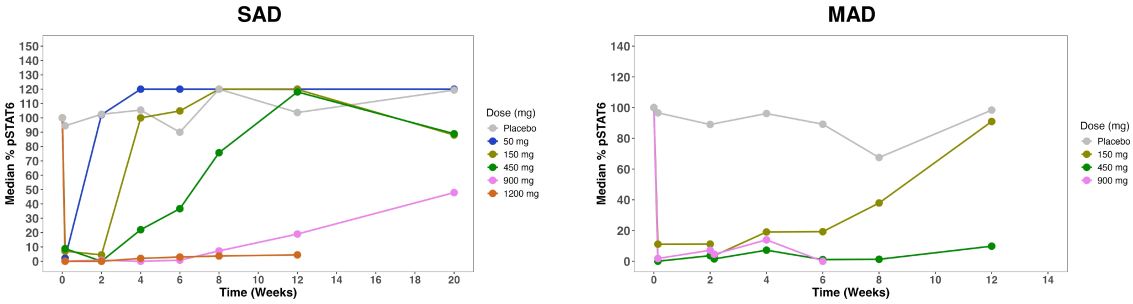
- ***Pharmacodynamics***: BBT002 demonstrated dose-dependent, rapid, complete, and sustained PD effects of at least eight weeks after a single dose and multiple doses:
  - ***IL-4Rα Binding:*** Near-complete receptor occupancy was achieved rapidly and sustained for at least eight weeks after a single dose of 450 mg or higher and multiple doses of 150, 450, and 900 mg.

Figure 37: BBT002 IL-4Rα Binding at Multiple Doses



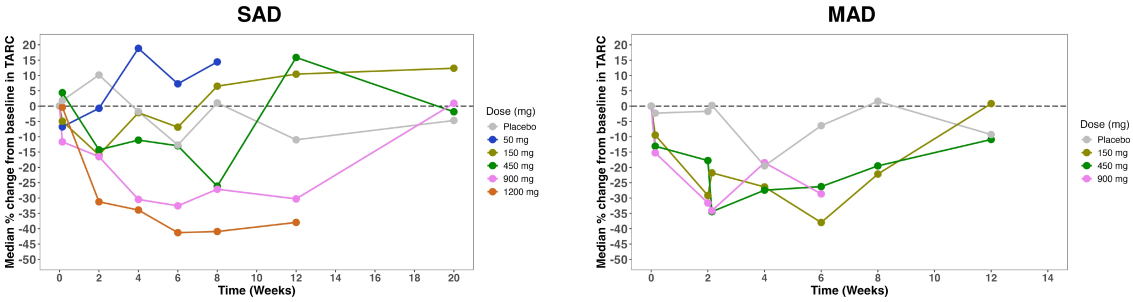
- ***pSTAT6 Inhibition:*** Rapid, dose-dependent inhibition of IL-4-stimulated pSTAT6 was observed, sustained for at least eight weeks after a single dose of 900 and 1200 mg and multiple doses of 150, 450, and 900 mg.

Figure 38: BBT002 pSTAT6 Inhibition at Multiple Doses



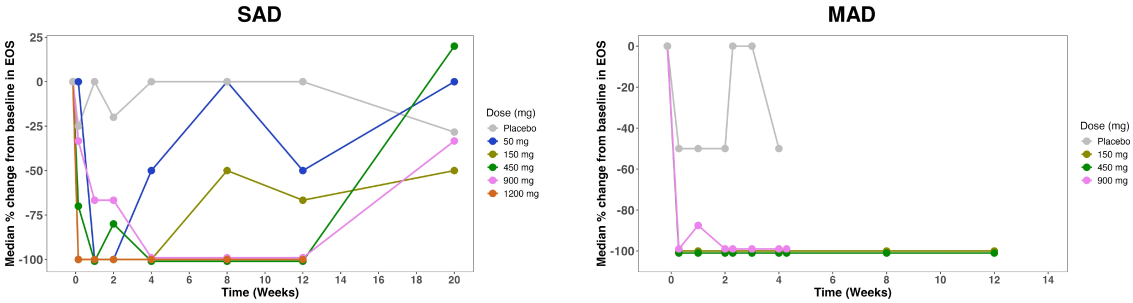
- ***TARC Reduction:*** Potent TARC suppression was demonstrated to be sustained at least eight weeks after a single dose of 900 and 1200 mg and multiple doses of 150, 450, and 900 mg.

Figure 39: BBT002 TARC Reduction at Multiple Doses



- ***EOS Reduction:*** EOS depletion was also observed for more than eight weeks after a single dose of 900 and 1200 mg and multiple doses of 150, 450, and 900 mg, validating the synergistic PD effects of dual targeting.

Figure 40: BBT002 EOS Reduction at Multiple Doses



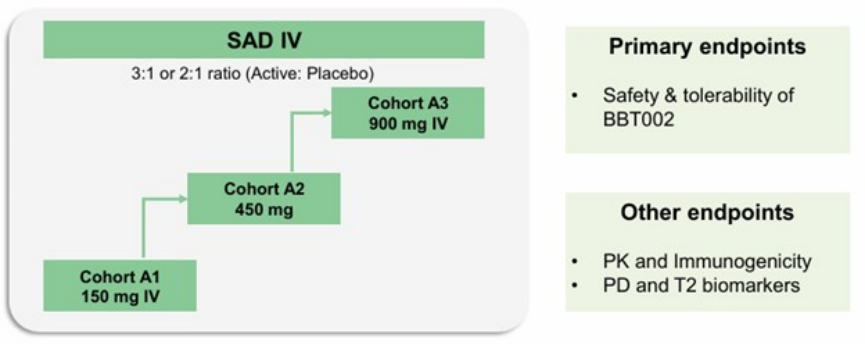
- ***Immunogenicity***: BBT002 showed very low immunogenicity, with treatment-emergent ADA observed in approximately 20.4% of subjects in the SAD portion and 12.3% of subjects in the MAD portion. ADA responses were low titer, with no apparent impact on PK or safety and no sign of neutralizing ADA.

Healthy Volunteers Portion of China COPD Study

We are currently conducting a parallel double-blind, placebo-controlled first-in-human Phase 1 substudy in an Asian population in China as part of our China COPD Study to evaluate BBT002 in 21 healthy volunteers who were assigned to receive a single dose of BBT002 by IV administration in three sequential ascending dose cohorts (150, 450, and 900 mg). The three participants in cohort A1 were randomized in a 2:1 ratio (active:placebo) with the remaining cohorts A2 and A3 randomized in a 3:1 ratio. Participants are dosed on Day 1 and return for several follow-ups through Day 141 to evaluate safety and tolerability of BBT002.

Consistent with the SAD and MAD portions of our Global BBT002 Study in Australia, the primary endpoints are safety and tolerability of BBT002, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT002, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including IL-4Rα receptor occupancy and pSTAT6, and CFB of Type 2 biomarkers, such as TARC.

Figure 41: Study Design of Healthy Volunteer Portion of China COPD Study



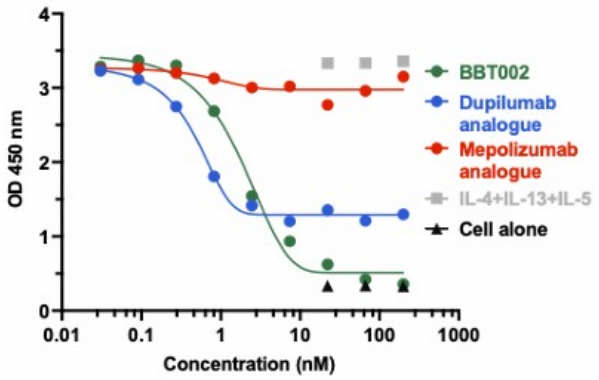
Preliminary results from our SAD healthy volunteer cohorts of our China COPD Study as of December 10, 2025 demonstrated an extended half-life and potent and sustained inhibition of key biomarkers, and as of January 19, 2026, low immunogenicity, consistent with the preliminary data from the Australia SAD and MAD cohorts of our Phase 1 Global BBT002 Study.

Our Preclinical Data

BBT002 has demonstrated compelling preclinical data:

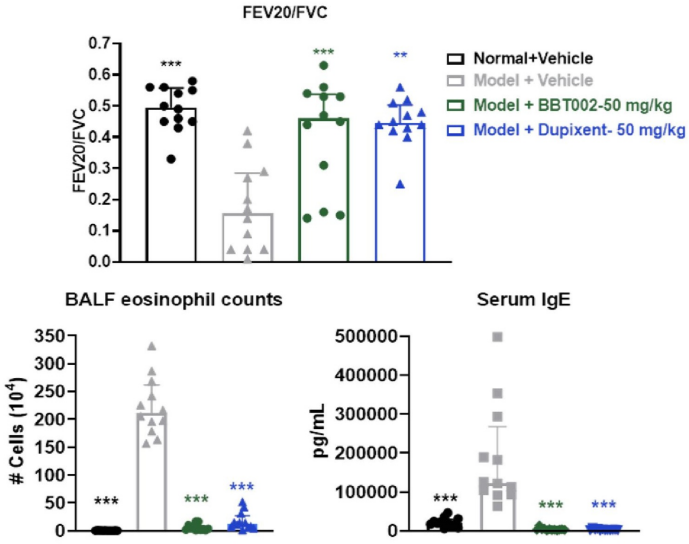
- Superior in vitro activity in a IL-4/IL-13/IL-5-induced TF-1 cell proliferation experiment comparing BBT002 to analogues of dupilumab and mepolizumab:

Figure 42: IL-4/IL-13/IL-5-induced TF-1 Cell Proliferation



- Improved lung function, measured by the ratio of forced expiratory volume in 20 milliseconds ("FEV20") to forced vital capacity ("FVC"), and anti-inflammatory effect, measured by bronchoalveolar lavage fluid ("BALF"), EOS counts, and serum IgE, compared to dupilumab in PPE-induced COPD KI mouse model with human IL-4/IL-4R:

Figure 43: Improved Lung Function and Anti-Inflammatory Effect in COPD Model



*p<0.05, **p<0.01, ***p<0.001, p****<0.0001 VS Model + PBS/Vehicle (One-way ANOVA)

Ongoing Clinical Development in COPD

We are continuing to evaluate BBT002 in patients with COPD in our Global BBT002 Study and our China COPD Study including:

- a Phase 1 substudy of patients with COPD in the United States, Australia, Europe, Georgia, and New Zealand who shall receive two doses of BBT002 over four weeks (as part of our Global BBT002 Study); and
- a Phase 2a substudy of patients with COPD in China who shall receive two doses of BBT002 over four weeks (as part of our China COPD Study).

Global 4-week Phase 1 Substudy in Patients with COPD

We are conducting a global randomized, double-blind, placebo-controlled Phase 1 PoC substudy within our Global BBT002 Study in patients with COPD in United States, Australia, Europe, Georgia, and New Zealand. We are currently enrolling 12 to 18 adult participants with COPD. At screening, all patients must be on a stable background therapy, which is defined as any monotherapy or combination of a LABA, a LAMA, or ICS for at least three months prior to randomization with the dose being stabilized for at least one month prior to screening and such participants shall continue their established dose and regimen of background therapy for COPD.

Each patient is assigned to receive two repeat doses of BBT002 by IV administration at 450 mg. Patients are being randomized in a 2:1 ratio (active:placebo). Patients are dosed on Day 1 and 29 and return for several follow-ups through Day 169 to evaluate safety and tolerability of BBT002.

Consistent with the SAD and MAD portions of our Phase 1 Global BBT002 Study, the primary endpoints are safety and tolerability of BBT002, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT002, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB of blood EOS, and clinical activity, including spirometry measures and FeNO.

Figure 44: 4-week PoC Study in COPD Patients



4-week Phase 2a Substudy in Patients with COPD in China

We are currently conducting a parallel Phase 2a PoC substudy in an Asian population in China within our China COPD Study, evaluating BBT002 in patients with COPD. We have dosed the first COPD patient.

BBT002 for the Treatment of Chronic Rhinosinusitis with Nasal Polyps ("CRSwNP")

Overview

BBT002 is designed as a pipeline-in-a-molecule for Type 2 inflammatory disorders. We are currently conducting a Phase 2a PoC study of BBT002 in patients with CRSwNP in China. We expect to report 12-week PoC results in patients with CRSwNP in the first half of 2027.

Disease Background and Market Opportunity

CRSwNP is a chronic inflammatory disease of the nasal passages and paranasal sinuses characterized by persistent mucosal inflammation and benign polyp growth that obstructs the nasal airway. Patients commonly experience nasal congestion or blockage, reduced or complete loss of smell (anosmia), facial pressure, sinus pain, chronic nasal drainage, postnasal drip, mouth breathing, snoring, sleep disruption, headaches, and fatigue. Symptoms are often persistent and can meaningfully impair quality of life, affecting sleep, productivity, concentration, and social functioning. CRSwNP is also associated with frequent recurrence following surgery and commonly coexists with asthma, allergic rhinitis, aspirin-exacerbated respiratory disease ("AERD"), and other Type 2 inflammatory conditions.

Mechanistically, CRSwNP is most often driven by Type 2 inflammation, particularly in Western populations. Key cytokine pathways include IL-4, IL-13, and IL-5. IL-4 and IL-13 contribute to epithelial barrier dysfunction, mucus production, goblet cell hyperplasia, tissue edema, and amplification of inflammatory signaling, while IL-5 is central to EOS maturation, recruitment, survival, and activation. EOS-mediated inflammation is a hallmark of many CRSwNP patients and is associated with more severe disease, recurrence risk, and comorbid asthma. Additional contributors may include local IgE production, mast cell activation, Staphylococcus aureus superantigen responses, and remodeling pathways that promote persistent polyp formation. This biology has validated CRSwNP as an important disease area for biologics targeting Type 2 pathways.

CRSwNP represents a meaningful and growing commercial opportunity within I&I. Chronic rhinosinusitis affects approximately 5% to 12% of adults globally, with nasal polyps present in an estimated 1% to 4% of the general population, translating to millions of patients across major markets. A substantial subset has inadequately controlled disease despite intranasal corticosteroids, repeated oral steroid use, or surgery. The emergence of biologics such as Dupixent, Nucala, and Xolair has created a rapidly expanding advanced-therapy segment, with future growth expected to be driven by increased diagnosis, broader biologic adoption, earlier use before repeat surgery, and next-generation therapies offering improved efficacy, durability, and dosing convenience. We estimate that the CRSwNP biologics market will approach $7 billion by 2030.

Current CRSwNP Treatment Options and Limitations

Current treatment of CRSwNP typically follows a stepwise approach aimed at reducing inflammation, shrinking polyp burden, restoring nasal airflow, improving smell, and preventing recurrence. First-line therapy generally includes saline irrigation and intranasal corticosteroid sprays or irrigations, which can improve congestion and local inflammation but may be insufficient in patients with moderate-to-severe disease. For symptomatic flares or more severe disease, short courses of systemic corticosteroids are commonly used and can provide rapid relief, although repeated use is limited by well-known steroid toxicities. When medical therapy is inadequate, endoscopic sinus surgery is frequently performed to remove polyps, open sinus passages, and improve delivery of topical treatments. However, recurrence after surgery is common, particularly in patients with eosinophilic disease, asthma, or AERD.

Important clinical assessments in CRSwNP clinical trials focus on symptom improvement, objective polyp reduction, and quality of life. Core endpoints commonly include the Nasal Polyp Score (NPS), which grades bilateral polyp size by endoscopy, and Nasal Congestion Score (“NCS”), a patient-reported symptom measure. Restoration of smell is highly important and may be assessed using University of Pennsylvania Smell Identification Test (“UPSIT”) or similar olfactory measures. Additional endpoints often include Lund-Mackay CT score, Sino-Nasal Outcome Test (“SNOT-22”), need for rescue systemic corticosteroids, need for repeat surgery, time to recurrence, asthma control in comorbid patients, and biomarker measures such as blood EOS or IgE. Clinically meaningful outcomes include improved breathing through the nose, regained smell, fewer infections/flares, reduced steroid exposure, avoidance of repeat surgery, and durable symptom control.

The modern treatment landscape has expanded with biologic therapies for patients with persistent or recurrent disease despite standard therapy.

Dupixent is an IL-4Rα inhibitor that blocks IL-4 and IL-13 signaling and is widely viewed as a leading biologic therapy for CRSwNP. By targeting central Type 2 inflammatory pathways, it has demonstrated meaningful reductions in nasal polyp burden, improvements in nasal congestion, restoration of smell, and decreased need for systemic corticosteroids or repeat sinus surgery. In CRSwNP, dosing is typically every two weeks following an initial loading regimen. While highly effective for many patients, some remain partial responders or require long-term continuous therapy, and the every-two-week injection schedule may present convenience limitations in a chronic disease setting.

Nucala is an anti-IL-5 monoclonal antibody that reduces EOS-mediated inflammation by inhibiting a key cytokine involved in EOS maturation and survival. In CRSwNP, it has shown benefit in reducing polyp size, improving symptoms, and lowering the need for surgery in patients with eosinophilic disease, particularly those with comorbid asthma. Nucala is generally administered once every four weeks as a SubQ injection. Because IL-5

primarily targets EOS biology rather than the broader Type 2 inflammatory cascade, clinical responses may be more selective depending on patient phenotype.

Xolair is an anti-IgE monoclonal antibody that reduces allergic and mast cell–mediated inflammatory signaling by binding circulating IgE. In CRSwNP, it has demonstrated improvements in nasal congestion, polyp burden, and quality of life, particularly in patients with allergic disease or elevated IgE biology. Dosing is administered by SubQ delivery every two or four weeks based on body weight and baseline IgE levels. While Xolair offers an important differentiated mechanism, individualized dosing complexity and variable response across heterogeneous CRSwNP populations may limit use in some patients.

Current treatment options for CRSwNP have improved disease management, but several important limitations remain:

- ***High Recurrence Rates and Chronic Disease Burden****:* CRSwNP is a relapsing disease, and many patients experience recurrent symptoms or regrowth of polyps despite medical therapy or prior surgery. Long-term disease control often requires repeated intervention.
- ***Persistent Symptoms Despite Treatment****:* Many patients continue to suffer from nasal congestion, impaired or lost sense of smell, facial pressure, drainage, poor sleep, fatigue, and reduced quality of life even while receiving standard therapies.
- ***Limitations of Intranasal Therapy****:* Intranasal corticosteroid sprays and irrigations are foundational treatments, but drug delivery can be inconsistent, particularly when large polyps obstruct nasal passages. As a result, efficacy may be limited in moderate-to-severe disease.
- ***Systemic Corticosteroid Burden****:* Oral corticosteroids can provide rapid symptomatic relief, but repeated use is associated with significant adverse effects, including weight gain, glucose intolerance, hypertension, osteoporosis, mood changes, and infection risk.
- ***Surgery is Not Curative****:* Endoscopic sinus surgery can improve airflow and remove polyp tissue, but recurrence after surgery is common, especially in patients with eosinophilic disease, asthma, or AERD. Some patients require multiple surgeries over time.
- ***Incomplete Response to Biologics****:* Biologics such as Dupixent, Nucala, and Xolair have validated Type 2 pathway targeting in CRSwNP, but not all patients achieve deep or complete responses. Some remain partial responders with persistent congestion, smell dysfunction, or residual polyp burden.
- ***Frequent Dosing and Treatment Convenience****:* Current biologics generally require dosing every two to four weeks, which may create treatment burden and impact adherence in a chronic maintenance setting.
- ***Heterogeneous Disease Biology****:* CRSwNP can involve multiple overlapping inflammatory drivers, including IL-4/IL-13, IL-5/EOS, IgE, epithelial dysfunction, and remodeling pathways. Single-pathway therapies may not fully address disease complexity across all patients.
- ***Comorbid Disease Complexity****:* Many patients also have asthma, allergic rhinitis, or AERD, creating broader systemic disease burden and making integrated disease control more challenging.

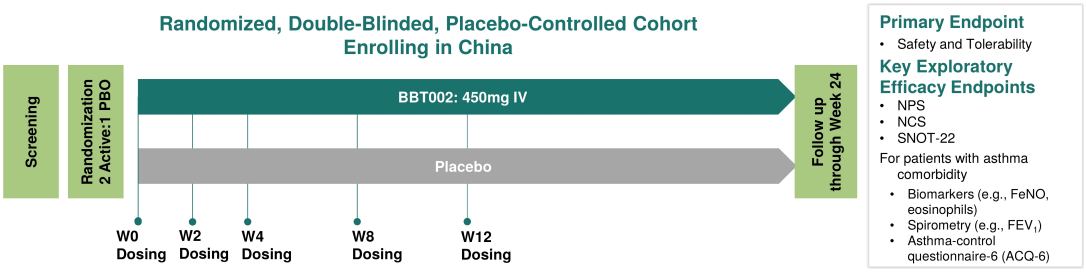
Phase 2a Study in CRSwNP

We are currently conducting one Phase 2a study of BBT002 in adult patients with CRSwNP in China. This Phase 2a study is a randomized, double-blind, placebo-controlled study to evaluate the safety and tolerability, PK, immunogenicity, PD, and clinical activity of 450 mg of BBT002 following five doses of IV administration. Participants are being randomized in a 2:1 ratio. Participants are dosed on Day 1, 15, 29, 57, and 85 and return for several follow-ups through Day 169.

The primary endpoints are safety and tolerability of BBT002, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT002, as measured by the number

and percentage of participants who developed ADA. The exploratory endpoints are PD, including CFB of periostin, and clinical activity, including endoscopic NPS, NCS severity score, and SNOT-22, and for patients with asthma comorbidity, certain biomarkers and spirometry measures.

Figure 45: 12-week PoC Study in CRSwNP Patients



BBT002 for the Treatment of Asthma

Overview

BBT002 is designed as a pipeline-in-a-molecule for Type 2 inflammatory disorders. We have initiated our global Phase 2a Asthma Study.

Disease Background and Market Opportunity

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation that can lead to variable expiratory airflow. Common symptoms include wheezing, shortness of breath, chest tightness, and cough. Airflow and symptoms can vary over time and in intensity, and can be affected by exercise, allergen or irritant exposure, changes in weather or respiratory infections, and may sometimes resolve spontaneously or with medication. In other cases, airflow limitation may become persistent or patients can experience episodic exacerbation attacks that could be life-threatening. Airway inflammation constitutes the core pathological mechanism of action for asthma, particularly for severe asthma, and uncontrolled inflammation can lead to adverse outcomes including airway remodeling. Airway inflammation is often characterized by the presence of cytokines such as IL-4, IL-5, and IL-13, which are well known hallmarks of Type 2 inflammation.

Asthma affects approximately 300 million individuals globally with prevalence estimates ranging from 1% to 29% of the population of different countries. The prevalence of asthma is increasing globally. Asthma is usually diagnosed through physical examination and lung function testing although access to spirometry may vary from community to community. If lung function testing is not available, elevated FeNo and/or blood EOS can support a diagnosis of Type 2 asthma.

Although the global asthma biologics market is well established with leading products, including Xolair, Dupixent, Nucala, Fasenra, and Tezspire, being multi-billion-dollar franchises, significant unmet medical need remains. Current biologics are primarily used in severe or inadequately controlled patients, leaving overall penetration low relative to the large prevalence of respiratory disease. In asthma, many patients continue to experience exacerbations, impaired lung function, or persistent symptoms despite treatment. We estimate that the next wave of innovation will expand the global asthma biologics market to $30 billion in 2030.

Current Asthma Treatment Options and Limitations

Current treatments fall into two categories: reliever medications for rapid symptom relief during acute episodes, such as short-acting beta-agonists (“SABA”), and controller medications for long-term clinical control of asthma through reduction of inflammation. Oral corticosteroids (“OCS”) can provide rapid symptomatic relief, but repeated use is associated with significant adverse effects, including obesity, diabetes, osteoporosis and fragility fractures, cataracts, hypertension and adrenal suppression; psychological side-effects such as depression and anxiety. Even short-term use of OCS is associated with sleep disturbance, and increased risk of infection, fracture and

thromboembolism. These days, ICS is the most common route of administration for controlling airway inflammation, reducing airway hyperresponsiveness, alleviating symptoms, improving lung function, and decreasing both the frequency and severity of asthma exacerbations. Sometimes patients are treated with a combination of ICS together with LABAs, although incorrect inhaler technique, poor adherence, over-use of SABAs, comorbidities, persistent environmental exposures or psychosocial factors can result in persistent symptoms and exacerbations due to inadequate control of asthma. Despite receiving optimal standard-of-care treatment, up to 10% of patients end up with severe asthma that cannot be managed by ICS and LABA.

Biologics have transformed the treatment of severe asthma by shifting care from broad symptom management toward targeted, pathway-based therapy. The advent of biologics have enabled deep symptom control and significant reduction of exacerbations in difficult-to-treat severe asthma through precise targeting of specific inflammatory pathways, while effectively minimizing systemic side effects associated with long-term corticosteroids exposure and improving patient's quality of life and treatment adherence. Currently, the most widely used targeted biologics in clinical practice include anti-IL-5/anti-IL-5R (such as Nucala, Fasenra, Cinqair and Exdensur), anti-IL-4Rα (such as Dupixent), anti-IgE (such as Xolair) and anti-TSLP (such as Tezspire) monoclonal antibodies, each exhibiting distinct effects on EOS, FeNO, IgE, exacerbation risk, lung function, and other manifestations of Type 2 and eosinophilic inflammation.

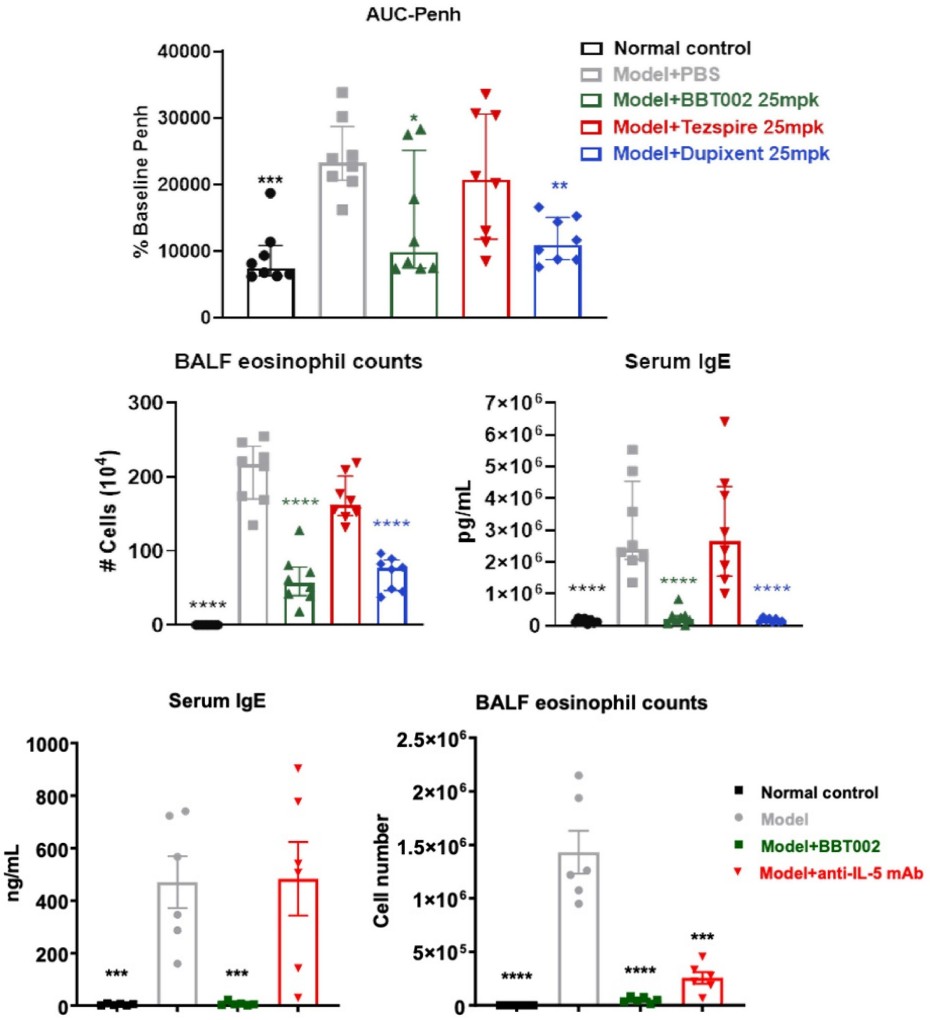
However several important limitations remain:

- ***Heterogeneous Response and Non-Responders***. Asthma is a biologically heterogeneous disease. As a result, single-mechanism therapies may not adequately address all underlying pathways, leading to variability in response and a subset of patients who do not respond to existing treatments.
- ***Incomplete Response to Biologics***. Many asthma patients continue to experience exacerbations, impaired lung function, or persistent symptoms despite treatment with biologics.
- ***Injection Burden and Treatment Convenience***. Biologic therapies such as Dupixent and Xolair are commonly administered every two to four weeks, often in a clinical setting, creating logistical challenges that may negatively affect long-term patient adherence and treatment persistence.
- ***Chronic Disease Burden***. Asthma often persists for years, requiring long-term management. Current therapies may control symptoms but do not consistently modify underlying disease biology to achieve sustained remission.
- ***Comorbid Disease Complexity.*** Many patients also have other comorbidities, creating broader systemic disease burden and making integrated disease control more challenging.

Our Preclinical Data

In an ovalbumin-induced asthma KI mouse model with human IL-4/IL-4R/TSLP/TSLPR, BBT002 improved lung function, measured by AUC-Penh, and anti-inflammatory effect, measured by BALF, EOS counts, and serum IgE, compared to Dupixent and Tezspire. Additionally, in an ovalbumin-induced asthma model using human IL-4/IL-4R KI mice, BBT002 demonstrated broader control of Type 2 inflammation, with greater reductions in serum IgE and BALF eosinophils than an anti-IL-5 antibody.

Figure 46: Improved Lung Function and Anti-Inflammatory Effect in Asthma Model



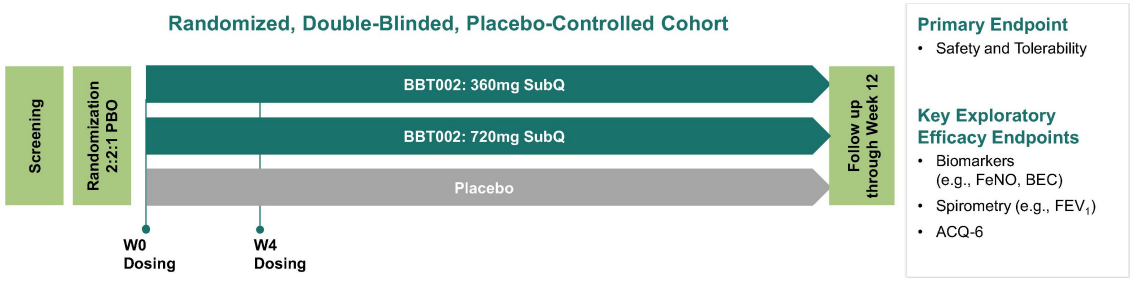
*p<0.05, **p<0.01, ***p<0.001, p****<0.0001 VS Model + PBS/Vehicle (One-way ANOVA)

Phase 2a Study in Asthma

We have initiated a Phase 2a study of a SubQ formulation of BBT002 in adult patients with asthma (the "Phase 2a Asthma Study"). This study is a multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and tolerability, PK, immunogenicity, PD, and exploratory clinical activity following SubQ administration of 360 mg or 720 mg of BBT002 or placebo. Participants are being randomized in a 2:2:1 ratio. Participants are dosed on Day 1 and 29 and return for several follow-ups through Day 85.

The primary endpoints are safety and tolerability of BBT002, including incidence, relatedness, and severity of AEs. The secondary endpoints are PK, including $t_{1/2}$, and immunogenicity of BBT002, as measured by the number and percentage of participants who developed ADA. The exploratory endpoints are PD and exploratory clinical activity, including FeNO, EOS levels, and FEV_1.

Figure 47: 4-week PoC Study in Asthma Patients



BBT002 Potential Program Expansion into Additional Target Indications

BBT002, designed as a pipeline-in-a-molecule, targets well-known pathways that underlie multiple indications in Type 2 inflammatory disorders in respiratory disease, with potential to expand development into other therapeutic areas such as dermatology and gastroenterology, including for the treatment of CSU, EoE, and food allergy.

Future Clinical Development Strategy

We plan to initiate study start-up activities for a Phase 2b dose-ranging clinical trial of a SubQ formulation of BBT002 in patients with one of the respiratory indications in 2027.

Preclinical Programs

BBT003 Program: Pipeline-in-a-Molecule for Gastroenterology Disorders

Overview

Our lead preclinical product candidate, BBT003, is a long-acting bispecific antibody designed to simultaneously target the clinically validated pathway mediated by TL1A and the commercially validated target IL-23p19. We believe our "dual-axis" therapeutic strategy of targeting two complementary pathways that have shown both anti-inflammatory and anti-fibrotic activity has the potential to address key unmet needs in immune-mediated diseases. We are initially developing BBT003 in gastroenterology indications, specifically inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Crohn's Disease ("CD"). We also see expansion opportunities in autoimmune diseases ("AID") and fibrosis. We expect to initiate clinical development of BBT003 by the end of 2026.

Disease Background, Scientific Rationale and Market Opportunity

IBD, comprising UC and CD, is a group of chronic, progressive, immune-mediated diseases of the gastrointestinal tract characterized by persistent inflammation, recurrent disease flares, and cumulative bowel damage over time. UC is characterized by continuous mucosal inflammation confined to the colon, whereas CD can involve any segment of the gastrointestinal tract and is driven by deeper, transmural inflammation that frequently results in strictures and fistulas. Patients commonly experience abdominal pain, diarrhea, rectal bleeding, fatigue, weight loss, and urgency, which can significantly impair quality of life, productivity, and daily functioning. Despite advances in treatment, many patients continue to experience periods of active disease, hospitalization, and disease-related complications that may ultimately require surgical intervention.

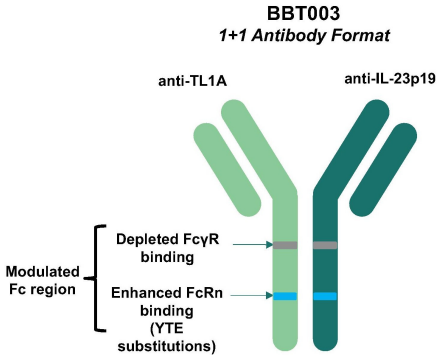
The pathogenesis of IBD involves a complex network of inflammatory pathways spanning both the innate and adaptive immune systems, including TNF, IL-23, interleukin-12 ("IL-12"), TNF-like ligand 1A ("TL1A"), integrin-mediated immune cell trafficking, and other downstream inflammatory signaling pathways. These pathways collectively drive chronic intestinal inflammation, epithelial barrier dysfunction, immune cell activation, and progressive tissue injury.

Current treatment options include corticosteroids, immunomodulators, biologics, and targeted small-molecule therapies designed to suppress inflammation and induce or maintain remission. Over the past two decades, therapies targeting TNF, IL-12/23, selective IL-23, integrins, and JAK signaling have transformed the treatment landscape and improved outcomes for many patients. However, a substantial proportion of patients fail to achieve durable remission, lose response over time, require dose escalation or treatment switching, or remain dependent on corticosteroids. While the clinical success of these therapies has validated the importance of individual pathways in disease pathogenesis, the continued burden of treatment failure highlights the potential limitations of single-pathway inhibition in a multifactorial disease.

IBD represents one of the largest commercial markets within I&I, with millions of patients affected globally. As treatment goals evolve from symptom control toward durable remission, endoscopic healing, and disease modification, significant opportunities remain for next-generation therapies capable of addressing the multiple inflammatory pathways that contribute to disease pathogenesis. We estimate that IBD will approach $39 billion in market size by 2030.

Our Solution for Inflammatory Bowel Disease: BBT003

Figure 48: BBT003 is a Bispecific IgG1 Antibody that Targets TL1A and IL-23p19 in a 1+1 Format



BBT003 is designed to combine the benefits of a clinically validated target and a commercially validated target to overcome some of the challenges of prior biologics:

- The core structural framework is a fully human IgG1 antibody with two distinct antigen-binding sites binding to TL1A and IL-23p19, labeled above as anti-TL1A and anti-IL-23p19, respectively.
  - TL1A is a clinically validated target with several monoclonal antibodies in late-stage Phase 3 clinical development in IBD. TL1A inhibitors have shown both anti-inflammatory and anti-fibrotic activity. Additionally, product candidates targeting TL1A have been attractive to biopharma. In 2023, MSD and Roche each acquired TL1A programs for $10.8 and $7.1 billion, respectively.
  - IL-23p19 is a commercially validated target with Skyrizi generating approximately $17.6 billion in global sales in 2025 across multiple indications, with $6.4 billion within IBD alone, and Tremfya, which targets IL-23, generating $5.2 billion in global sales.
- The Fc region of the IgG1 antibody has been modulated in two ways:
  - Depleting FcγR binding to reduce ADCC and CDC effects;
  - Enhancing FcRn binding through a YTE (M252Y/S254T/T256E) substitution to enhance FcRn-mediated antibody recycling and extend serum half-life. The YTE substitution can also slightly reduce FcγR binding, to decrease immune effector functions like ADCC.

Our goal is to develop BBT003 to be a first line therapy for IBD. BBT003 is designed to:

- ***Address Inflammation and Fibrosis***: By simultaneously blocking TL1A and IL-23p19, BBT003 is designed to have both anti-inflammatory and anti-fibrotic activity. Both targets are orthogonal and either clinically or commercially validated. We believe sparing the DcR3 blockade has the potential to provide more effective inhibition of the TL1A signaling pathway.
- ***Achieve Faster Onset and Break the Therapeutic Ceiling***: We believe dual targeting of both the inflammatory and fibrotic pathways has the potential to provide faster onset and deeper response compared to single-target approaches due to the complementarity of the targets.
- ***Enable Extended Dosing Intervals***: Fc modifications using a YTE (M252Y/S254T/T256E) substitution increase FcRn affinity and extend drug half-life.
- ***Provide High-Concentration SubQ Delivery***: We have developed a high-concentration SubQ formulation to enable commercial presentation in a low-volume injection for convenient at-home administration.

Scientific Rationale

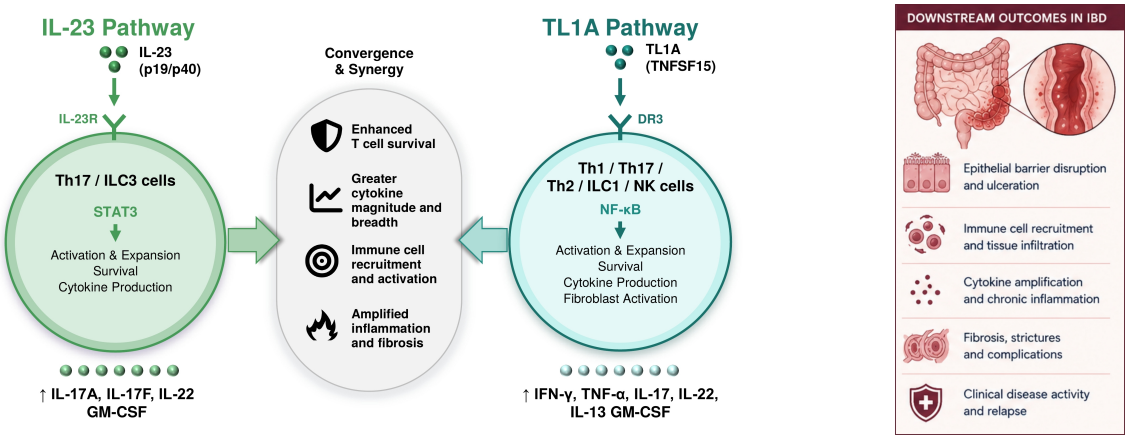
We believe that dual targeting IL-23 and TL1A represents the most compelling and complementary strategy to maximize therapeutic potential.

The rationale for simultaneously targeting IL-23 and TL1A is based on the complementary and non-redundant roles of these pathways in inflammation and fibrosis:

- IL-23 is a central driver of chronic, pathological inflammation. IL-23 promotes the expansion, maintenance and inflammatory activity of T-helper 17 (“Th17”) cells and group 3 innate lymphoid cells (“ILC3s”), which contributes to both adaptive and innate immunity. Triggered by IL-23, these responses increase the production of inflammatory mediators, including granulocyte–macrophage colony-stimulating factor (“GM-CSF”), and promote the recruitment and activation of myeloid cells, including neutrophils, contributing to persistent mucosal inflammation and tissue injury.
- The TL1A pathway amplifies multiple inflammatory pathways and directly contributes to profibrotic signaling. TL1A provides co-stimulatory signals to a variety of T-helper subsets and modulates innate immune cells, including the group 1 innate lymphoid cells (“ILC1”) and natural killer (“NK”) cells. In addition, TL1A directly activates fibroblasts and promotes pathological fibrosis through mechanisms independent of its proinflammatory effects.

Dual blockade is therefore designed to reduce both the magnitude and breadth of inflammation while addressing the fibrotic component that remains a major unmet need in IBD.

Figure 49: Dual Targeting of IL-23 and TL1A Addresses Complementary Drivers of Inflammation and Fibrosis in IBD



Our Preclinical Data

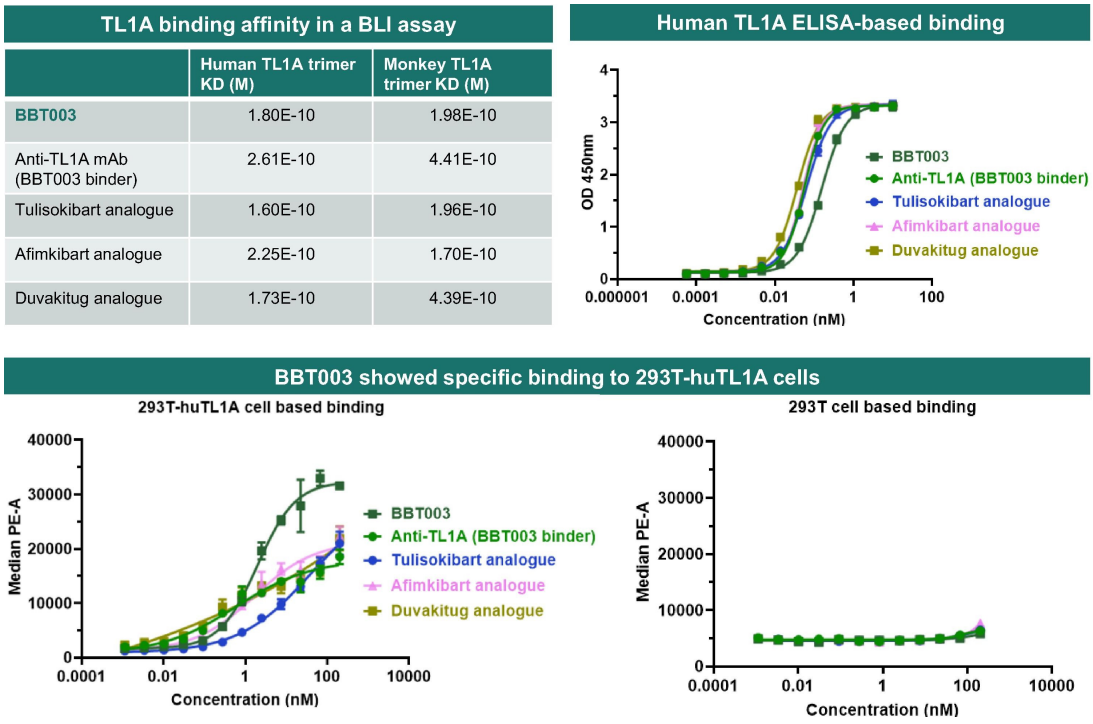
To date, BBT003 has demonstrated compelling preclinical data showing:

- ***Potent binding affinity to both human and monkey TL1A***, including TL1A that is expressed on the cell surface, at levels comparable to conventional monoclonal antibodies that bind TL1A with two arms.

Figure 50: BBT003 Binding Affinity to Human and Monkey TL1A

TL1A binding affinity in a BLI assay

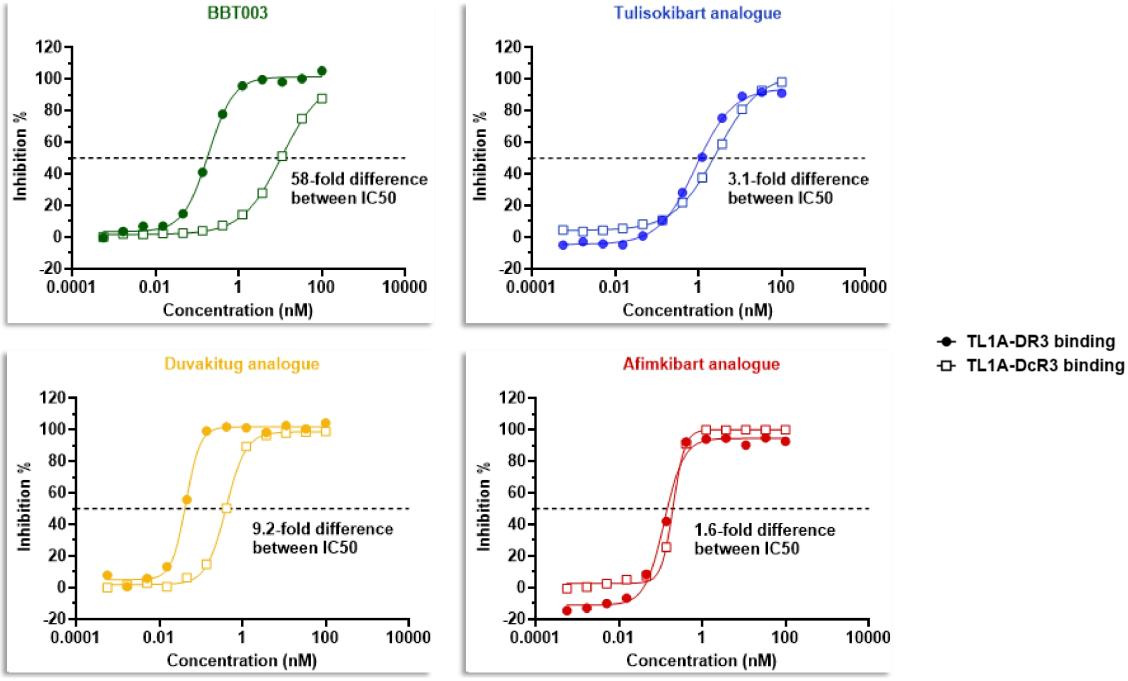
	Human TL1A trimer KD (M)	Monkey TL1A trimer KD (M)
BBT003	1.80E-10	1.98E-10
Anti-TL1A mAb (BBT003 binder)	2.61E-10	4.41E-10
Tulisokibart analogue	1.60E-10	1.96E-10
Afimkibart analogue	2.25E-10	1.70E-10
Duvakitug analogue	1.73E-10	4.39E-10



Sequence of tulisokibart analogue was from patent US20220259320 clone A219; sequence of duvakitug analogue was from KEGG DRUG database D12950; sequence of afimkibart analogue was from patent US20220390463 clone 1D1 1.31

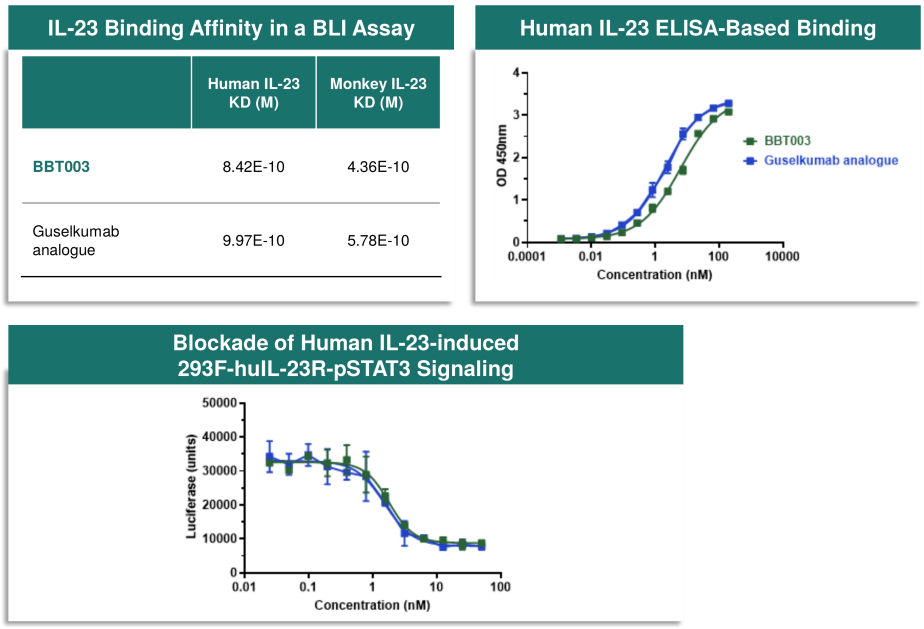
- ***Selective blockade of TL1A binding to DR3***, the TL1A signaling receptor, but not DcR3, an endogenous soluble decoy that can sequester and neutralize TL1A.

Figure 51: Selective Blockade of TL1A Binding to DR3 but not DcR3 by BBT003



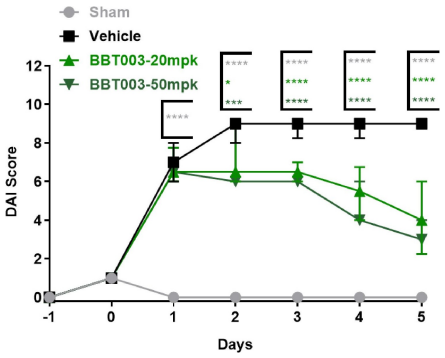
- ***High binding affinity to human and monkey IL-23 and blocking pSTAT3 signaling, demonstrating functional blocking of IL-23.*** Binding affinities (KD values) of BBT003 and the control antibody (guselkumab analogue) for human and/or monkey IL-23 proteins were measured by biolayer interferometry (BLI), with human IL-23 binding confirmed by ELISA. Blockade of IL-23–induced STAT3 signaling was demonstrated by reduced luciferase activity in engineered cells expressing human IL-23 receptors and a STAT3-responsive reporter.

Figure 52: BBT003 Binding Affinity to Human and Monkey IL-23



- 67% reduction in the disease activity index (DAI) on day 5 in a mouse colitis model using trinitrobenzene sulfonic acid (TNBS) to induce severe, localized inflammation. In this study, human TL1A/IL23A/IL12B knock-in mice with TNBS-induced colitis on Day 0 received intraperitoneal injection of 20 mpk or 50 mpk of BBT003 or vehicle on Day -1, 1 and 3, whereas mice in the sham group did not receive TNBS or BBT003 treatment. DAI score was calculated by summing the subscores for mouse body weight loss, stool consistency and blood in the stool.

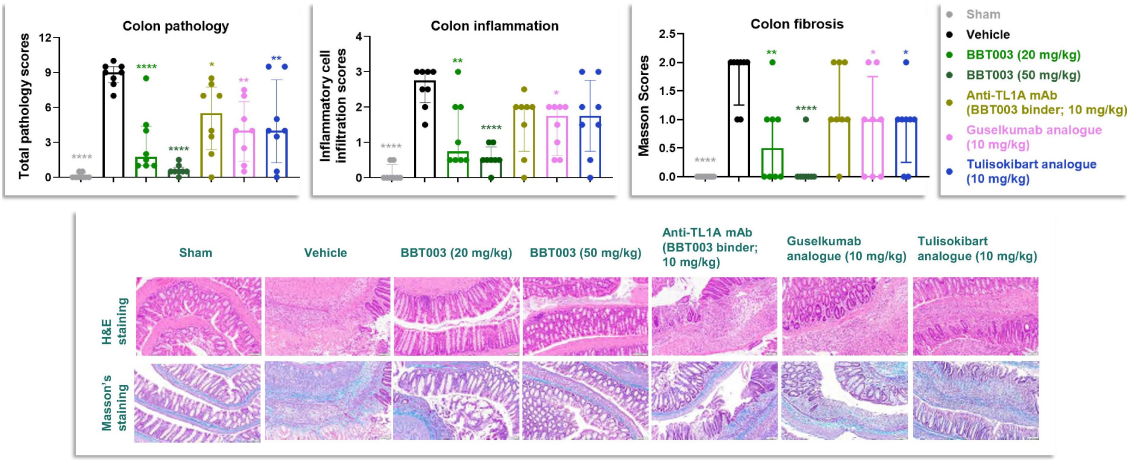
Figure 53: BBT003 on Mouse IBD Disease Activity



*p<0.05, ***p<0.001, ****p<0.0001 vs. Vehicle

- ***Significant improvements on colon pathology, inflammation and fibrosis***. Mouse colon tissues were processed for H&E and Masson's staining. Images were graded by a pathologist blinded to animal ID to determine the colon pathology and colon inflammation scores based on H&E staining results, and colon fibrosis scores based on Masson's staining results, respectively.

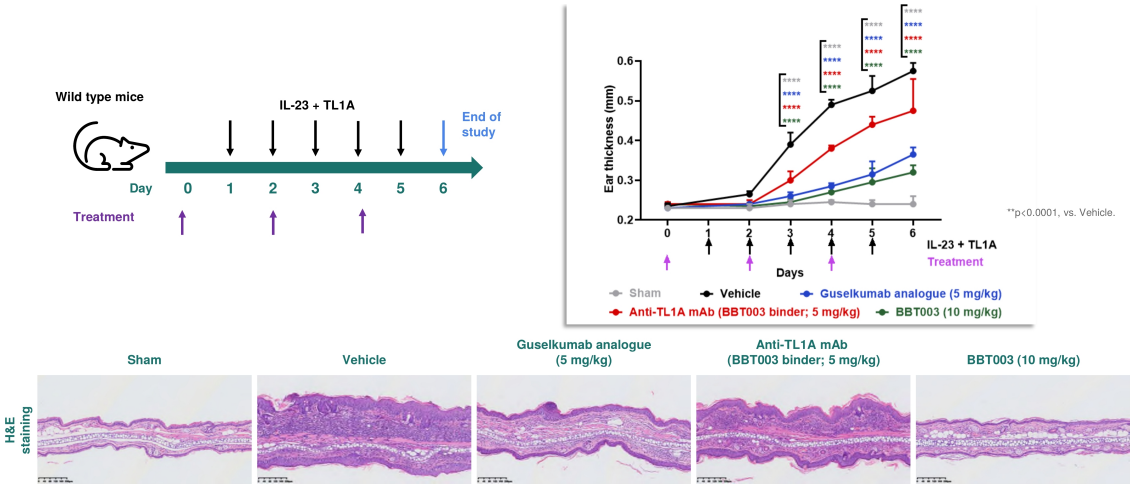
Figure 54: BBT003 on Mouse Colon Pathology, Inflammation and Fibrosis



*p<0.05, **p<0.01, ****p<0.0001 vs. Vehicle

- ***Reduction of ear tissue thickening and inflammation in wild type mice***. Daily SubQ injections of human IL-23 and TL1A into the right ear of wild type mice starting Day 1 induced ear thickening and histologically confirmed inflammation. To assess therapeutic efficacy, these mice received intraperitoneal injections of BBT003, control antibodies (anti-TL1A monoclonal or guselkumab analogue), or vehicle on Days 0, 2, and 4. Sham mice received neither human cytokines nor antibodies.

Figure 55: BBT003 on Mouse Ear Tissue Thickness and Inflammation



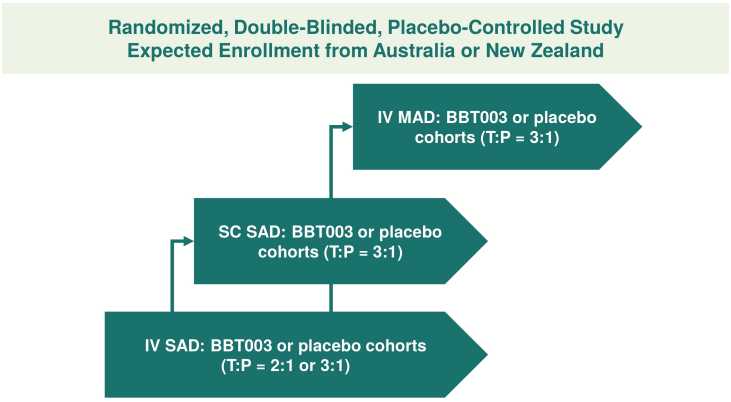
- ***Favorable safety and immunogenicity data in NHPs***. NHPs were administered with vehicle, 30 mg/kg, 100 mg/kg, or 300 mg/kg (2 animals/dose level), once every week for 4 weeks (5 doses in total). No animal died during the study. No micro- or macro- findings related to BBT003 were observed (NOAEL: 300 mg/kg). No ADA was detected from any animals. The exposure increased dose proportionally. There were no observed gender differences and no observed exposure accumulation between Day 1 and Day 22 in the 100 mg/kg and 300 mg/kg groups.

Future Clinical Development Strategy

We expect BBT003 to be ready to enter clinical development by the end of 2026, and currently plan to prioritize development in IBD, including UC and CD, with potential future expansion opportunities in AID and fibrosis.

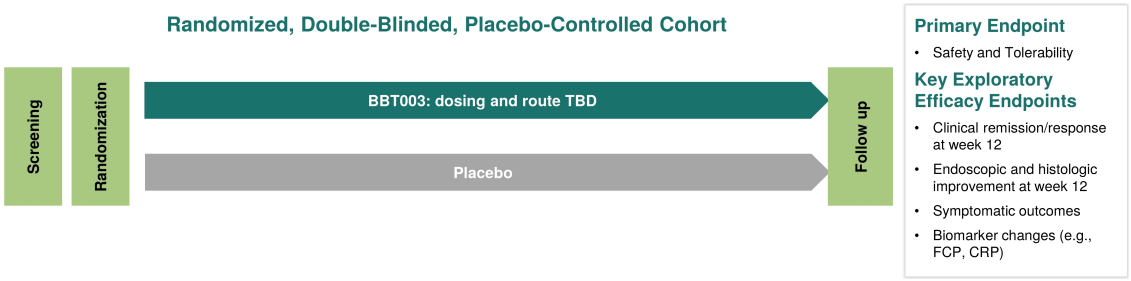
The BBT003 first-in-human program is designed as a randomized, double-blind, placebo-controlled study of healthy volunteers with SAD and MAD IV cohorts and a SAD SubQ cohort. The primary endpoint is safety and tolerability. Secondary and exploratory work will characterize PK, immunogenicity and pharmacodynamic markers, with follow-up extending to six months to capture the consequences of a long half-life.

Figure 56: BBT003 First-in-Human Study Design



We are also planning a PoC Study in UC patients that will enroll adults with moderately to severely active disease who have failed conventional or advanced therapy. The study is randomized and placebo controlled. In addition to safety, we will assess clinical response and remission, endoscopic and histologic improvement, symptoms and biomarkers such as fecal calprotectin ("FCP") and C-reactive protein ("CRP") at Week 12. Dosing and route of administration will be finalized using the Phase 1 healthy volunteer data.

Figure 57: BBT003 PoC Study in UC Patients



BBT004 Program: Pipeline-in-a-Molecule for Autoantibody-Driven Autoimmune Disorders

Overview

Our second preclinical product candidate, BBT004, is a 1+1 bispecific antibody designed to simultaneously target two validated pathways in B-cell depletion. BBT004 is intended to enable deep and durable B-cell depletion through depletion of both pathogenic B cells and antibody-producing plasma cells, and incorporates engineering features designed to minimize the risk of cytokine release syndrome. We have provided written notice to BioNTech Zhuhai to exercise an option to license an additional antibody candidate discovered and developed by BioNTech Zhuhai directed to the BBT004 program. We are initially developing BBT004 for autoantibody-driven AID.

Disease Background, Scientific Rationale, and Market Opportunity

Antibody-mediated autoimmune diseases represent a heterogeneous group of chronic, immune-mediated conditions characterized by a loss of self-tolerance and persistent production of pathogenic autoantibodies. In conditions such as SLE, LN, MG, Sjögren's disease, rheumatoid arthritis, and IgG4-RD, this drives persistent inflammation, progressive multi-organ damage, and debilitating complications including renal failure, neuromuscular dysfunction, and irreversible tissue injury. Despite available therapies, disease burden remains substantial, with many patients experiencing inadequate disease control, treatment-related toxicity, and diminished quality of life.

The pathogenesis of antibody-mediated autoimmune disease is driven by dysregulation across the full B-cell lineage. Autoreactive B-cell populations can persist, expand, and mature into antibody-secreting cells, including plasmablasts and long-lived plasma cells that continuously produce pathogenic autoantibodies and may survive for prolonged periods in protective tissue niches such as the bone marrow. As B cells undergo terminal differentiation, their surface phenotype, survival dependencies, and sensitivity to different therapeutic interventions change substantially. As a result, therapies directed toward a single stage of B-cell development may reduce part of the pathogenic compartment while leaving other disease-sustaining populations intact. This creates the potential for residual autoantibody production, immune reconstitution from upstream autoreactive reservoirs, and eventual clinical relapse.

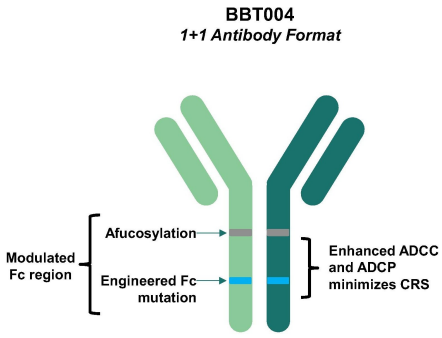
Over the past two decades, advances in B-cell-directed therapy have meaningfully expanded treatment options for antibody-mediated autoimmune diseases. Therapeutic approaches that modulate or deplete selected B-cell subsets, inhibit B-cell survival pathways, reduce pathogenic immunoglobulin levels, or target antibody-secreting populations have each demonstrated clinical benefit, collectively validating the central role of the B-cell lineage in these diseases. However, available approaches generally address only a portion of the pathogenic humoral immune axis. No broadly approved therapy has yet demonstrated reliable, simultaneous elimination of both the autoreactive B-cell reservoir and the mature antibody-secreting compartment. Consequently, a substantial proportion of patients continue to experience persistent autoantibody-driven disease activity, relapse, and progressive organ damage.

The clinical potential of deeper B-lineage reset has been suggested by emerging cell therapy experience in refractory AID, including SLE and LN, where durable, drug-free remissions have been reported in selected patients. However, the logistical complexity, individualized manufacturing, cost, and safety considerations associated with autologous cell therapy limit its applicability to the broader AID population. These limitations highlight a significant unmet need for therapies capable of achieving deeper and more durable control of pathogenic humoral immunity in a format that is practical, scalable, and suitable for broad clinical use.

Antibody-mediated AID represent a large and growing commercial opportunity, with B-cell-directed biologics generating multi-billion-dollar annual revenues globally. As the field moves toward deeper, more durable disease control, the demand for effective, accessible, and broadly deployable B-cell depleting therapies is substantial, and significant opportunities remain for next-generation therapies capable of achieving complete B-cell and plasma cell depletion in a format suitable for wider patient access.

Our Solution for Autoantibody-Driven AID: BBT004

Figure 58: BBT004 is a Bispecific IgG1 Antibody in a 1+1 Format



BBT004 is designed to combine the benefits of commercially validated targets to overcome key challenges of prior biologics:

- The core structural framework is a human IgG1 antibody with two distinct antigen-binding sites binding to two validated B-cell lineage targets.
- The Fc region of the IgG1 antibody has been modified with an Fc mutation and afucosylation to enhance ADCC and ADCP.

Future Clinical Development Strategy

We believe BBT004 is well-positioned for a number of autoimmune indications, and plan to initially focus on development in autoantibody-driven AID. We are currently conducting IND-enabling studies for BBT004.

Manufacturing

We do not own or operate and currently have no plans to establish any manufacturing facilities. We rely on and expect to continue to rely on third-party contract development and manufacturing organizations ("CDMOs") for the manufacturing of our product candidate and related raw materials for clinical development, as well as for the commercial manufacturing of any of our product candidate that receive marketing approval in the future. WuXi Biologics is currently our sole manufacturer for BBT001, BBT002, and BBT003, and BioNTech Zhuhai is currently the sole manufacturer for BBT004. We believe there are multiple sources for all of the materials required for the manufacturing of our product candidate and development program and may in the future engage additional CDMOs to provide biological development and manufacturing services. As our product candidate advances through development, we expect to diversify our supply chain across multiple qualified suppliers, CDMOs, and geographic regions and enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our production needs. If our current CDMO becomes unavailable to us for any reason, we believe that there are a number of potential replacements, and we will need to identify and qualify such replacements.

We also rely on CDMOs to perform all chemistry, manufacturing, and controls activities. Our agreements with CDMOs may obligate them to develop or transfer upstream and downstream processes, develop or transfer drug product manufacturing processes, develop or transfer suitable analytical methods for release and stability testing, and qualify these methods for use with our product candidates, produce drug substance for preclinical testing, and produce drug substance or drug product under current Good Manufacturing Practice ("cGMP") for use in clinical trials among other activities. In addition, we rely on CDMOs to operate facilities that meet regulatory requirements for production and testing of clinical and commercial products and to work closely with us to validate manufacturing processes prior to commercial launch. We qualify CDMOs prior to initiation of cGMP regulated activities and periodically thereafter as part of the supplier qualification program. We oversee CDMOs by performing technical and quality assurance review and/or approval of cGMP documentation, establishing quality agreements to define

responsibilities and expectations for goods and services, and observing production and testing activities as a person-in-plant, among other activities.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary and novel products and product candidates. Our product candidates, if approved, are designed to potentially address a range of I&I indications. Ultimately, the indications our product candidates target, and for which we may receive marketing authorization, will determine our competition. Our product candidates, if approved, will have to compete with existing therapies and new therapies that may become available in the future.

Our competitors have developed, are developing, or may in the future develop product candidates and products competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors include larger and better-funded pharmaceutical, biotechnological, and therapeutics companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Moreover, we may also compete with universities, governmental agencies, and other public and private research institutions that may be active in research in our target indications and could be in direct competition with us. We also compete with these organizations to recruit management, scientists, and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and enrolling subjects for clinical trials and in identifying and in-licensing intellectual property related to new product candidates, as well as entering into partnerships, collaborations and license arrangements.

Because our product candidates are designed to have clinically or commercially validated targets, there are a number of approved products and clinical-stage product candidates in development targeting the same mechanisms. I&I is a particularly crowded field with a large number of approved and late-stage clinical assets in development in each of the indications that we are targeting, including:

- Atopic Dermatitis (“AD”):
  - *Approved:* AbbVie’s Rinvoq (upadacitinib) targeting JAK-1; Eli Lilly’s Ebglyss (lebrikizumab) targeting IL-13; Galderma’s Nemluvio (nemolizumab) targeting IL-31Rα; LEO Pharma’s Adbry (tralokinumab) targeting IL-13; Pfizer’s Cibinqo (abrocitinib) targeting JAK-1; Regeneron/Sanofi’s Dupixent (dupilumab) targeting IL-4Rα;
  - *Late Clinical-Stage:* Apogee’s zumilokibart (now acquired by AbbVie) targeting IL-13; Corvus’s soquelitinib targeting ITK; Evommune’s EVO301 targeting IL-18; Kymera’s KT-621 targeting STAT6; Pfizer’s trispecific antibodies, tilrekimig targeting anti-IL-4/IL-13/TSLP and ompekimig targeting anti-IL-4/IL-13/IL-33; UCB’s galvokimig targeting IL-13/IL-17A/F;
- Chronic Spontaneous Urticaria (“CSU”):
  - *Approved:* Genentech/Novartis’s Xolair (omalizumab) targeting IgE; Novartis’s Rhapsido (remibrutinib) targeting BTK; Regeneron/Sanofi’s Dupixent (dupilumab) targeting IL-4Rα;
  - *Late Clinical-Stage:* Celldex’s barzolvolimab targeting C-kit (CD117); Sanofi’s rilzabrutinib targeting BTK;
- Chronic Obstructive Pulmonary Disease (“COPD”):
  - *Approved:* GSK’s Nucala (mepolizumab) targeting IL-5; Regeneron/Sanofi’s Dupixent (dupilumab) targeting IL-4Rα; Verona Pharma (Merck)’s Ohtuvayre (ensifentrine) targeting PDE3 / PDE4;
  - *Late Clinical-Stage:* AstraZeneca/Amgen’s Tezspire (tezepelumab) targeting TSLP; GSK’s GSK5784283 targeting TSLP; AstraZeneca’s tozorakimab targeting IL-33; Pfizer’s tilrekimig targeting IL-4/IL-13/TSLP; Sanofi’s lunsekimig targeting IL-13/TSLP;

- Chronic Rhinosinusitis with Nasal Polyps ("CRSwNP"):
  - *Approved:* AstraZeneca/Amgen's Tezspire (tezepelumab) targeting TSLP; Genentech/Novartis's Xolair (omalizumab) targeting IgE; GSK's Exdensur (depemokimab) targeting IL-5 and Nucala (mepolizumab) targeting IL-5; Regeneron/Sanofi's Dupixent (dupilumab) targeting IL-4Rα;
  - *Late Clinical-Stage:* Eli Lilly's Ebglyss (lebrikizumab) targeting IL-13; GSK's GSK5784283 targeting TSLP; Sanofi's lunsekimig targeting IL-13/TSLP;
- Asthma:
  - *Approved:* AstraZeneca/Amgen's Tezspire (tezepelumab) targeting TSLP; AstraZeneca's Fasenra (benralizumab) targeting IL-5Rα; Genentech/Novartis's Xolair (omalizumab) targeting IgE; GSK's Exdensur (depemokimab) targeting IL-5 and Nucala (mepolizumab) targeting IL-5; Regeneron/Sanofi's Dupixent (dupilumab) targeting IL-4Rα; Teva's Cinqair (reslizumab) targeting IL-5;
  - *Late Clinical-Stage:* Sanofi's lunsekimig targeting IL-13/TSLP; Pfizer's tilrekimig targeting IL-4/IL-13/TSLP; Generate Biomedicines' GB-0895 targeting TSLP; GSK's GSK5784283 targeting TSLP;
- Inflammatory Bowel Disease ("IBD"), including Ulcerative Colitis ("UC") and Crohn's Disease ("CD"):
  - *Approved:* AbbVie's Humira (adalimumab) targeting TNF-α, Rinvoq (upadacitinib) targeting JAK-1, and Skyrizi (risankizumab) targeting IL-23p19; Bristol Myers Squibb's Zeposia (ozanimod) targeting S1P1/5; Eli Lilly's Omvoh (mirikizumab) targeting IL-23p19; Janssen (J&J)'s Remicade (infliximab) targeting TNF-α, Simponi (golimumab) targeting TNF-α, Stelara (ustekinumab) targeting IL-12/23p40; and Tremfya (guselkumab) targeting IL-23p19; Pfizer's Xeljanz (tofacitinib) targeting JAK1/3 and Velsipity (etrasimod) targeting S1P1/4/5; Takeda's Entyvio (vedolizumab) targeting α4β7 integrin; UCB's Cimzia (certolizumab pegol) targeting TNF-α;
  - *Late Clinical-Stage:* Abivax's obefazimod, a miR-124 regulator; Merck's tulisokibart targeting TL1A; Roche's afimkibart targeting TL1A; and Sanofi/Teva's duvakitug targeting TL1A.

If our product candidates do not offer advantages over available products or products in development, we may not be able to successfully compete against our current and future competitors. For example, Regeneron/Sanofi's Dupixent (dupilumab) targeting IL-4Rα is approved for many of the same indications that we are targeting, including moderate-to-severe AD, CSU, COPD, CRSwNP, and asthma, among other indications. Our preliminary clinical data of BBT001 and BBT002 demonstrated a half-life that is more than two times as long as our estimate of Dupixent's half-life of 12.7 days, calculated based on the popPK model from the FDA's clinical pharmacology and biopharmaceutics review report, although no head-to-head clinical study has been conducted comparing the half-life of BBT001 or BBT002 against Dupixent. However, a number of current and future competitors are developing therapies with the potential for improved efficacy and improved dosing intervals (i.e., less frequent dosing). If our subsequent clinical data do not continue to support the potential for a half-life advantage compared to Dupixent or the other therapies being approved or developed or the half-life of our product candidates does not translate to improved dosing intervals, our product candidates may not be commercially viable.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates, technology, and know-how, to operate without infringing the proprietary or intellectual property rights of others, and to prevent others from infringing our proprietary or intellectual property rights. We seek to protect our proprietary and intellectual property position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and drug candidates that are important to the development and implementation of our business. We also rely on trade secrets, know-how, trademarks, continuing technological innovation, and licensing opportunities to develop and maintain our proprietary and intellectual property position. The development of our drug candidates and technology is at an early stage and consequently, our

patent portfolio is also at an early stage. Presently, our patent portfolio is pending in prosecution and we do not own or in-license any issued patents. Many of our and our licensor's patent applications are either at the provisional stage or at an early stage in prosecution. We cannot be sure that any patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our technology and drug candidates.

We currently, and expect that we will continue to own or in-license patent applications related to our key drug candidates in an effort to establish intellectual property positions protecting these drug candidates, as well as their use in the treatment of various diseases. As of October 9, 2026, we own a patent portfolio consisting of seven patent families and in-license five patent families from BioNTech Zhuhai relating to our technology and drug candidates. For our drug candidates, we generally pursue multilayered patent protection covering compositions of matter, methods of use, and methods of manufacture. We also intend to pursue patent protection, if available, with respect to biomarkers that may be useful in selecting a patient population for use of our drug candidates. We intend to strengthen the patent protection of our drug candidates and technologies through additional patent application filings.

BBT001 & BBT002

We own one patent family that covers methods of treatment, methods of manufacture, and compositions of matter of BBT001, including one non-expired PCT application and one pending Taiwanese application, which if issued as U.S. or foreign patents will start to expire in 2045, in each case, excluding any patent term adjustments, any patent term extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. We also own two patent families that cover methods of treatment of BBT001, including three pending U.S. provisional patent applications, which if issued as U.S. or foreign patents will start to expire in 2047, in each case, excluding any patent term adjustments, any patent term extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees.

We own one patent family that cover methods of treatment, methods of manufacture, and compositions of matter of BBT002, including one non-expired PCT application and one pending Taiwanese patent application, which if issued as U.S. or foreign patents will start to expire in 2045, in each case, excluding any patent term adjustments, any patent term extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. We also own three patent families that cover methods of treatment of BBT002, including five pending U.S. provisional patent applications, which if issued as U.S. or foreign patents will start to expire in 2047, in each case, excluding any patent term adjustments, any patent term extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees.

We in-license three patent families non-exclusively from BioNTech Zhuhai that relate to the individual, monospecific binding arms of BBT001 and BBT002, and methods of use thereof, including three non-expired PCT applications, which if issued as U.S. or foreign patents will start to expire in 2045, in each case, excluding any patent term adjustments, any patent term extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees.

BBT003

We also in-license two patent families from BioNTech Zhuhai, which cover methods of treatment, methods of manufacture, and compositions of matter of BBT003, including two non-expired PCT applications, which if issued as U.S. or foreign patents will start to expire in 2046, in each case, excluding any patent term adjustments, any patent term extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries in which we file, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application, subject to the payment of applicable maintenance, renewal, annuity, and other governmental fees. In the United States, the patent term may, in certain cases, be lengthened by patent term

adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in examining and granting a patent, subject to applicable statutory requirements, or may be shortened by patent term adjustment if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. Additionally, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time a drug is under regulatory review while a patent that covers the drug is in force, subject to applicable statutory and regulatory requirements. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended, such patent may be extended only once, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our drug candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, if available. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and, if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Intellectual Property." Expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us.

In addition to patent protection, we also rely on trade secrets, know-how, trademarks, other proprietary information, and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Intellectual Property."

The patent positions of biopharmaceutical companies like ours are generally uncertain and involve complex legal, scientific, and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our drugs or processes, obtain licenses, or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see the section titled "Risk Factors—Risks Related to Intellectual Property."

Our Collaboration, License, and Services Agreements

BioNTech Zhuhai Agreements

Assignment Agreement

On March 18, 2024, we entered into an Assignment Agreement with BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"), which was amended and restated in its entirety on December 11, 2024 and further amended by Amendment No. 1 to Amended and Restated Assignment Agreement on September 2, 2026 (the "BioNTech Zhuhai Assignment Agreement"). Pursuant to the BioNTech Zhuhai Assignment Agreement, we obtained two bispecific antibody programs from BioNTech Zhuhai: the BBT001 program, which identifies, evaluates, and develops bispecific antibody candidates directed to both IL-4Rα and IL-31, and the BBT002 program, which identifies, evaluates, and develops bispecific antibody candidates directed to both IL-4Rα and IL-5, together with BioNTech Zhuhai's entire right, title, and interest in these bispecific programs, as well as certain related research materials, data packages, and intellectual property rights solely related to the bispecific programs. BioNTech Zhuhai granted us a non-exclusive license under its patent rights and know-how existing as of March 18, 2024 and related to mono-specific antibodies directed to IL-4Rα, IL-31 and IL-5 solely to practice and exploit such intellectual property in connection with the BBT001 and BBT002 programs.

Under the BioNTech Zhuhai Assignment Agreement, as of June 30, 2026, we have made cash payments to BioNTech Zhuhai totaling approximately $4.8 million, including approximately $0.2 million in 2024 and $4.6 million in 2025, and we are obligated to (i) share a portion of a platform fee owed by BioNTech Zhuhai to BioNTech Zhuhai's upstream licensor Alloy Therapeutics, LLC ("Alloy") in the amount of $7,500 per program until May 2026, (ii) pay, for each program, a $50,000 annual fee for so long as the program remains active and the relevant rights have not been terminated or abandoned before the applicable anniversary date, and (iii) pay, when invoiced, product-specific milestone payments that flow through BioNTech Zhuhai's agreement with Alloy, with aggregate development milestone payments that could reach approximately $1.8 million per program and aggregate commercial milestone payments that could reach $11.0 million per program.

We are obligated to use commercially reasonable efforts to obtain IND approval of a product containing the lead antibody candidates in each program.

On a program-by-program basis, until the earlier of five years following the date on which we first obtain IND approval of a product or the termination of the BioNTech Zhuhai Assignment Agreement, BioNTech Zhuhai and its affiliates are restricted from researching, developing, manufacturing, or commercializing or collaborating or partnering with a third party to research, develop, manufacture, or commercialize any antibody directed to (i) both IL-4Rα and IL-31 for the BBT001 program, and (ii) both IL-4Rα and IL-5 for the BBT002 program without our prior written consent, in each case, subject to certain exceptions.

The BioNTech Zhuhai Assignment Agreement will continue in full force until terminated. Either we or BioNTech Zhuhai may terminate the BioNTech Zhuhai Assignment Agreement in the event of the other party's material breach, subject to certain notice and cure periods, and BioNTech Zhuhai may also terminate in the event of our bankruptcy or failure to make any due payment within a certain period. If BioNTech Zhuhai terminates the BioNTech Zhuhai Assignment Agreement, we are obligated to, among other things, assign, transfer, and convey back to BioNTech Zhuhai, free of charge, all right, title, and interest in related intellectual property and regulatory materials to enable BioNTech Zhuhai to continue development and commercialization of such compounds or products.

Research Collaboration and Option Agreement

On April 12, 2024, we entered into a Research Collaboration and Option Agreement with BioNTech Zhuhai ("BioNTech Zhuhai Option Agreement"), pursuant to which (i) the parties agreed to collaborate with respect to the discovery and preclinical development of novel bispecific antibodies directed to certain target combinations of interest and (ii) BioNTech Zhuhai granted us an exclusive option to license the resulting antibodies developed under such discovery and preclinical development.

We have the right to nominate a certain number (up to 10) of target combinations during the three-year period (through April 12, 2027) following the effective date of the agreement, and for each nominated target combination, BioNTech Zhuhai is responsible for conducting a research program to design, identify, generate, and evaluate bispecific antibody candidates directed to such target combination pursuant to a research plan. We have the right to exercise the option to license such bispecific antibody candidates and upon exercise, the parties will negotiate exclusively and execute a license agreement within a specified period. If we do not exercise the option, or if the parties fail to execute a license agreement within a specified period, BioNTech Zhuhai is free to develop the applicable target combination and related compounds or enter into a license agreement with a third party on terms no less favorable to BioNTech Zhuhai than the terms offered by us to BioNTech Zhuhai.

For each research program conducted under the BioNTech Zhuhai Option Agreement, we are obligated to pay BioNTech Zhuhai a one-time research fee of $0.5 million, subject to adjustment if we request additional research or development activities. If a compound becomes abandoned and BioNTech Zhuhai subsequently licenses such compound to a third party, BioNTech Zhuhai is obligated to pay us a revenue share equal to certain percentages of the licensing net proceeds, ranging from mid-single-digit to sub-teen percentages, with the applicable percentage dependent on the development stage of such compound at the time BioNTech Zhuhai licenses such compound, subject to a minimum payment.

Within five years following the effective date of the agreement, if BioNTech Zhuhai identifies a bispecific antibody in the field of inflammatory diseases and immunology that is not subject to our option and intends to license it to a third party, BioNTech Zhuhai must notify us and we have the right to notify BioNTech Zhuhai of our interest within a specified period. Upon our notice, the parties will negotiate in good faith on a non-exclusive basis for a certain period of time to reach a binding term sheet for a subsequent license agreement, and if we do not notify BioNTech Zhuhai or the parties fail to reach a binding term sheet or enter into a subsequent license agreement within a specified period, BioNTech Zhuhai is free to grant to any third party licenses or rights to such compounds.

Unless earlier terminated, the BioNTech Zhuhai Option Agreement will remain in effect for three years following the effective date of the agreement, subject to renewal upon mutual agreement. Each party may terminate in the event of the other party's material breach, subject to a customary cure period, or bankruptcy, or, in BioNTech Zhuhai's case, for our non-payment for a specified period.

Exclusive License Agreement

Pursuant to the BioNTech Zhuhai Option Agreement, we exercised an option to license a certain antibody candidate discovered and developed by BioNTech Zhuhai directed to TL1A and IL-23p19, the BBT003 program, and entered into an Exclusive License Agreement with BioNTech Zhuhai on September 28, 2025 (the "BioNTech Zhuhai License Agreement"), pursuant to which BioNTech Zhuhai granted us an exclusive, royalty-bearing, sublicensable (subject to certain notice or consent rights of BioNTech Zhuhai) license under certain intellectual property rights controlled by BioNTech Zhuhai and its affiliates to develop, manufacture, and commercialize the licensed compounds and related products worldwide. We have provided written notice to BioNTech Zhuhai to exercise an option to license an additional antibody candidate discovered and developed by BioNTech Zhuhai directed to the BBT004 program.

We are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for at least one licensed product in each Major Market (the United States, Europe, Japan, and Greater China), and, if we obtain regulatory approval for a licensed product in any country in a Major Market, commercialize such licensed product, including obtaining pricing and reimbursement approval. In addition, we must obtain IND approval for at least one licensed product in any country worldwide on or before the two-year anniversary of October 9, 2025 and dose the first patient with a licensed product in a Phase 2 clinical trial on or before the four-year anniversary of October 9, 2025; in each case subject to our 12-month extension right.

We are subject to certain notice obligations to BioNTech Zhuhai if we develop a licensed product in the oncology field, which may prompt BioNTech Zhuhai to buy back the rights in such licensed product in the oncology field. Until May 7, 2028, BioNTech Zhuhai and its affiliates are restricted from developing any bispecific antibody

that is not a licensed compound or licensed product and that is directed to TL1A and IL-23p19 as a primary mechanism of action in the I&I field.

Under the BioNTech Zhuhai License Agreement, we paid BioNTech Zhuhai a $1.0 million upfront payment in cash during the year ended December 31, 2025, and are obligated to pay them an annual license fee of $57,500 until the first commercial sale of the first licensed product, with aggregate development milestone payments that could reach $6.9 million, aggregate first commercial sale milestone payments that could reach $57.5 million, and additional aggregate sales milestones that could reach $217.5 million, with each milestone payment payable only once upon the first achievement of the applicable milestone event, as well as royalties in a low-single-digit percentage of net sales by us, our affiliates, or sublicensees on a licensed product-by-licensed product and country-by-country basis, subject to certain customary reductions. Our obligation to pay BioNTech Zhuhai royalties will commence on the first commercial sale of a licensed product in a given country and end, on a licensed product-by-licensed product and country-by-country basis, upon the latest of patent expiration, regulatory exclusivity expiration, or termination, or ten years after such first commercial sale in such country (the "Royalty Term"). Pursuant to a certain payment agreement entered into among BioNTech Zhuhai, its upstream licensor Adimab, LLC ("Adimab"), and us on September 29, 2025, the rights of which are sublicensed to us under the BioNTech Zhuhai License Agreement, we have paid a one-time fee of $0.5 million in 2025 directly to Adimab and are obligated to make payments directly to Adimab to satisfy certain payment obligations owed by BioNTech Zhuhai to Adimab, which include aggregate development milestone payments that could reach $3.0 million and marketing approval milestone payments that could reach $3.0 million, on a licensed product-by-licensed product basis, and royalties in a low-single-digit percentage of net sales of certain of the licensed products under the BioNTech Zhuhai License Agreement by us, our affiliates, or sublicensees, subject to certain customary reductions.

Unless earlier terminated, the BioNTech Zhuhai License Agreement will expire on a licensed product-by-licensed product and country-by-country basis at the end of the applicable Royalty Term and we may terminate for any or no reason upon advance written notice to BioNTech Zhuhai. BioNTech Zhuhai may terminate if we or our sublicensees shelve development or pre-launch commercialization of a program for a certain time period without justification and we fail to cure such shelving event, or if we or our sublicensees challenge the patents licensed to us by BioNTech Zhuhai. In addition, either party may terminate for the other party's material breach or insolvency or as a result of certain force majeure circumstances, each subject to certain notice and/or cure periods. Upon termination (but not expiration), all licenses and all other rights granted to us terminate, and we are obligated to grant BioNTech Zhuhai a reversion license under certain intellectual property rights controlled by us and used in connection with the licensed products, and transfer all regulatory materials and know-how within the reversion IP to BioNTech Zhuhai.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing.

Our product candidates are regulated as biologics. Biologics are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local, and foreign statutes and regulations. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by comparable foreign regulatory agency before they may be legally marketed in foreign countries.

U.S. Biological Products Development Process

The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests and preclinical animal trials and applicable requirements for the humane use of laboratory animals and formulation studies, with certain studies

conducted in accordance with applicable regulations, including good laboratory practice ("GLP") requirements;

- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") or ethics committee before each clinical site may initiate each trial;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practice ("GCP") regulations and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use and proposed doses.
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of the BLA to file the application for substantive review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP requirements to assure that the facilities, methods, and controls are adequate to preserve the biological product's identity, strength, quality, and purity;
- potential FDA audit of the clinical study sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. An IND sponsor must submit, among other things, the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, requests additional information, requires changes to the protocol, or places the IND on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding questions or concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance with FDA requirements, in which case clinical trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. FDA may also place a trial on a partial clinical hold. A partial clinical hold is a delay or suspension of only part of the clinical work requested or ongoing under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only begin or resume after the FDA has notified the sponsor that the investigation may proceed.

Clinical trials involve the administration of the investigational product to human subjects, and must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria, and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be

submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse reactions, findings from other studies suggesting a significant risk to humans exposed to the same or similar biologics or, in the case of biologic-device combination products, the device component, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Furthermore, an independent IRB or ethics committee must review and approve each protocol before each institution participating in the clinical trial can commence the trial at that institution, review and approve the relevant information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed, and otherwise comply with IRB regulations. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Human clinical trials are typically conducted in phases that may overlap or be combined:

- ***Phase 1***. The biological product candidate is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- ***Phase 2***. The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance, optimal dosage, and dosing schedule.
- ***Phase 3***. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, purity and potency, and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

During all phases of clinical development, regulatory agencies require extensive reporting, monitoring, and auditing of all clinical activities, clinical data, and clinical study investigators.

A sponsor, an IRB or independent ethics committee, the FDA, or other regulatory or monitoring authorities may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk, failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols, failure to demonstrate a benefit from using the investigational drug, or changes in government regulations or administrative actions.

Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to submit a summary of the results of their clinical trials after completion of a trial, unless an extension or a certification permitting delayed submission is obtained from the government.

U.S. FDA Review and Approval Processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies, or from a number of alternative sources, such as studies initiated by investigators or other third parties. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to an annual program fee. A waiver of certain user fees may be obtained under certain limited circumstances.

When a BLA is submitted, the FDA conducts a preliminary review within the first 60 days after submissions to determine whether the application is sufficiently complete to be accepted for filing. If it is not, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the supplemental information, and review of the application is delayed. Upon accepting the BLA for filing, the FDA will conduct an in-depth review of the BLA to determine, among other things, whether the product is safe, pure, and potent (or effective) for its intended use. As part of the BLA review, FDA also evaluates whether the manufacturing of the products is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of ten months for a standard review and six months for priority review from the date of "filing" of an original BLA to review and act on the submission. A standard review typically takes 12 months, and a priority review typically takes eight months, from the date the NDA or BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The FDA does not always meet its PDUFA goal dates. The review process can be significantly extended by FDA requests for additional information or clarification, the applicant's submission of additional information, or other reasons. The review process may also take more than one cycle or FDA could fail to meet the PDUFA goal date.

The FDA may refer an application for a novel biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and may provide a recommendation as to whether the application should be approved and under what conditions. This advisory committee makes a recommendation to the FDA, which is not binding on the FDA, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and cGCP requirements.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the FDA decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor (for example, requiring labeling changes) or major (for example, requiring additional clinical trials). Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the FDA may impose limitations on the proposed indication or the proposed labeling, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk evaluation and mitigation strategy ("REMS"), or otherwise limit the scope of any approval. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS in connection with the application. The FDA will not approve the application without an approved REMS, if one is required. A REMS may include various elements,

ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug or other elements to assure safe use, depending on what the FDA considers necessary for the safe use of the drug. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Under the Pediatric Research Equity Act ("PREA"), certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Under PREA, original NDAs and BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness, or safety, purity, and potency, of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe, pure, and potent. The FDA may waive or defer the requirement for a pediatric assessment, either at a company's request or by the FDA's initiative. A deferral may be granted for several reasons, including a finding that the biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional data need to be collected before the pediatric clinical trials begin.

Expedited development and review programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational product. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a marketing application is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the applications and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A BLA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of BLAs with a standard review designation under its current PDUFA review goals.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

The Orphan Drug Act established incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States at the time of the request for orphan designation or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition and meets other applicable requirements, the FDA may grant Orphan Drug Designation to the product for that use. Orphan designation must be requested before submitting a BLA. After the FDA grants Orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has Orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to Orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with Orphan exclusivity or inability to manufacture the product in sufficient quantities of the Orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same approved indication or use, or the same drug or biologic for a different indication or use. The other benefits of Orphan Drug Designation include tax credits for clinical testing expenses and exemption from user fees.

A designated Orphan drug may not receive Orphan drug exclusivity if it is approved for a use that is broader than the disease or condition for which it received Orphan designation. In addition, Orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with Orphan exclusivity within the relevant approved use or indication or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs relating to the approved use or indication of patients with the relevant rare disease or condition.

FDA Regulation of Combination Products

A combination product is a product composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product, including:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for reviewing a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA centers for different components for a

combination product, although it does not preclude consultations by the lead center with other centers of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a biologic-device combination product is attributable to the biologic component, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues related to combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products and for assignment of the FDA center that has primary jurisdiction for reviewing combination products where the jurisdiction is unclear or in dispute.

A combination product with a biologic primary mode of action generally would be reviewed and approved pursuant to the biologics approval processes under the FDCA. In reviewing the BLA application for such a biologic-led combination product, however, FDA reviewers at CBER could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability, and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both biologics and devices, including the Quality Management System Regulation ("QMSR") applicable to medical devices. Failure to comply with applicable regulatory requirements with respect to any component of a combination product can result in enforcement action by the FDA, which may include any of the following sanctions: warning or untitled letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, refusal or denial of submissions for new products, or withdrawal of approval.

Post-Approval Regulatory Requirements

Even if regulatory approval is granted, a marketed product is subject to continuing comprehensive requirements under federal, state, and foreign laws and regulations, including requirements and restrictions regarding adverse event reporting, recordkeeping, marketing, and compliance with cGMPs. Adverse events reported after approval of a drug can result in additional restrictions on the use of a marketed product or requirements for additional post-marketing studies or clinical trials. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use.

Manufacturers of our product candidates are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Other post-approval requirements applicable to biological products include record-keeping requirements, reporting of adverse effects, and reporting updated safety and efficacy information. Once an approval is granted, the FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements relating to the manufacture or promotion of an approved product may result in restrictions on the marketing of a product, revisions to the approved labeling to add new safety

information, imposition of requirements for post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program, fines, warning letters, or untitled letters, clinical holds on ongoing or planned clinical studies, refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals, product seizure or detention, or refusal to permit the import or export of products, consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs, mandated modification of promotional materials and labeling and the issuance of corrective information, issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product, or withdrawal of the product from the market as well as significant administrative, civil, or criminal sanctions. In addition, the FDA closely regulates the marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may legally prescribe commercially-available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Combination Products

The SubQ formulations of our product candidates are being developed together with an injector device, such as an autoinjector, pre-filled syringe, or on-body device, which will render them combination products with a device component. Specifically, under regulations issued by the FDA, a combination product may include:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and composed of drug and device products, device and biological products, biological and drug products or biological products, drug products and device products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product, the labeling of the other product would need to be updated (e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose); or
- an investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although it does not preclude consultations by the lead center with another FDA center. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. The FDA has established an Office of Combination Products to address issues regarding combination products and provide more certainty to the regulatory review process. This office is responsible for developing guidance and regulations to clarify the regulation of combination products, and for assigning the FDA center that will have primary jurisdiction for review of a combination product where the jurisdiction is unclear or in dispute.

Following approval of a combination product, each component of a combination product retains its regulatory status (as a biologic or device, for example) and is subject to the requirements established by the FDA for that type of component.

A combination product candidate with a biologic primary mode of action, as we expect our combination products to be regulated, generally would be reviewed and approved pursuant to a BLA. In reviewing the BLA for such a product, however, FDA reviewers in the biologic center could consult with their counterparts in the device center to ensure that the drug and device component of the combination product candidate, as applicable, met all requirements applicable to its category. In addition, under FDA regulations, combination products are subject to the cGMP requirements applicable to each component within the combination.

Biosimilars and Exclusivity in the United States

The 2010 Patient Protection and Affordable Care Act ("PPACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through, as applicable, analytical studies, animal studies, and a clinical study or studies. Interchangeability means that a product is biosimilar to the reference product and can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as the first interchangeable for biologic products. Substitution at the pharmacy level of biosimilar products deemed to be interchangeable is governed by state pharmacy law.

A biologic product can also obtain pediatric exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity protection. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Foreign Regulatory Review Process

In addition to regulations in the United States, sponsors are subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies, marketing approval of new medicines, and any commercial sales and distribution of our product candidates. Requisite approvals from regulatory authorities in foreign countries must be obtained prior to the commencement of clinical studies or marketing of any approved product in those countries. Certain countries outside of the United States have a similar process that require the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. For example, in the European Union, the Clinical Trials Regulation ("CTR") repealed the Clinical Trials Directive (EC) No. 2001/20/EC in the EU Member States. The CTR harmonizes the processes for assessment and supervision of clinical trials throughout the EU. Clinical trial sponsors must apply to start a new clinical trial via the Clinical Trials Information System ("CTIS"), and any trials approved under the Clinical Trials Directive that continue running need to comply with the CTR, and their sponsors must have recorded information on them in CTIS. National regulators in the EU Member States and EU/EEA countries use the CTIS. The requirements and the process governing the conduct of clinical studies, product licensing, coverage, pricing, and reimbursement vary from country to country. In all cases, clinical studies must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on pricing and the availability of coverage and adequate reimbursement from third-party payors. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Third-party payors may attempt to control costs by limiting coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication, requiring pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies, and by limiting the amount of reimbursement for particular procedures or drug treatments. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. The Medicare and Medicaid programs are often used as models by private payors and other governmental payors to develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for the product or will provide coverage at an adequate reimbursement rate.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products to obtain third-party payor coverage, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, pricing, reimbursement, and healthcare payment systems vary significantly by country, and many countries have implemented price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability or our partners' ability to sell our products profitably.

U.S. Healthcare Reform

The United States and some other jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our future products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a

maximum fair price for certain high-priced single-source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. In June 2026, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule that would codify policies established in guidance documents for the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and beyond. CMS plans to release guidance in 2026 to implement policies related to the effectuation of the maximum fair price ("MFP") for the Medicare Drug Price Negotiation Program for 2028, consistent with sections 11001(c) and 11002(c) of the Inflation Reduction Act. This guidance will specify the requirements that will be applicable to manufacturers and Part B providers for the effectuation of the MFP in 2028.

Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through which U.S. patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. In November 2025, the Centers for Medicare & Medicaid Services announced a voluntary initiative called the GENEROUS Model to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. In addition, in April 2026, the Trump administration issued a proclamation imposing tariffs under Section 232 of the Trade Expansion Act on imports of brand pharmaceuticals, biologics, and associated pharmaceutical ingredients, beginning July 31, 2026. Exempted from these tariffs, among others, are companies that have executed or are negotiating agreements with the federal government regarding most favored nation pricing and onshoring of production and research and development. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs or that increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover research and development costs, ability to attract potential investors and potential buyers in the future, or the pricing of our approved product in the United States and in foreign countries. The impact of these and future legislative, executive, and administrative actions implemented by the government on us and the pharmaceutical industry as a whole is unclear.

We expect that these and other reform measures that may be adopted in the future, may result in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once regulatory approval is obtained.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug products are subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state attorneys general, and other state and local government agencies.

If our operations are found to be in violation of any of the U.S. federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts, and

the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We may also be subject to additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement with a governmental entity to resolve allegations that we have violated these laws. To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-approval requirements, including safety surveillance, anti-fraud, and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations, and standards govern the collection, use, access to, confidentiality, and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital

As of September 30, 2026, we had 30 full-time employees, 24 of whom were engaged in research and development activities. None of our employees are represented by a labor union or covered under a collective bargaining agreement. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors, and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain, and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters are located in Boston, Massachusetts, where we have access to approximately 250 square feet of office space pursuant to a services agreement that expires on April 28, 2027. We do not own any real property. We believe that our existing facilities are adequate for our current needs but expect to need additional space as we grow. We believe that suitable additional or alternative space would be available as required in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our current executive officers and directors as of October 26, 2026:

Name	Age	Position(s)
Executive Officers		
Shanshan Xu, M.D., Ph.D., M.B.A.	43	Co-Founder, Chief Executive Officer, President, and Chairperson
Jonathan I. Lieber, M.B.A.	57	Chief Financial Officer
Thang Ho, Ph.D.	42	Co-Founder and Chief Development Officer
Key Employee		
Crystal MacKay	48	Chief Operating Officer
Non-Employee Directors		
Derek DiRocco, Ph.D.[(1)(2)]	46	Director
Christian Foerster, M.Sc.[(1)(3)]	48	Director
Helmut Jeggle, M.B.A.[(3)]	56	Co-Founder and Director
Howard Liang, Ph.D., M.B.A.[(1)(2)]	63	Lead Independent Director

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee

Executive Officers

Shanshan Xu, M.D., Ph.D., M.B.A. is our co-founder and has served as our Chief Executive Officer and President and a member of our board of directors since our Inception. Since September 2026, she has served as Chairperson of our board of directors. From May 2024 to May 2026, Dr. Xu served as a Special Advisor to BioNTech, a publicly-traded biotechnology company focused on immunotherapies against cancer and infectious disease. From November 2020 to May 2024, Dr. Xu held various leadership roles of increasing responsibility at BioNTech, including most recently as Vice President, Asia Pacific and China Development and then as Vice President, External Innovations. Prior to BioNTech, from September 2018 to April 2020, Dr. Xu served as Senior Biotech Research Analyst at Berenberg Capital Markets, a privately-held investment bank. From 2017 to 2018, Dr. Xu served as an Associate Analyst at Deutsche Bank Securities, a global investment bank, and from 2016 to 2017, she served as an Associate Analyst at Cowen and Company (now known as TD Cowen). Dr. Xu holds a Bachelor of Medicine in Clinical Medicine from Peking University, a Ph.D. in Biomedical Engineering from the University of California, Irvine, and an M.B.A. from the Massachusetts Institute of Technology.

We believe Dr. Xu is qualified to serve on our board of directors because of the perspective and experience she brings as our Chief Executive Officer and as our co-founder, her scientific and medical expertise, her deep understanding of our business and strategy, and her extensive experience in business development and strategic partnerships in the biotechnology industry.

Jonathan I. Lieber, M.B.A. has served as our Chief Financial Officer since September 2026. He is also currently serving part-time as Chief Financial Officer of Rallybio Corporation, a clinical-stage biotechnology company, a position he has held since February 2023. Prior to joining Bambusa, from September 2021 to November 2022, Mr. Lieber served as the Chief Financial Officer of Applied Genetic Technologies Corporation, a publicly-traded clinical-stage biotechnology company. From December 2018 to September 2021, Mr. Lieber was a Managing Director at Danforth Advisors, a firm providing strategic and operational finance and accounting for life science companies. From July 2015 until December 2018, Mr. Lieber served as Chief Financial Officer of Histogenics Corporation, a publicly-traded cell therapy company. Mr. Lieber also previously served as the Chief Financial Officer of Metamark Genetics, Inc., Repligen Corporation, Xcellerex, Inc., and Altus Pharmaceuticals. Mr. Lieber

began his career in healthcare as an investment banker at Salomon Brothers/Salomon Smith Barney and SG Cowen. He has been a member of the board of directors of Decoy Therapeutics, Inc., a publicly-traded biotechnology company, since June 2020, Mindwalk Holdings Corp., a publicly-traded bio-native AI company, since July 2025, and Zola Therapeutics, a privately-held biotechnology company, since February 2024. Mr. Lieber holds a B.S. in business administration and finance from Boston University and an M.B.A. in finance from New York University's Leonard N. Stern School of Business.

Thang Ho, Ph.D. is our co-founder and has served as our Chief Development Officer since March 2026. He previously served as our Chief Scientific Officer from October 2025 to March 2026 and as our Senior Vice President, Head of Development Science from April 2024 to October 2025. Prior to joining Bambusa, from November 2021 to April 2024, Dr. Ho served in various leadership roles of increasing responsibility at BioNTech, including most recently Director, Clinical Pharmacology and Pharmacometrics from December 2022 to April 2024. From April 2021 to November 2021, Dr. Ho was Associate Director, Quantitative Pharmacology Lead, Cell Therapies, at Takeda Pharmaceutical Company, a publicly traded pharmaceutical company. From March 2020 to April 2021, Dr. Ho served as Senior Scientist at Vertex Pharmaceuticals, a publicly-traded biotechnology company. From October 2018 to March 2020, Dr. Ho served as Senior Scientist at CytomX Therapeutics, a public biotechnology company. Dr. Ho holds a B.S. and an M.S. in Chemical Engineering from the University of Arkansas, and a Ph.D. in Chemical Engineering from the University of Pittsburgh.

Key Employee

Crystal MacKay has served as our Chief Operating Officer since July 2026. She previously served as our Senior Vice President, Finance and Business Operations from September 2025 to July 2026, our Vice President, Finance and Business Operations from August 2025 to September 2025, and our Vice President and Chief of Staff from October 2024 to August 2025. Prior to joining Bambusa, from August 2019 to September 2023, Ms. MacKay served in various roles of increasing responsibility at BTIG, a privately-held financial services firm, including most recently Director of Healthcare Investment Banking from January 2023 to September 2023. From July 2018 to September 2018 Ms. MacKay served as Director, Billing and Managed Care Strategy, and from October 2018 to August 2019, Ms. MacKay served as Director, Business Operations, at Oxford Immunotec (acquired by PerkinElmer, now known as Revvity), a diagnostics company that was publicly traded at the time. From February 2016 to July 2018, Ms. MacKay served as Director of Revenue Cycle and Managed Care Contracting at Strata Pathology Services, a privately-held diagnostic laboratory. From March 2004 to October 2015, Ms. MacKay served in various roles of increasing responsibility at Calloway Labs, a privately-held clinical toxicology laboratory, including as a member of the board of directors. Ms. MacKay holds a B.A. in Business Communications from the University of Massachusetts.

Non-Employee Directors

Derek DiRocco, Ph.D. has served as a member of our board of directors since February 2025. Dr. DiRocco is currently a Partner at RA Capital Management, L.P., a multi-stage investment manager dedicated to evidence-based investing in healthcare and life science companies, where he has served in various roles of increasing responsibility since July 2013. Dr. DiRocco currently serves on the boards of several publicly-traded biotechnology companies, including Acrivon Therapeutics since November 2021, Mineralys Therapeutics, Inc. since June 2022, and Evommune since October 2024. Dr. DiRocco previously served on the boards of publicly-traded clinical-stage biopharmaceutical companies Achilles Therapeutics plc, Connect Biopharma Holdings Limited, Werewolf Therapeutics, Inc., 89bio, Inc., and iTeos Therapeutics, Inc., and also serves on the boards of several privately-held biotechnology companies. Dr. DiRocco holds a B.A. in Biology from the College of the Holy Cross and a Ph.D. in Pharmacology from the University of Washington, and conducted his postdoctoral research at Brigham and Women's Hospital/Harvard Medical School.

We believe Dr. DiRocco is qualified to serve on our board of directors because of his extensive investment experience in biopharmaceutical companies as well as his academic background and public company board experience.

Christian Foerster, M.Sc. has served as a member of our board of directors since July 2026. Since October 2026, Mr. Foerster has served as Chief Operating Officer of neoshare AG, a privately-held software company. Since August 2026, Mr. Foerster has served as a consultant at ATHOS, a privately-held family investment office investing in the life science industry, where he previously served as Managing Director from October 2024 to July 2026. From October 2007 to September 2024, Mr. Foerster served in various leadership roles of increasing responsibility at Nokia Corporation, a publicly-traded telecommunications, information technology, and consumer electronics corporation, including most recently as Chief Operating Officer, Cloud and Network Services from January 2021 to September 2024. Mr. Foerster holds a Master of Science (Dipl. Ing), Industrial Engineering & Management from Munich University of Applied Sciences.

We believe Mr. Foerster is qualified to serve on our board of directors because of his operational leadership experience at publicly-traded and privately-held companies and the investment experience in the pharmaceutical and biotechnology industries he has gained through his roles at ATHOS.

Helmut Jeggle, M.B.A. is our co-founder and has served as a member of our board of directors since June 2024. From September 2007 to May 2021, Mr. Jeggle served in various leadership roles of increasing responsibility at ATHOS, a privately-held family investment office, including most recently as General Partner. In May 2021, he founded his own family office, Salvia. The investment vehicle Salvia GmbH, originally established as an angel investment vehicle in August 2012, has been managed by him as Managing Director since its incorporation. Salvia Investment GmbH is a 100% subsidiary of Salvia GmbH. Mr. Jeggle serves on the supervisory boards of several publicly-traded companies, including as Chairman of the supervisory board of BioNTech and as a member of the supervisory board of 4SC AG, and also serves on the supervisory boards of several privately-held companies. Mr. Jeggle holds a degree in business administration from the University of Applied Sciences Neu-Ulm and an M.B.A. from the Stuttgart Institute of Management and Technology.

We believe Mr. Jeggle is qualified to serve on our board of directors because of his investment experience in biopharmaceutical companies as well as his academic background and public company board experience.

Howard Liang, Ph.D., M.B.A. has served as a member of our board of directors since July 2026. From July 2021 to December 2025, Dr. Liang served in various leadership roles at Tessera Therapeutics, a privately-held biotechnology company, including as President and previously as President and Chief Financial Officer. From July 2015 to June 2021, Dr. Liang served as the Chief Financial Officer and Chief Strategy Officer at BeiGene Ltd (now known as BeOne Medicines), a publicly-traded biotechnology company. From 2005 to 2015, Dr. Liang served in various leadership roles of increasing responsibility at Leerink Partners LLC, an investment bank specializing in the healthcare industry, including most recently as Managing Director and Head of Biotechnology Equity Research. Dr. Liang served as a Senior Biotechnology Analyst at two investment banks: A.G. Edwards Inc. (now known as Wells Fargo Advisors), from 2004 to 2005, and JMP Securities (now known as Citizens JMP Securities, LLC), from 2003 to 2004. From 2000 to 2003, Dr. Liang served as an Associate Analyst at Prudential Securities, where he covered major and specialty pharmaceuticals. From 1992 to 2000, Dr. Liang was at Abbott Laboratories (now known as Abbvie), where he was a Senior Scientist and a member of a structure-based discovery team. Dr. Liang has served on the board of directors of Tenacia Biotechnology, a privately-held biotechnology company, since February 2023, and served as a member of the HKEx Biotech Advisory Panel from 2018 to 2024. Dr. Liang holds a B.S. in Chemistry from Peking University and both his M.B.A. and Ph.D. in Biochemistry and Molecular Biology from The University of Chicago.

We believe Dr. Liang is qualified to serve on our board of directors because of his leadership experience at a publicly-traded biotechnology company, his scientific expertise, and his extensive experience in healthcare financing.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Code of Business Conduct and Ethics

Our board of directors has adopted, effective prior to the completion of this offering, a code of business conduct and ethics. Our code of business conduct and ethics will apply to all of our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, as well as our contractors, consultants, and agents. Following this offering, the full text of our code of business conduct and ethics will be posted on the investor relations page on our website at www.bambusatx.com. We intend to disclose any amendments to our code of business conduct and ethics, or waivers of its requirements, applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on our website identified above, or in filings under the Exchange Act.

Board of Directors

Our business and affairs are managed under the direction of our board of directors. Our board of directors currently consists of five directors. After this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation, or removal.

Classified Board

Our amended and restated certificate of incorporation that will be effective prior to the completion of this offering, will divide our board of directors into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be Christian Foerster, M.Sc. and Helmut Jeggle, M.B.A., and their terms will expire at the annual meeting of stockholders to be held in 2027;
- the Class II director will be Derek DiRocco, Ph.D., and his term will expire at the annual meeting of stockholders to be held in 2028; and
- the Class III directors will be Howard Liang, Ph.D., M.B.A. and Shanshan Xu, M.D., Ph.D., and M.B.A., and their terms will expire at the annual meeting of stockholders to be held in 2029.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our amended and restated certificate of incorporation and our amended and restated bylaws. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The classification of our board of directors with staggered three-year terms may have the effect of delaying or preventing changes in control of our company. See the section titled “Description of Capital Stock—Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Certificate of Incorporation and Our Bylaws.”

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment, and affiliations, our board of directors has determined that Derek DiRocco, Ph.D., Christian Foerster, M.Sc., Helmut Jeggle, M.B.A., and Howard Liang, Ph.D., M.B.A., representing four of our five directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is an “independent director” as defined under the listing standards of Nasdaq. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our

company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Lead Independent Director

Our board of directors has adopted, effective prior to the completion of this offering, corporate governance guidelines. Our corporate governance guidelines provide that one of our independent directors may serve as our lead independent director at any time when the Chairperson of our board of directors is not independent, including when our Chief Executive Officer serves as the Chairperson of our board of directors. Because Shanshan Xu, M.D., Ph.D., M.B.A. is our Chairperson and also our Chief Executive Officer, our board of directors has appointed Howard Liang, Ph.D., M.B.A. to serve as our lead independent director. As lead independent director, Dr. Liang will preside over periodic meetings of our independent directors, serve as a liaison between our chairperson and our independent directors and perform such additional duties as our board of directors may otherwise determine and delegate.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks, and operational risks. The compensation committee established by the board of directors will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee established by the board of directors will be responsible for overseeing the management of risks relating to accounting matters and financial reporting, as well as compliance with legal and regulatory requirements and risks and exposures associated with cybersecurity, information security, and privacy matters. The nominating and corporate governance committee established by the board of directors will be responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee will be responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is and will continue to be regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected the board of directors' leadership structure.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will have the composition and responsibilities described below. Members will serve on these committees until the earlier of their resignation or removal by our board of directors in its discretion.

Audit Committee

Immediately following this offering, the members of our audit committee will be Derek DiRocco, Ph.D., Christian Foerster, M.Sc., and Howard Liang, Ph.D., M.B.A., with Howard Liang, Ph.D. serving as chairperson, each of whom meets the requirements for independence under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to audit committee members. Each member of our audit committee also meets the financial literacy requirements of the listing standards of Nasdaq. In addition, our board of directors has determined that Howard Liang, Ph.D., M.B.A. is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act. Following completion of this offering, our audit committee will, among other things:

- select, retain, compensate, evaluate, oversee and, where appropriate, terminate and replace our independent registered public accounting firm;
- review and approve in advance the scope and plans for the audits and the audit fees and approve all non-audit and tax services to be performed by the independent auditor;

- evaluate the independence and qualifications of our independent registered public accounting firm;
- review our financial statements, and discuss with management and our independent registered public accounting firm the results of the annual audit and the quarterly reviews;
- review and discuss with management and our independent registered public accounting firm the quality and adequacy of our internal controls and our disclosure controls and procedures;
- discuss with management our procedures regarding the presentation of our financial information, and review earnings press releases and guidance;
- oversee the implementation and performance of our internal audit function, if any;
- set hiring policies with regard to the hiring of employees and former employees of our independent auditor and oversee compliance with such policies;
- review, approve, and monitor related party transactions;
- adopt and oversee procedures to address complaints regarding accounting, internal accounting controls, and auditing matters, including confidential, anonymous submissions by our employees of concerns regarding questionable accounting or auditing matters;
- review and discuss with management and our independent auditor the adequacy and effectiveness of our legal, regulatory, and ethical compliance programs; and
- review and discuss with management and our independent auditor our guidelines and policies to identify, monitor, and address enterprise risks, including major financial risks exposures and risks and exposures associated with cybersecurity, information security, and privacy matters.

Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Compensation Committee

The members of our compensation committee are Derek DiRocco, Ph.D. and Howard Liang, Ph.D., M.B.A., with Derek DiRocco, Ph.D. serving as chairperson, each of whom meets the requirements for independence under the rules and regulations of the SEC and the listing standards of Nasdaq applicable to compensation committee members. Each member of our compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act. Following completion of this offering, our compensation committee will, among other things:

- review, approve, or make recommendations to our board of directors regarding the compensation for our executive officers, including our chief executive officer;
- review, approve, and administer our employee benefit and equity incentive plans;
- establish and review the compensation plans and programs of our employees, and ensure that they are consistent with our general compensation strategy;
- make recommendations to our board of directors regarding non-employee director compensation; and
- approve or make recommendations to our board of directors regarding the creation or revision of any clawback policy.

Our compensation committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq.

Nominating and Corporate Governance Committee

Immediately following this offering, the members of our nominating and corporate governance committee will be Christian Foerster, M.Sc. and Helmut Jeggle, M.B.A., with Christian Foerster, M.Sc. serving as chairperson, each of whom meets the requirements for independence under the listing standards of Nasdaq. Following completion of this offering, our nominating and corporate governance committee will, among other things:

- review and assess and make recommendations to our board of directors regarding desired qualifications, expertise, and characteristics sought of board members;
- identify, evaluate, select, or make recommendations to our board of directors regarding nominees for election to our board of directors;
- develop policies and procedures for considering stockholder nominees for election to our board of directors;
- review our succession planning process for our chief executive officer and any other members of our executive management team;
- review and make recommendations to our board of directors regarding the composition, organization, and governance our board of directors and its committees;
- review and make recommendations to our board directors regarding our corporate governance guidelines and corporate governance framework;
- oversee director orientation for new directors and continuing education for our directors;
- oversee the evaluation of the performance of our board of directors and its committees;
- review and monitor compliance with our code of business conduct and ethics, and review conflicts of interest of our board members and officers other than related party transactions reviewed by our audit committee;
- administer policies and procedures for communications with the non-management members of our board of directors; and
- monitor compliance with any stock ownership guidelines.

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable listing standards of Nasdaq.

Compensation Committee Interlocks and Insider Participation

Immediately following this offering, the members of our compensation committee will be Derek DiRocco, Ph.D. and Howard Liang, Ph.D., M.B.A., neither of whom is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Non-Employee Director Compensation

Prior to this offering, we have not implemented a formal policy with respect to compensation payable to our non-employee directors for services on our board of directors. We reimburse our directors for expenses associated with attending meetings of our board of directors and its committees.

In September 2024, we entered into a consulting agreement with Marett Consulting GmbH (the “Marett Consulting Agreement”) pursuant to which Sean Marett, who served on our Board until December 31, 2025, will

provide consulting services to the Company until September 2026, unless otherwise determined. As consideration for his services, Mr. Marett was granted options to purchase shares of our common stock in December 2024, as described in the table below.

None of our non-employee directors earned or were awarded any compensation for service on our board of directors for the year ended December 31, 2025, and accordingly there is no compensation to report in the Director Compensation Table for 2025. Dr. Xu is our only director who was an officer during 2025. See the section titled "Executive Compensation" for information about Dr. Xu's compensation that she received for serving as an officer of our Company during 2025. Dr. Xu did not receive any additional compensation for serving on our board of directors during 2025.

The following table lists all outstanding equity awards held by non-employee directors as of December 31, 2025:

	Option Awards				Stock Awards
Name	Grant Date	Number of Securities Underlying Unexercised Options	Option Exercise Price Per Share	Option Expiration Date	Number of Shares Underlying Unvested Stock Awards
Derek DiRocco, Ph.D.	–	–	–	–	–
Helmut Jeggle, M.B.A.	5/6/2024	–	–	–	1,901,354 (4)
Sean Marett, M.B.A.(1)	12/19/2024	6,129 (2)	$0.34	12/18/2034	–
	12/19/2024	245,181 (3)	$0.34	12/18/2034	
	12/19/2024	55,165 (3)	$0.34	12/18/2034	

(1) Sean Marett, M.B.A. served on our board of directors until December 31, 2025.
(2) The option was granted as compensation for Mr. Marett's service as a non-employee director.
(3) The options were granted as compensation for Mr. Marett's services under the Marett Consulting Agreement.
(4) The shares were granted pursuant to a common stock purchase agreement, by and between the Company and Salvia Investment GmbH, dated May 6, 2024.

In July 2026, Dr. Liang commenced services as a non-employee director pursuant to a director offer letter dated June 18, 2026 (the "Liang Agreement"). Pursuant to the Liang Agreement, Dr. Liang is paid an annual cash retainer of $35,000, made on a quarterly basis in arrears. In addition, in July 2026, our board of directors granted Dr. Liang an option to purchase 153,908 shares of our common stock at an exercise price per share of $8.04. The option vests monthly over three years commencing on July 1, 2026, subject to Dr. Liang continuing to provide services to the Company through each such date. Upon Dr. Liang's termination, he will have 12 months to exercise the vested portion of the option. The option will fully accelerate upon a change in control. The Liang Agreement provides that in the event of an initial public offering of the Company's common stock, Dr. Liang's annual cash retainer is expected to increase to $40,000, with an additional annual cash retainer of $15,000 for service as Chair of our Audit Committee, which may be adjusted pursuant to the terms of the outside director compensation policy adopted in connection with such initial public offering.

Outside Director Compensation Policy

We approved a formal compensation policy for our non-employee directors, which will govern their cash and equity compensation effective in connection with this offering. Our stockholders also approved the initial terms of our outside director compensation policy. The compensation provided under this policy is summarized below.

Cash Compensation

Under the outside director compensation policy, the following cash compensation program has been adopted for our non-employee directors to be effective in connection with and following this offering:

- $40,000 per year for service as a non-employee director (the "non-employee director retainer");
- $30,000 per year for service as non-executive chair of the board of directors;

- $20,000 per year for service as chair of the audit committee;
- $10,000 per year for service as a member of the audit committee;
- $15,000 per year for service as chair of the compensation committee;
- $7,500 per year for service as a member of the compensation committee;
- $10,000 per year for service as chair of the nominating and corporate governance committee; and
- $5,000 per year for service as a member of the nominating and corporate governance committee.

Each non-employee director who serves as a committee chair of our board of directors will receive the cash retainer fee as the chair of the committee but not the cash retainer fee as a member of that committee, provided that the non-employee director who serves as the non-executive chair of the board of directors will receive the annual retainer fees for such role as well as the annual retainer fee for service as a non-employee director. In addition, the above-listed fees for service as chair or member of any committee are payable in addition to the non-employee director retainer. These cash fees to our non-employee directors will be paid quarterly in arrears, prorated based on the number of days during the quarter that the director served in the applicable capacity. We do not pay per-meeting fees for attending meetings of our board of directors or its committees. Under the outside director compensation policy, we also will reimburse our non-employee directors for reasonable travel expenses to attend meetings of the board of directors and its committees.

Equity Compensation

Initial Award. Pursuant to the outside director compensation policy, each person who first becomes a non-employee director after the effective date of the outside director compensation policy will receive, on the first trading day on or after the date such individual first becomes a non-employee director, an initial award of options (the "Initial Award") covering 45,000 shares of our common stock. Each Initial Award will be scheduled to vest in equal monthly installments over a three-year period following the Initial Award's grant date, in each case subject to continued services through the applicable vesting date. If the individual was an employee director, then becoming a non-employee director due to termination of employment will not entitle the person to an Initial Award.

Annual Award. Pursuant to the outside director compensation policy, each non-employee director will receive, on the first trading day immediately following each annual meeting of our stockholders (an "Annual Meeting") that occurs after the effective date of the outside director compensation policy, an annual award of options (the "Annual Award") covering 22,500 shares of our common stock, provided that the first Annual Award granted to an individual who first becomes a non-employee director following the effective date of the outside director compensation policy will cover the number of shares of our common stock equal to the product of (A) 22,500 and (B) a fraction, (i) the numerator of which is the number of fully completed days between the non-employee director's initial start date and the date of the first annual meeting of our stockholders to occur after such individual first becomes a non-employee director, and (ii) the denominator of which is 365, with the resulting fraction rounded down to the nearest whole share and in no event will be greater than one. Each Annual Award will be scheduled to vest in full on the one-year anniversary of the grant date or, if earlier, the date immediately before the date of the next Annual Meeting after the grant date, subject to continued services through the applicable vesting date.

Other Award Terms. Each Initial Award and Annual Award will be granted under the 2026 Plan (or its successor plan, as applicable) and form of award agreement under such plan. Each Initial Award and Annual Award will have a post-termination exercise period for vested options upon the non-employee's termination as a service provider (as defined in the 2026 Plan) of no shorter than 12 months from the date of termination (subject to earlier termination as provided in the 2026 Plan or as a result of the maximum term of the option). Each Initial Award and Annual Award will be a nonstatutory stock option with an exercise price per share equal to 100% of the fair market value of our common stock on the grant date and a term of ten years from the grant date (subject to earlier termination as provided in the 2026 Plan).

Change in Control. In the event we experience a change in control, as defined in the 2026 Plan, each non-employee director's outstanding equity awards covering shares of our common stock will accelerate vesting in full as of immediately prior to such change in control, provided that a non-employee director remains such through the date of such change in control.

Director Compensation Limits. Pursuant to the outside director compensation policy and the 2026 Plan, beginning with the first fiscal year that commences following the effective date of the registration statement of which this prospectus forms a part, no non-employee director may be granted equity awards (the value of which will be based on their grant date fair value determined according to GAAP) and be provided any cash retainer fees in amounts that in the aggregate exceed $750,000 (provided that in the fiscal year of the individual's initial service as a non-employee director, such amount is increased to $1,000,000). Compensation for services as an employee or consultant (other than as a non-employee director) and any incremental fair value resulting from the modification of an award held by a non-employee director do not count toward this limit.

Limitation of Liability and Indemnification of Officers and Directors

We have adopted, effective prior to the completion of this offering, an amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and which contains provisions that limit the liability of our directors and officers for monetary damages to the fullest extent permitted by the Delaware General Corporation Law (the "DGCL"). In addition, if the DGCL is amended to provide for further limitations on the personal liability of directors and officers of corporations, then the personal liability of our directors and officers will be further limited to the greatest extent permitted by the DGCL.

In addition, we have adopted, effective prior to the completion of this offering, amended and restated bylaws, which provide that we will indemnify our directors and officers, and may indemnify our employees, agents, and any other persons, to the fullest extent permitted by the DGCL. Our amended and restated bylaws also provide that we must advance expenses incurred by or on behalf of a director or officer in advance of the final disposition of any action or proceeding, subject to limited exceptions.

Further, we have entered into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements also require us to advance all expenses reasonably and actually incurred by the directors and executive officers in investigating or defending any such action, suit, or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

We have obtained insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against loss arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer, including claims relating to public securities matters, and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law. At present, we are not aware of any pending litigation or proceeding involving any person who is or was one of our directors or officers, or is or was one of our directors or officers serving at our request as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise, for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

EXECUTIVE COMPENSATION

Our named executive officers, consisting of our principal executive officer and our other executive officer serving as of December 31, 2025, were:

- Shanshan Xu, M.D., Ph.D., M.B.A., our Chief Executive Officer; and
- Thang Ho, Ph.D., our Chief Development Officer (as of March 2026) and former Chief Scientific Officer (prior to March 2026).

Other than Drs. Xu and Ho, there were no other executive officers who served during 2025. In September 2026, we entered into an offer letter agreement with Jonathan Lieber who commenced employment with us as our Chief Financial Officer on September 15, 2026. While Mr. Lieber was not an executive officer in 2025 and is not a named executive officer for 2025, we have provided a summary of Mr. Lieber's initial compensation terms as our Chief Financial Officer in an effort to provide information that may be useful to our stockholders.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table for Fiscal 2025

The following table sets forth information regarding the compensation awarded to, earned by, or paid to our named executive officers for the fiscal year ended December 31, 2025:

Name and Principal Position	Year	Salary ($)	Bonus ($)[2]	Stock Awards ($)	Option Awards ($)[1]	All Other Compensation ($)[3]	Total ($)
Shanshan Xu, M.D., Ph.D., M.B.A. *Chief Executive Officer*	2025	458,750	257,508	—	427,514	12,250	1,156,022
Thang Ho, Ph.D. *Chief Development Officer*[4]	2025	337,500	150,009	—	328,719	8,312	824,540

(1) The amount in the "Option Awards" column reflects the aggregate grant-date fair value of the options granted during 2025 and calculated in accordance with FASB, ASC Topic 718, rather than the amounts paid or realized by the named executive officer. The assumptions used to calculate the value of our option awards are the same as those provided in Note 9 to our audited financial statements included elsewhere in this prospectus with respect to the value of the options.
(2) The amount reported represents the discretionary performance bonus payment earned for 2025, as described in the "Annual Performance Bonus Opportunity" section below.
(3) The amount reported represents 401(k) matching contributions paid by us.
(4) Dr. Ho was appointed as Chief Scientific Officer of the Company in October 2025 and promoted to Chief Development Officer in March 2026.

Fixed Cash Compensation

The annual base salary rates for our named executive officers for 2025 were as follows:

Name	2025 Base Salary
Shanshan Xu, M.D., Ph.D., M.B.A.[1]	$ 525,000
Thang Ho, Ph.D.[2]	$ 375,000

(1) In February 2025, Dr. Xu's base salary was increased from $325,000 to $468,000. In June 2025, her base salary was increased from $468,000 to $510,000, then in October 2025, Dr. Xu's base salary was increased from $510,000 to $525,000. In February 2026, Dr. Xu's base salary was increased to $542,063, reflecting a standard cost of living adjustment that was applicable to U.S. employees generally.
(2) In February 2025, Dr. Ho's base salary was increased from $275,000 to $350,000. In September 2025, in connection with his promotion to Chief Scientific Officer, Dr. Ho's base salary was increased from $350,000 to $375,000. In February 2026, in connection with his annual performance review, Dr. Ho's base salary was increased from $375,000 to $430,000. In April 2026, following his promotion to Chief Development Officer, Dr. Ho's base salary was increased from $430,000 to $450,000.

Annual Performance Bonus Opportunity

Our named executive officers are eligible to receive discretionary performance-based cash bonuses, based on individual performance, Company performance, or as otherwise determined appropriate by our board of directors. For 2025, Dr. Xu's annual target bonus was 50% of her annual base salary, and Dr. Ho's annual target bonus was 35% of his annual base salary. For 2026, Dr. Xu's and Dr. Ho's annual target bonuses remain unchanged.

Each of our named executive officers earned discretionary performance-based bonuses for 2025 performance, as set forth in the Summary Compensation Table for Fiscal 2025 above.

Stock-Based Incentive Awards

Our stock-based incentive awards are designed to more closely align our interests and those of our stockholders with the interests of our employees and consultants, including our named executive officers.

Prior to this offering we have only granted equity awards in the form of stock options and RSUs under the terms of our 2024 Plan. In addition, we have granted restricted stock awards pursuant to common stock purchase agreements and value appreciation rights under value appreciation right agreements. Following this offering, we will grant equity awards (including the IPO PSUs and IPO Options, as described below) under the terms of our 2026 Equity Plan. The terms of the 2024 Plan and the 2026 Plan are described below under the section titled "Employee Benefit and Stock Plans." All stock options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award as determined by our board of directors based on an independent third-party valuation.

2025 Option Grants

In August 2025, our board of directors granted Dr. Xu an option to purchase 167,124 shares of common stock and Dr. Ho an option to purchase 128,503 shares of common stock, each with a per share exercise price of $1.84. Such options vest as to $1/4^{th}$ of the shares subject to the option on the one-year anniversary of the vesting commencement date and as to $1/48^{th}$ of the total shares subject to the option monthly thereafter, subject to the applicable service provider continuing to provide services to the Company through each such date. The vesting commencement date of each of the options is June 19, 2025.

2026 Equity Grants

In September 2026, our board of directors granted Dr. Ho an option to purchase 261,079 shares of common stock with a per share exercise price of $13.57. The option vests as to $1/4^{th}$ of the shares subject to the option on the one-year anniversary of the grant date and as to $1/48^{th}$ of the total shares subject to the option monthly thereafter, subject to Dr. Ho continuing to provide services to the Company through each such date.

In connection with this offering, on October 20, 2026, our compensation committee of the board of directors approved option grants to purchase 379,102 shares of common stock (the "IPO Options") and performance-based restricted stock unit awards to be issued up to 758,204 shares of common stock (the "IPO PSUs") to Dr. Xu under the 2026 Plan, which were effective upon the pricing of this offering (or, in the case of IPO PSUs, upon our filing of an S-8 registration statement covering such IPO PSUs). The IPO Options have a per share exercise price equal to the initial public offering price per share and vest over a four-year period, with 25% of the awards vesting after one year and the remaining portion vesting monthly thereafter over the remaining vesting period.

The IPO PSUs vest in full only if we achieve a stock price hurdle of two times the initial public offering price per share, as measured over a 30-day period (the "Stock Price Hurdle"), within a three-year performance period commencing April 1, 2027 (the "Performance Period"). Vesting requires both achievement of the Stock Price Hurdle and continued service through such vest date. If a change in control (as defined in the 2026 Plan) occurs during the Performance Period, the IPO PSU will vest if the per share consideration in the change in control meets or exceeds the Stock Price Hurdle. If the Stock Price Hurdle is not achieved during the Performance Period, no portion of the IPO PSU will vest and the IPO PSU will be forfeited in its entirety. Dr. Xu will generally forfeit the IPO PSUs if her service terminates prior to the Stock Price Hurdle achievement.

Outstanding Equity Awards at Fiscal 2025 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2025.

	Option Awards[1]					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)[2]	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Shanshan Xu, M.D., Ph.D., M.B.A.	5/30/2024					2,593,822 [6]	12,476,284 [7]
	12/19/2024 [3]	97,050	148,131	$0.364	12/18/2029		
	8/16/2025 [4]		167,124	$1.840	8/15/2035		
Thang Ho, Ph.D.	12/19/2024 [3]	58,869	82,421	$0.340	12/18/2034		
	12/19/2024 [5]	50,847	91,664	$0.340	12/18/2034		
	8/16/2025 [4]		128,503	$1.840	8/15/2035		

(1) All of the outstanding stock option awards were granted under and subject to the terms of the 2024 Plan.

(2) The stock option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, or in the case of Dr. Xu's stock option award granted on December 19, 2024, at a per share exercise price equal to 110% of the fair market value on the date of grant, as determined in good faith by our board of directors based on third-party valuations of our common stock.

(3) 1/48th of the shares subject to the option vest on the one-month anniversary of the vesting commencement date, and 1/48th of the total shares subject to the option vest monthly thereafter, subject to the applicable service provider continuing to provide services to the Company through each such date. The vesting commencement date is April 15, 2024 for Dr. Ho and May 1, 2024 for Dr. Xu.

(4) 1/4th of the shares subject to the option vest on the one-year anniversary of the vesting commencement date, and 1/48th of the total shares subject to the option vest monthly thereafter, subject to the applicable service provider continuing to provide services to the Company through each such date. The vesting commencement date is June 19, 2025.

(5) With respect to this option, (i) 103,891 of the shares subject to the option vest as follows: 1/4th of such shares on the 12-month anniversary of the vesting commencement date (April 15, 2024) and an additional 1/48th of such shares on the corresponding day of each month thereafter; (ii) 23,172 of the shares subject to the option vest as follows: 1/48th of such shares on each monthly anniversary of the date that the Company obtains its first first-in-human trial approval from the FDA or a comparable non-U.S. regulatory body (which was obtained on January 31, 2025); and (iii) 15,448 of the shares subject to the option vest as follows: 1/48th of the total number of such shares on each monthly anniversary of the date that the Company obtains its second first-in-human trial approval from the FDA or a comparable non-U.S. regulatory body (which was obtained on May 6, 2025), in each case subject to the applicable service provider continuing to provide services to the Company through each such date.

(6) The shares were granted pursuant to a common stock purchase agreement, by and between the Company and MiNeng, Inc. ("MiNeng"), dated May 30, 2024, which was subsequently amended on June 12, 2024 and February 12, 2025. Dr. Xu is the sole stockholder of MiNeng and therefore has sole voting and dispositive power with regard to the shares held by MiNeng. The shares are subject to a repurchase option, which shall lapse as follows: 1/2 of the shares were released from the repurchase option on the initial closing of the Company's Series A preferred stock financing (February 12, 2025), and a pro rata portion of the other 1/2 of the shares shall be released on the same day of each month thereafter, such that all shares shall be released from the repurchase option on the three-year anniversary of the purchase date (May 30, 2024), subject to Dr. Xu continuing to provide services to the Company. If Dr. Xu's services are terminated without cause or if Dr. Xu resigns for good reason, then the repurchase option shall lapse as to the number of unvested shares that, but for such termination or resignation, would have vested in the nine month period following the termination date. Upon a change of control, the repurchase option shall lapse as to 50% of the unvested shares. If Dr. Xu's services are terminated without cause or Dr. Xu resigns for good reason, in each case within the period that is three months prior to or 12 months following a change of control, the repurchase option shall lapse in full.

(7) Our common stock was not publicly traded as of December 31, 2025. Amounts reported are calculated by multiplying the applicable number of shares by $4.81, which was the fair value of our common stock for accounting and financial reporting purposes as of December 31, 2025.

Agreements with our Named Executive Officers

Offer Letters

The employment of each of our named executive officers is "at will" and may be terminated at any time. We entered into offer letters with each of our named executive officers in 2024 (the "2024 Offer Letters") that provide for their initial terms of employment, including annual base salary and, in the case of Dr. Ho, an annual target performance bonus opportunity and an initial stock option to purchase 142,511 shares, which was granted on December 19, 2024 at an exercise price per share of $0.34. 103,891 shares subject to Dr. Ho's initial stock option

vest over a four-year period measured from his commencement of employment, while 38,620 shares subject to Dr. Ho's initial stock option vest over a four-year period commencing following the achievement of certain performance milestones, in all cases subject to continued service with us, as further described above under "Outstanding Equity Awards at Fiscal 2025 Year-End."

In connection with this offering, we entered into a confirmatory offer letter with each of our named executive officers, which will supersede the 2024 Offer Letters effective in connection with this offering.

Shanshan Xu, M.D., Ph.D., M.B.A

Our confirmatory offer letter with Dr. Xu provides for her continued employment with us on an at-will basis, effective in connection with the completion of this offering. Under her confirmatory offer letter, Dr. Xu's annual base salary will be $672,700 and her annual target bonus opportunity will be 60% of her annual base salary ($403,620). Dr. Xu will also be eligible for certain severance and change in control benefits as described below under "Post-IPO Change in Control and Severance Benefits," which will supersede the terms of her 2024 Offer Letter.

Thang Ho, Ph.D.

Our confirmatory offer letter with Dr. Ho provides for his continued employment with us on an at-will basis, effective in connection with the completion of this offering. Under his confirmatory offer letter, Dr. Ho's annual base salary will be $523,000, and his annual target bonus opportunity will be 40% of his annual base salary ($209,200). Dr. Ho will also be eligible for certain severance and change in control benefits as described below under "Post-IPO Change in Control and Severance Benefits," which will supersede the terms of his 2024 Offer Letter.

Each of Drs. Xu and Ho has executed a confidential information and invention assignment agreement that includes covenants not to compete and not to solicit our employees, customers or other contractors or suppliers for a period of 12 months following termination of the executive's employment with us.

Pre-IPO Change in Control and Severance Benefits

Drs. Xu and Ho are entitled to severance benefits pursuant to their 2024 Offer Letters, which will be superseded in connection with this offering by the applicable participation agreement with respect to each of Drs. Xu and Ho under the Severance Plan (as defined and described below). The 2024 Offer Letters provided for the following benefits in the event of a termination of employment by us without "cause" (and other than due to the executive officer's death or "disability") or by the executive for "good reason" (as such terms are defined in the offer letters), subject to a release of claims:

- continuation of base salary payments for six months for Dr. Xu and three months for Dr. Ho; and
- payment of 100% of the premium costs of continued health coverage under the Consolidated Omnibus Reconciliation Act of 1985, as amended ("COBRA") for a period of up to six months for Dr. Xu and three months for Dr. Ho.

Certain of Dr. Xu's outstanding equity awards are also subject to potential accelerated vesting pursuant to the terms of such awards, as disclosed above under "Outstanding Equity Awards At Fiscal 2025 Year-End". Such awards will continue to remain outstanding and subject to their terms following this offering.

Post-IPO Change in Control and Severance Benefits

We have adopted a Change in Control and Severance Plan (the "Severance Plan") that will become effective in connection with this offering and will supersede and replace any other severance payments and benefits to which a participant was entitled, including pursuant to the 2024 Offer Letters with each of our named executive officers. Each of our named executive officers is a participant under our Severance Plan eligible for the payments and benefits described below.

In the event of a termination of employment by us without "cause" (and other than due to death or "disability") or by the executive for "good reason" (as such terms are defined in our Severance Plan), that occurs outside of the "change in control period" (as described below), our named executive officers will be eligible to receive the following payments and benefits:

(i) continuation of base salary payments for 12 months for Dr. Xu and nine months for Dr. Ho;

(ii) payment of premiums for continued health coverage under COBRA for a period of up to 12 months for Dr. Xu and nine months for Dr. Ho; and

(iii) with respect to Dr. Xu only, vesting acceleration of any then-outstanding time-vesting equity awards as to the portion of such equity awards that was scheduled to vest under such time-vesting schedule during the 12-month period following such termination date, as if Dr. Xu had remained employed through such date.

In addition, if the executive's termination or resignation occurs after year end but prior to payment of the annual bonus for such year, such executive remains eligible to earn such bonus, with the amount (if any) determined by our board of directors (or a committee thereof) based on achievement of the applicable performance goals, which will be paid at the same time annual bonuses are paid to other similarly situated executives and no later than March 15 of the year following the year in which the bonus relates (the "Bonus Payout").

In the event of a termination of employment by us without "cause" (and other than due to death or "disability") or by the executive for "good reason," in either case, occurring within a period beginning three months prior to and ending 12 months following the closing of a "change in control" (as defined in our Severance Plan, and such period the "change in control period"), our named executive officers will be eligible to receive the following payments and benefits:

(i) a lump-sum payment equal to 1.5 times (for Dr. Xu) or one time (for Dr. Ho) the sum of (A) 12 months of annual base salary, plus (B) the target annual bonus as in effect for the fiscal year in which the qualifying termination of employment occurs;

(ii) the Bonus Payout;

(iii) payment of premiums for continued health coverage under the COBRA for a period of up to 18 months for Dr. Xu and 12 months for Dr. Ho; and

(iv) 100% accelerated vesting of all outstanding equity awards, and, with respect to equity awards that vest based on the achievement of performance criteria, all performance criteria will be deemed achieved at 100% of target levels for the relevant performance period(s), unless otherwise determined by the applicable agreement governing such equity award.

The receipt of the payments and benefits provided for under our Severance Plan described above is conditioned on the executive (i) resigning from all officer, director or other service positions with us, (ii) signing and not revoking a separation and release of claims agreement, (iii) continuing to comply with the confidential information, invention assignment, and arbitration agreement applicable to the executive, and (iv) returning all documents and other company property.

If any of the payments or benefits provided for under our Severance Plan or otherwise payable to the executive would constitute "parachute payments" within the meaning of Section 280G of the Code and could be subject to the related excise tax, our Severance Plan provides that, unless otherwise provided in an offer letter or other individual agreement with the executive, the executive will receive either full payment of such payments and benefits or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive.

In addition, each of the confirmatory offer letters for Drs. Xu and Ho provide for a special bonus payment if, after good faith reasonable mitigation efforts, the executive would receive payments or benefits in connection with certain change in control events that would be subject to the 20% excise tax under Section 4999 of the Code. The special bonus payment is a potential tax gross up for this excise tax, subject to certain thresholds, conditions and an

overall cap on aggregate special bonus payments for all executives with similar tax gross up benefits of no more than 1.0% of the enterprise value in the change in control. The receipt of any special bonus is conditioned upon the executive (A) cooperating with the Company to engage in good faith reasonable mitigation strategies to reduce the excise tax, (B) continuing to be employed with the Company as of immediately prior to the closing of the change in control (unless terminated by the Company without cause or the executive resigns for good reason prior to such time); and (C) continuing to comply with the terms of executive's written agreements with the Company including confidential information, invention assignment, and arbitration agreement applicable to the executive.

Arrangements with Mr. Lieber

On September 12, 2026, we entered into an offer letter with Mr. Lieber (the "Lieber Letter") providing for his commencement of employment with us as our Chief Financial Officer on or around September 15, 2026. Pursuant to the Lieber Letter, effective upon Mr. Lieber's employment start date of September 15, 2026, Mr. Lieber's initial annual base salary is $500,000, and the target amount of his annual performance bonus opportunity is 40% of his annual base salary. Any bonus deemed earned for 2026 will be pro-rated to 50% of target. Mr. Lieber is eligible to participate in the employee benefit plans generally available to our employees and employed "at will." Mr. Lieber has executed a confidential information and invention assignment agreement that includes covenants not to compete or solicit our employees, customers, or other contractors or suppliers for a period of 12 months following termination of his employment with us. Pursuant to the Lieber Letter, Mr. Lieber is eligible to receive severance benefits similar to Dr. Ho's benefits under the Severance Plan, as described above, which will be superseded in connection with this offering by the applicable participation agreement with respect to Mr. Lieber under the Severance Plan.

In September 2026, in accordance with the terms of the Lieber Letter, our board of directors granted Mr. Lieber a stock option to purchase 440,282 shares at an exercise price per share of $13.57, which vests over four years, measured from his commencement of employment, and subject to his continued employment through each applicable vesting date.

In connection with this offering, we entered into a confirmatory offer letter with Mr. Lieber that provides for his continued employment with us on an at-will basis and will supersede the Lieber Letter. Pursuant to his confirmatory offer letter, Mr. Lieber's annual base salary and his annual target bonus opportunity remain unchanged. Mr. Lieber will also be eligible for a capped tax gross-up and for severance and change in control benefits, as set forth in our Severance Plan, each on the same terms as Dr. Ho, which will supersede the terms of the Lieber Letter.

Other Elements of Compensation and Compensation Policies

Health and Welfare Benefits; Perquisites

We provide benefits to Drs. Xu and Ho on the same basis as provided to all of our employees, including health, dental, and vision insurance; life insurance; accidental death and dismemberment insurance; short-and long-term disability insurance; and a tax-qualified Section 401(k) plan.

We generally do not provide material perquisites or personal benefits to our executive officers. None of our executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our board of directors may elect to adopt qualified or non-qualified defined benefit plans in the future if it determines that doing so is in our best interests.

None of our executive officers participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a 401(k) retirement savings plan ("401(k) plan"), which is intended to be a tax qualified defined contribution plan under Section 401(k) of the Code for the benefit of our employees, including certain of our named

executive officers, who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax ("traditional") or post-tax ("Roth") basis, through contributions to the 401(k) plan. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan. We provide safe harbor matching contributions under the 401(k) plan equal to 100% of each participant's contributions, up to 1% of the participant's eligible compensation, and equal to 50% of each participant's contributions that exceed 1% of eligible compensation up to 6% of the participant's eligible compensation, subject to the limits provided in the Code. Such matching contributions vest over a two-year service period.

Clawback Policy

We adopted a compensation recovery policy effective in connection with this offering, that complies with the SEC rules under the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Clawback Policy"). Subject to the terms of the Clawback Policy, the Clawback Policy requires us to recover certain cash or stock-based incentive compensation payments or awards made or granted to an executive officer in the event we are required to prepare an accounting restatement due to our material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

Policies and Practices Related to the Grant of Certain Equity Awards

From time to time, we grant stock options to our named executive officers, our employees, and our other service providers. Historically, we have granted new-hire option awards on or soon after a new-hire's employment start date and refresh, promotion, or retention option grants when and as determined by our board of directors. In response to Item 402(x)(1) of Regulation S-K, we have no specific policy or practice on the timing of options or other equity awards in relation to the public disclosure of material nonpublic information by us, and we have no 2025 stock option or other awards to disclose under Item 402(x)(2).

Employee Benefit and Stock Plans

2024 Stock Plan

Our 2024 Plan was adopted by our board of directors and approved by our stockholders on March 15, 2024. Our 2024 Plan was most recently amended by our board of directors and our stockholders in October 2026. Our 2024 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, restricted stock, and other awards (including restricted stock units) (collectively, "Awards") to eligible employees and consultants.

Our 2024 Plan terminated in connection with the effectiveness of our 2026 Plan (described below), and we will not grant any additional Awards under our 2024 Plan following its termination. However, our 2024 Plan will continue to govern the terms and conditions of the outstanding Awards previously granted under our 2024 Plan.

As of June 30, 2026, stock options covering 1,550,428 shares of our common stock were outstanding under our 2024 Plan and there were no restricted stock awards outstanding under our 2024 Plan.

Authorized Shares. Subject to the adjustment provisions in our 2024 Plan, the maximum aggregate number of shares of common stock that may be granted under our 2024 Plan is 4,208,339 shares of common stock. The shares of common stock issued under the 2024 Plan may be authorized, but unissued, or reacquired shares of common stock.

If an Award should expire or become unexercisable for any reason without having been exercised in full, or is surrendered pursuant to an option exchange program, the unissued shares of common stock that were subject thereto shall continue to be available under the 2024 Plan for issuance pursuant to future Awards, unless the 2024 Plan has

been terminated. In addition, any shares of common stock which are retained by the Company upon exercise of an Award in order to satisfy the exercise or purchase price for such Award or any withholding taxes due with respect to such Award shall be treated as not issued and shall continue to be available under the 2024 Plan for issuance pursuant to future Awards. Shares of common stock issued under the 2024 Plan and later forfeited to the Company due to failure to vest or repurchased by the Company at the original purchase price paid to the Company for the shares of common stock (including, without limitation, upon forfeiture to or repurchase by the Company in connection with the termination of a participant's continuous service) shall again be available for future grant under the 2024 Plan.

Plan Administration. Our 2024 Plan is administered by our board of directors or a committee appointed by our board of directors, or a combination thereof, as determined by our board of directors, which we refer to as the "administrator" herein.

Subject to the provisions of our 2024 Plan and, in the case of the committee, the specific duties delegated by the board of directors to such committee, the administrator shall have the authority, in its sole discretion, to administer our 2024 Plan, including but not limited to the power: to determine the fair market value of our common stock in accordance with the provisions of our 2024 Plan; select the employees and consultants to whom Awards may be granted; determine the number of shares of common stock covered by each Award; approve form(s) of award agreement(s) and other related documents for use under our 2024 Plan; determine the terms and conditions, not inconsistent with the terms of our 2024 Plan, of any Award granted hereunder, which terms and conditions include but are not limited to the exercise or purchase price, the time or times when Awards may vest and/or be exercised (which may be based on performance criteria), any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award, optioned stock, or restricted stock; to amend any outstanding Award or related agreement, provided that no amendment shall be made that would materially and adversely affect the rights of any participant without the participant's consent; to determine whether and under what circumstances a stock option may be settled in cash under the 2024 Plan's buyout provisions; subject to applicable laws, to implement an option exchange program and establish the terms and conditions of such option exchange program without consent of the holders of capital stock of the Company, provided that no amendment or adjustment to stock option that would materially and adversely affect the rights of any participant shall be made without participant's consent; to approve addenda pursuant to the 2024 Plan's addenda provision or to grant Awards to, or to modify the terms of, any outstanding option agreement or restricted stock purchase agreement or any agreement related to any optioned stock or restricted stock held by participants who are foreign nationals or employed outside the United States in order to accommodate differences in local law, tax policy, or custom; and to construe and interpret the terms of our 2024 Plan and awards granted under it. The administrator's constructions, interpretations, and decisions will be final and binding on all participants.

Stock Options. Our 2024 Plan permits the grant of stock options. Incentive stock options may be granted only to employees of the Company. Each stock option shall be designated in an option agreement as either as an incentive stock option or a nonstatutory stock option. The maximum aggregate number of shares of common stock with respect to which incentive stock options may be granted under our Plan is 4,208,339.

The term of each stock option shall be the term stated in the applicable option agreement; provided that the term shall be no more than ten years from the date of grant, or such shorter term as may be provided in the option agreement. In the case of an incentive stock option granted to a person who at the time of such grant owns more than ten percent of the voting power of all classes of our stock, the term of the stock option shall be five years from the date of grant or such shorter term as may be provided in the applicable option agreement.

The per share exercise price of options granted under our 2024 Plan will be a price determined by the administrator and set forth in the applicable option agreement. In the case of incentive stock options granted to an employee who, at the time of grant, owns more than ten percent of the voting power of all classes of our stock, the exercise price must equal at least 110% of the fair market value of our common stock on the grant date. In the case of an incentive stock option granted to other employees, the exercise price must equal at least one hundred percent of the fair market value of our common stock on the grant date. In the case of nonstatutory stock options, the per share exercise price shall be such price as is determined by the administrator, provided that, if the per share exercise price is less than one hundred percent of the fair market value on the date of grant, it shall otherwise comply with all

applicable laws, including Section 409A of the Code. However, notwithstanding the foregoing, options may be granted with a per share exercise price other than as required above pursuant to a merger or other corporate transaction.

The administrator determines the consideration to be paid for shares of common stock issued upon exercise of a stock option, including the methods of payment (in the case of incentive stock options and to the extent required by applicable laws, this will be determined at the time of grant) and may consist entirely of (1) cash, (2) check, (3) to the extent permitted under, and in accordance with, applicable laws, delivery of a promissory note, (4) cancellation of indebtedness, (5) other previously owned shares of common stock that have a fair market value on the date of surrender equal to the aggregate exercise price of the shares of common stock to which the stock option is exercised, (6) a cashless exercise method, including a broker-assisted cashless exercise, (7) such other consideration or method of payment permitted under applicable law, or (8) any combination of the foregoing methods of payment.

The administrator will establish in the applicable option agreement the terms and conditions in which a stock option will remain exercisable, if at all, following termination of a participant. Unless the administrator provides in the applicable option agreement, if an option holder does not exercise their stock option to the extent they are entitled to do so within the time specified in their option agreement, the stock option will terminate and the optioned stock underlying the unexercised portion of the stock option will revert to our 2024 Plan. In no event may the stock option be exercised after the expiration of its term. If an employee, director, or consultant is terminated other than for death or disability or for cause, the option holder may exercise any outstanding option at any time within three months following such termination to the extent the option holder is vested in the optioned stock (they may exercise their stock option for 12 months in the event of termination due to disability or death). If terminated for cause, a participant's stock options (whether vested or unvested) will immediately terminate in their entirety. The administrator may at any time offer to buy out for a payment in cash or shares an option previously granted under our 2024 Plan based on such terms and conditions as the administrator shall establish and communicate to the option holder at the time such offer is made.

Other Awards. Other awards may be granted under the 2024 Plan. Other stock awards are awards valued in whole or in part by reference to, or otherwise based on, shares, including restricted stock units to be issued shares of common stock or awards based on the appreciation in value of common stock. Subject to the provisions of the 2024 Plan, the administrator will have the authority to determine the terms and conditions of such other awards in its sole and complete discretion.

Restricted Stock Units. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2024 Plan, the administrator will determine the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of performance or individual goals (including, but not limited to, continued employment or service and/or the occurrence of certain liquidity events), or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Non-Transferability of Awards. Our 2024 Plan generally does not allow Awards (or any rights related to such Awards) to be sold, pledged, encumbered, assigned, hypothecated, or disposed of or otherwise transferred in any manner other than by will, or by the laws of descent or distribution. The designation of a beneficiary by a participant will not constitute a transfer. A stock option may be exercised, during the lifetime of the holder of the stock option, only by such holder or a transferee permitted by our 2024 Plan. The administrator may, in its sole discretion, provide that nonstatutory stock options may be transferred by instrument to an inter vivos trust or certain testamentary trusts or by gift to family members, as further provided in our 2024 Plan.

Changes in Capitalization. Subject to any action required under the applicable laws by the holders of capital stock of the Company, (i) the numbers and class of shares of common stock or other stock or securities: (x) available for future Awards under our 2024 Plan and (y) covered by each outstanding Award, (ii) the exercise price per share of common stock of each such outstanding stock option, and (iii) any repurchase price per share of common stock applicable to shares of common stock issued pursuant to any Award, shall be automatically proportionately adjusted

in the event of a stock split, reverse stock split, stock dividend, combination, consolidation, reclassification of the shares of common stock, or a subdivision of the shares of common stock. In the event of any increase or decrease in the number of issued shares of common stock effected without receipt of consideration by the Company, a declaration of an extraordinary dividend with respect to the shares of common stock payable in a form other than the shares of common stock in an amount that has a material effect on the fair market value, a recapitalization (including a recapitalization through a large nonrecurring cash dividend), a rights offering, a reorganization, merger, a spin-off, split-up, change in corporate structure, or similar occurrence, the administrator shall make appropriate adjustments, in its discretion, in one or more of (i) the numbers and class of shares of common stock or other stock or securities: (x) available for future Awards under our 2024 Plan and (y) covered by each outstanding Award, (ii) the exercise price per share of common stock of each outstanding stock option, and (iii) any repurchase price per share of common stock applicable to the shares of common stock issued pursuant to any Award, and any such adjustment by the administrator shall be made in the administrator's sole and absolute discretion and shall be final, binding, and conclusive.

Dissolution or Liquidation. In the event of our liquidation or dissolution, each Award will terminate immediately prior to the consummation of such action, unless otherwise determined by the administrator.

Corporate Transactions. Our 2024 Plan provides that in the event of: (i) a transfer of all or substantially all of our assets, (ii) a merger, consolidation, or other capital reorganization or business combination transaction of the Company with or into another corporation, entity, or person, or (iii) the consummation of a transaction, or series of related transactions, in which any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of more than 50% of our then outstanding capital stock (a "Corporate Transaction"), each outstanding Award, vested or unvested, will be treated as the administrator determines, which determination may be made without the consent of any participant and need not treat all outstanding awards, or portion therefore, in an identical manner. Such determination without consent of any participant may provide, without limitation, for one or more of the following in the event of a Corporate Transaction: (A) the continuation of such outstanding Awards by the Company (if the Company is the surviving corporation); (B) the assumption of such outstanding Award by the surviving corporation or its parent; (C) the substitution by the surviving corporation or its parent of new options or equity awards for such Awards; (D) the cancellation of such Awards in exchange for a payment to the participants equal to the excess of (1) the fair market value of the shares of common stock subject to such awards as of the closing date of such Corporate Transaction over (2) the exercise price or purchase price paid or to be paid for the shares of common stock subject to the awards; or (E) the cancellation of any outstanding stock options or an outstanding right to purchase restricted stock, in either case, for no consideration.

Notwithstanding anything under our 2024 Plan, any Award agreement, or otherwise, any escrow, holdback, earn-out, or similar provisions agreed to pursuant to, or in connection with, a Corporate Transaction shall, unless otherwise determined by the board of directors, apply to any payment or other right a participant be entitled to under our 2024 Plan, if any, to the same extent and in the same manner as such provisions apply generally to the holders of the Company's common stock with respect to the Corporate Transaction, but only to the extent permitted by applicable law, including (without limitation), Section 409A of the Code.

Amendment and Termination. The board of directors may at any time amend or terminate our 2024 Plan, but no amendment or termination shall be made that would materially and adversely affect the rights of any participant under any outstanding award, without the participant's consent. In addition, to the extent necessary and desirable to comply with applicable laws, the Company shall obtain approval of holders of capital stock with respect to any amendment of our 2024 Plan in such a manner and to such a degree as required.

2026 Equity Incentive Plan

In October 2026, our board of directors adopted, and our stockholders approved, the 2026 Plan, which became effective on the business day prior to the effective date of the registration statement of which this prospectus forms a part. Our 2026 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory

stock options, restricted stock, restricted stock units, stock appreciation rights, performance awards, or other stock awards to our employees, directors, and consultants, and our subsidiary corporations' employees and consultants.

Authorized Shares. A total of 5,560,163 shares of our common stock are reserved for issuance pursuant to our 2026 Plan. In addition, the shares reserved for issuance under our 2026 Plan will also include (i) shares that remained available for grant under our 2024 Plan as of the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part and (ii) shares of our common stock subject to or issued pursuant to awards granted under our 2024 Plan that, on or after the effective date of the registration statement of which this prospectus forms a part, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by us for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by us due to failure to vest (provided that the maximum number of shares that may be added to the 2026 Plan pursuant to (i) and (ii) is 4,208,339 shares). The number of shares available for issuance under our 2026 Plan will also include an annual increase on the first day of each fiscal year for a period of ten years, beginning with our 2027 fiscal year, equal to the lesser of:

- five percent (5%) of the total number of shares of our fully diluted common stock (as defined in the 2026 Plan) outstanding on the last day of the immediately preceding fiscal year; and
- such other number of shares as the administrator of the 2026 Plan may determine.

The maximum amount of shares that may be issued under our 2026 Plan "incentive stock options" is 48,842,510 shares, subject to the overall share reserve described above.

Shares issuable under our 2026 Plan will be authorized, but unissued, or reacquired shares of our common stock. If an award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such award having been issued, including pursuant to an exchange program or (ii) is settled in cash, such expiration, termination, or settlement will not reduce (or otherwise offset) the number of shares that may be available for issuance under the 2026 Plan, and the unissued shares subject to such award will be available for future issuance under the 2026 Plan. If any shares issued pursuant to an award are reacquired or repurchased by us because of the failure to meet a contingency or condition required to vest, or are otherwise forfeited to us, then the shares that are repurchased, reacquired, or forfeited will revert to and again become available for issuance under the 2026 Plan. Any shares reacquired or withheld by the Company in satisfaction of tax withholding obligations on an award or as consideration for the exercise or purchase price of an award will again become available for issuance under the 2026 Plan.

Plan Administration. Our board of directors or one or more committees appointed by our board of directors will administer our 2026 Plan. We expect that the compensation committee of our board of directors will initially administer our 2026 Plan. Subject to the provisions of our 2026 Plan, the administrator has the power to administer our 2026 Plan and make all determinations deemed necessary or advisable for administering the 2026 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2026 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions, and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2026 Plan and awards granted under it, prescribe, amend, and rescind rules relating to our 2026 Plan, including creating sub-plans, modify or amend each award, including but not limited to the discretionary authority to extend the post-termination exercisability period of awards (except no option or stock appreciation right will be extended past its original maximum term), and allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type, and/or cash or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations, and other actions are final and binding on all participants.

Stock Options. Both incentive stock options and non-statutory stock options may be granted under our 2026 Plan. The exercise price of options granted under our 2026 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any parent or subsidiary of ours) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares, or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director, or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for six months following the termination of service. In all other cases (other than a termination for cause, in which case the option, including any vested portion, will terminate immediately unless otherwise provided in an award agreement or other written agreement), in the absence of a specified time in an award agreement, the option will remain exercisable for 30 days following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2026 Plan, the administrator will determine the other terms of options.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2026 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding ten years. After the termination of service of an employee, director, or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for six months following the termination of service. In all other cases (other than a termination for cause, in which case the stock appreciation right, including any vested portion, will terminate immediately unless otherwise provided in an award agreement or other written agreement), in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for 30 days following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2026 Plan, the administrator will determine the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2026 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director, or consultant and, subject to the provisions of our 2026 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), except the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Recipients of restricted stock awards generally will not be entitled to receive dividends and other distributions paid with respect to such shares while such shares are unvested, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2026 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2026 Plan, the administrator will determine the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, in shares or in some

combination thereof. In addition, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Awards. Performance awards may be granted under the 2026 Plan. Performance awards are awards that may be earned in whole or in part upon the attainment of performance goals or other vesting criteria that the administrator may determine, and that may be denominated in cash or stock. Subject to the terms and conditions of the 2026 Plan, the administrator will determine the terms and conditions of performance awards, including any vesting criteria and form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Other Stock Awards. Other stock awards may be granted under the 2026 Plan. Other stock awards are awards valued in whole or in part by reference to, or otherwise based on, shares, including the appreciation in value thereof. Subject to the terms and conditions of the 2026 Plan, the administrator will have the authority to determine the terms and conditions of such other stock awards in its sole discretion.

Outside Directors. All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2026 Plan. To provide a maximum limit on the cash compensation and equity awards that can be made to our outside directors, our 2026 Plan provides that beginning with the first fiscal year that commences following the registration date (as defined in the 2026 Plan), an outside director will not be granted cash retainer fees and equity awards with an aggregate value greater than $750,000, increased to $1,000,000 for the first fiscal year in which such outside director is first appointed or elected to the board, in each case with the value of each equity award based on its grant date fair value as determined according to U.S. GAAP for purposes of this limit. Any cash compensation paid or awards granted to an individual for his or her services as an employee or consultant (other than as an outside director), and any incremental fair value resulting from the modification of an option or other equity award held by an outside director, will not count toward this limit. This maximum limit provision does not reflect the intended size of any potential grants or a commitment to make grants to our outside directors under our 2026 Plan in the future.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2026 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments. In the event of certain changes in our capitalization, such as a dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase or exchange of our shares, or other change in our corporate structure affecting our shares (other than ordinary dividends or other ordinary distributions), in order to prevent diminution or enlargement of the benefits or potential benefits available under our 2026 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2026 Plan and/or the number, class, and price of shares covered by each outstanding award and any numerical share limits set forth in our 2026 Plan.

Dissolution or Liquidation. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and, to the extent not exercised, all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control. Our 2026 Plan provides that in the event of a merger or change in control, as defined under our 2026 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator is not required to treat all awards, all awards held by a participant, or all awards of the same type similarly.

If a successor corporation or its parent or subsidiary does not continue an outstanding award, then vesting of such award (and, with respect to outstanding options and stock appreciation rights, the time when such award may

be exercised) will be accelerated in full, and all restrictions on such outstanding award will lapse, and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other written agreement applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met. If an option or stock appreciation right is not continued in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that such vested option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, in the event of a change in control, the vesting of such awards (and, with respect to outstanding options and stock appreciation rights, the time when such award may be exercised) will be accelerated in full, and all restrictions on such outstanding awards will lapse and, for awards with performance-based vesting, unless specifically provided for otherwise under the applicable award agreement or other agreement or policy applicable to the participant, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

Clawback. Awards will be subject to any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our stock is listed or as otherwise required by applicable laws, and the administrator also may specify in an award agreement that the participant's rights, payments, and/or benefits with respect to an award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return, or reimburse us all or a portion of the award and/or shares issued under the award, any amounts paid under the award, and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment; Termination. The administrator has the authority to amend, alter, suspend, or terminate our 2026 Plan, provided such action does not materially impair the rights of any participant. No incentive stock options may be granted after ten years from the date our board of directors adopted the 2026 Plan.

2026 Employee Stock Purchase Plan

In October 2026, our board of directors adopted, and our stockholders approved, the ESPP. Our ESPP became effective upon the business day immediately prior to the date of the registration statement of which this prospectus forms a part. However, no offering period or purchase period under the ESPP will begin unless and until otherwise determined by our board of directors.

Authorized Shares. A total of 505,469 shares of our common stock are available for sale under our ESPP. The number of shares of our common stock that are available for sale under our ESPP also includes an annual increase on the first day of each fiscal year for a period of ten years beginning with our fiscal year 2027, equal to the least of:

- 1,516,407 shares;
- one percent (1%) of the total number of shares of our fully diluted common stock (as defined in the ESPP) outstanding on the last day of the immediately preceding fiscal year; and
- such other number of shares as the administrator of the ESPP may determine.

ESPP Administration. The compensation committee of our board of directors will administer our ESPP and will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the ESPP, designate our subsidiaries and affiliates as participating in the ESPP, determine eligibility, adjudicate all disputed claims filed under the ESPP, and establish procedures that it deems necessary for the administration of the ESPP, including, but not limited to, adopting such procedures and sub-plans as are necessary or appropriate to permit participation in the ESPP by employees who are foreign nationals or employed outside the United States. The administrator's findings, decisions, and determinations are final and binding on all participants to the full extent permitted by law.

Eligibility. Generally, all of our employees are eligible to participate in the ESPP if they are customarily employed by us, or any participating subsidiary or affiliate, for at least 20 hours per week and more than five months in any calendar year. The administrator, in its discretion, may, prior to an enrollment date, for all purchase rights to be granted on such enrollment date in an offering, determine that an employee who (i) has not completed at least two years of service (or a lesser period of time determined by the administrator) since his or her last hire date; (ii) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator); (iii) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator); (iv) is a highly compensated employee within the meaning of Section 414(q) of the Code; or (v) is a highly compensated employee within the meaning of Section 414(q) of the Code with compensation above a certain level or is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in such offering period.

However, an employee may not be granted rights to purchase shares of our common stock under our ESPP if such employee:

- immediately after the grant would own capital stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of capital stock of ours or of any parent or subsidiary of ours; or
- holds rights to purchase shares of our common stock under all employee stock purchase plans of ours or any parent or subsidiary of ours that accrue at a rate that exceeds $25,000 worth of shares of our common stock for each calendar year in which such rights are outstanding at any time.

Offering Periods and Purchase Periods. Our ESPP includes a component (the "423 Component"), that is intended to qualify as an "employee stock purchase plan" under Code Section 423, and a component that does not comply with Code Section 423 (the "Non-423 Component"). For purposes of this summary, a reference to our ESPP generally will mean the terms and operations of the 423 Component. Our ESPP will provide for certain periods during which shares of common stock may be purchased under the ESPP as determined by the administrator in its discretion and on a uniform and nondiscriminatory basis. The administrator is authorized to change the duration of future offering periods and purchase periods under our ESPP, including the starting and ending dates of offering periods and purchase periods and the number of purchase periods in any offering periods, provided that no offering period will have a duration exceeding 27 months. Unless otherwise determined by the administrator, a purchase period will have the same duration as the offering period. Unless otherwise determined by the administrator, in any offering period with more than one purchase date, if the fair market value of a share of our common stock on a purchase date is less than the fair market value on the first trading day of the offering period, participants in that offering period will be withdrawn from that offering period following their purchase of shares on that purchase date and automatically will be enrolled in a new offering period.

Contributions. Our ESPP permits participants to purchase shares of our common stock through contributions (in the form of payroll deductions or otherwise to the extent permitted by the administrator) of up to 15% of their eligible compensation. A participant may purchase a maximum number of shares of our common stock during a purchase period as determined by the administrator.

Exercise of Purchase Right. If our board of directors authorizes an offering and purchase period under the ESPP, amounts contributed and accumulated by the participant during any offering period will be used to purchase shares of our common stock at the end of each purchase period. The purchase price of the shares will be no less than 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the exercise date. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer rights granted under our ESPP (other than by will, the laws of descent and distribution).

Merger or Change in Control. Our ESPP provides that in the event of a merger or change in control, as defined under our ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor

corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set that will be before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's purchase right will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment; Termination. The administrator has the authority to amend, suspend, or terminate our ESPP. Our ESPP automatically will terminate in 2046, unless we terminate it sooner.

Employee Incentive Compensation Plan

In October 2026, our board of directors adopted an employee incentive compensation plan (the "Incentive Compensation Plan"). Our board of directors or a committee appointed by our board of directors will administer the Incentive Compensation Plan, provided that unless and until the board of directors determines otherwise, the compensation committee will administer the Incentive Compensation Plan. The Incentive Compensation Plan allows the administrator to provide awards to employees selected for participation, which may include certain of our named executive officers, and which awards may be based upon performance goals established by the administrator. The administrator may establish a target award for each participant under the Incentive Compensation Plan, which may be expressed as a percentage of the participant's average annual base salary for the applicable performance period, a fixed dollar amount, or such other amount or based on such other formula or factors as the administrator determines to be appropriate.

Under the Incentive Compensation Plan, the administrator determines the performance goals, if any, applicable to any target award (or portion thereof) for a performance period, which may include, without limitation, goals related to: attainment of research and development milestones; sales bookings; business divestitures and acquisitions; capital raising; cash flow; cash position; contract awards or backlog; corporate transactions; customer renewals; customer retention rates from an acquired company, subsidiary, business unit, or division; earnings (which may include any calculation of earnings, including but not limited to earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation, and amortization, and net taxes); earnings per share; expenses; financial milestones; gross margin; growth in stockholder value relative to the moving average of the S&P 500 Index or another index; internal rate of return; leadership development or succession planning; license or research collaboration arrangements; market share; net income; net profit; net sales; new product or business or product development; new product invention or innovation; number of customers; operating cash flow; operating expenses; operating income; operating margin; overhead or other expense reduction; patents; procurement; product defect measures; product release timelines; productivity; profit; regulatory milestones or regulatory-related goals; retained earnings; return on assets; return on capital; return on equity; return on investment; return on sales; revenue; revenue growth; sales results; sales growth; savings; stock price; time to market; total stockholder return; working capital; unadjusted or adjusted actual contract value; unadjusted or adjusted total contract value; and individual objectives such as peer reviews or other subjective or objective criteria. As determined by the administrator, the performance goals may be based on U.S. GAAP or non-U.S. GAAP results and any actual results may be adjusted by the administrator for one-time items or unbudgeted or unexpected items and/or payments of awards under the Incentive Compensation Plan when determining whether the performance goals have been met. The performance goals may be based on any factors the administrator determines relevant, including without limitation on an individual, divisional, portfolio, project, business unit, segment, or company-wide basis. The performance goals may differ from participant to participant and from award to award.

The administrator may, in its sole discretion and at any time, increase, reduce, or eliminate a participant's actual award, and/or increase, reduce, or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at, or above a participant's target award, in the administrator's discretion. The administrator may determine the amount of any increase, reduction, or elimination on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards under the Incentive Compensation Plan generally will be paid in cash (or its equivalent) in a single lump sum only after they are earned and approved by the administrator, provided that the administrator

reserves the right, in its sole discretion, to settle an actual award with a grant of an equity award with such terms and conditions, including vesting requirements, as determined by the administrator in its sole discretion. Unless otherwise determined by the administrator, to earn an actual award, a participant must be employed by us (or one of our affiliates) through the date the bonus is paid. Payment of bonuses occurs as soon as administratively practicable after the end of the applicable performance period, but in no case after the later of (i) the 15th day of the third month of the fiscal year immediately following the fiscal year in which the bonuses vest and (ii) March 15 of the calendar year immediately following the calendar year in which the bonuses vest.

The administrator has the authority to amend or terminate the Incentive Compensation Plan. However, such action may not alter or impair the existing rights of any participant with respect to any earned bonus without the participant's consent. The Incentive Compensation Plan will remain in effect until terminated in accordance with the terms of the Incentive Compensation Plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including employment, termination of employment, and change in control arrangements, discussed in the sections titled "Management" and "Executive Compensation," the following is a description of each transaction since Inception and each currently proposed transaction, in which:

- we have been or are to be a participant;
- the amount involved will exceed the lesser of (i) $120,000 and (ii) 1% of the average of our total assets as of the end of the last two completed fiscal years; and
- any of our directors, executive officers, or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Convertible Preferred Stock Financings

Series Seed Preferred Stock Financing

In June 2024, we issued and sold an aggregate of 5,329,584 shares of our Series Seed convertible preferred stock ("Series Seed Preferred Stock") at a purchase price of $0.9570 per share for an aggregate purchase price of approximately $5.1 million. The following table summarizes purchases of our Series Seed Preferred Stock by related persons:

Stockholder	Affiliated Director	Shares of Series Seed Preferred Stock	Total Purchase Price
Shanshan Xu, M.D., Ph.D., M.B.A.[1]	-	104,500	$ 100,000
RLG	Sean Marett, M.B.A.[2]	209,002	$ 199,999
Salvia Investment[3]	Helmut Jeggle, M.B.A.	3,762,061	$ 3,599,999
Entities Affiliated with INCE Capital[3]	-	1,254,021	$ 1,200,000

(1) Represents shares issued to MiNeng, 10,450 of which were subsequently transferred to the Shanshan Xu 2025 Irrevocable Family Trust (the "Xu Trust") in May 2026. Dr. Xu is the sole stockholder of MiNeng and therefore has sole voting and dispositive power with regard to the shares held by MiNeng. Dr. Xu may be deemed to have voting and dispositive power with regard to the shares held by the Xu Trust. Dr. Xu through MiNeng and the Xu Trust holds more than 5% of a class of our outstanding capital stock.
(2) Sean Marett, M.B.A. was appointed to our board of directors on December 19, 2024 and served on our board of directors until December 31, 2025.
(3) Holder of more than 5% of a class of our outstanding capital stock.

Series Seed Plus Preferred Stock Financing

In August 2024, we issued and sold an aggregate of 3,740,038 shares of our Series Seed Plus convertible preferred stock ("Series Seed Plus Preferred Stock") at a purchase price of $2.4064 per share for an aggregate purchase price of approximately $9.0 million. The following table summarizes purchases of our Series Seed Plus Preferred Stock by related persons:

Stockholder	Affiliated Director	Shares of Series Seed Plus Preferred Stock	Total Purchase Price
Shanshan Xu, M.D., Ph.D., M.B.A.[1]	-	41,554	$ 99,997
RLG	Sean Marett, M.B.A.[2]	83,111	$ 199,998
Entities Affiliated with Thomas Strüngmann, Ph.D.	Thomas Strüngmann, Ph.D.; Christian Foerster, M.Sc.[3]	207,779	$ 499,996
Entities Affiliated with Biotechnology Value Fund[4]	-	1,662,239	$ 3,999,989
Dawn Holdco[4]	-	1,662,244	$ 3,999,997

(1) Represents shares issued to MiNeng, 4,155 of which were subsequently transferred to the Xu Trust in May 2026. Dr. Xu is the sole stockholder of MiNeng and therefore has sole voting and dispositive power with regard to the shares held by MiNeng. Dr. Xu may be deemed to have voting and dispositive power with regard to the shares held by the Xu Trust. Dr. Xu through MiNeng and the Xu Trust holds more than 5% of a class of our outstanding capital stock.
(2) Sean Marett, M.B.A. was appointed to our board of directors on December 19, 2024 and served on our board of directors until December 31, 2025.
(3) Thomas Strüngmann, Ph.D. was appointed to our board of directors on January 1, 2026 and resigned from our board of directors on July 7, 2026. Christian Foerster, M.Sc. was elected to our board of directors on July 15, 2026.
(4) Holder of more than 5% of a class of our outstanding capital stock.

Series A-1 Preferred Stock Financing

From February 2025 through April 2025 and in June 2025, we issued and sold an aggregate of 15,593,907 shares of our Series A convertible preferred stock, which were subsequently reclassified in October 2025 in connection with the sale of our Series A-2 Preferred Stock (as defined below) ("Series A-1 Preferred Stock") at a purchase price of $5.6997 per share for an aggregate purchase price of approximately $88.9 million. The 6,237,556 shares issued and sold in June 2025 were in a milestone closing pursuant to the terms of the Series A preferred stock purchase agreement. The following table summarizes purchases of our Series A-1 Preferred Stock by related persons:

Stockholder	Affiliated Director	Shares of Series A-1 Preferred Stock	Total Purchase Price
Shanshan Xu, M.D., Ph.D., M.B.A.(1)	-	17,542	$ 99,991
Entities Affiliated with RA Capital(2)	Derek DiRocco, Ph.D.	4,123,058	$ 23,499,984
RLG	Sean Marett, M.B.A.(3)	400,023	$ 2,279,993
Salvia Investment(2)	Helmut Jeggle, M.B.A.	1,579,041	$ 8,999,983
Entities Affiliated with Thomas Strüngmann, Ph.D.(2)	Thomas Strüngmann, Ph.D.; Christian Foerster, M.Sc.(4)	1,754,493	$ 9,999,996
Entities Affiliated with Biotechnology Value Fund(2)	-	1,315,866	$ 7,499,991
Dawn Holdco(2)	-	657,932	$ 3,749,986
Entities Affiliated with INCE Capital(2)	-	657,932	$ 3,749,986
Janus Henderson(2)	-	1,315,868	$ 7,499,990
Redmile Biopharma(2)	-	1,315,868	$ 7,499,990

(1) Represents shares issued to MiNeng, 1,753 of which were subsequently transferred to the Xu Trust in May 2026. Dr. Xu is the President and sole stockholder of MiNeng and therefore has sole voting and dispositive power with regard to the shares held by MiNeng. Dr. Xu may be deemed to have voting and dispositive power with regard to the shares held by the Xu Trust. Dr. Xu through MiNeng and the Xu Trust holds more than 5% of a class of our outstanding capital stock.
(2) Holder of more than 5% of a class of our outstanding capital stock.
(3) Sean Marett, M.B.A. was appointed to our board of directors on December 19, 2024 and served on our board of directors until December 31, 2025.
(4) Thomas Strüngmann, Ph.D. was appointed to our board of directors on January 1, 2026 and resigned from our board of directors on July 7, 2026. Christian Foerster, M.Sc. was elected to our board of directors on July 15, 2026.

Series A-2 Preferred Stock Financing

In October 2025 and January 2026, we issued and sold an aggregate of 2,728,032 shares of our Series A-2 convertible preferred stock ("Series A-2 Preferred Stock") at a purchase price of $12.1225 per share for an aggregate purchase price of approximately $33.1 million. In January 2026, we issued and sold 82,490 shares in an

additional closing pursuant to the terms of the Series A-2 preferred stock purchase agreement. The following table summarizes purchases of our Series A-2 Preferred Stock by related persons:

Stockholder	Affiliated Director	Shares of Series A-2 Preferred Stock	Total Purchase Price
Entities Affiliated with RA Capital[1]	Derek DiRocco, Ph.D.	352,880	$ 4,277,765
RLG	Sean Marett, M.B.A.[2]	41,244	$ 499,981
Salvia Investment[1]	Helmut Jeggle, M.B.A.	185,604	$ 2,249,991
Entities Affiliated with Thomas Strüngmann, Ph.D.[1]	Thomas Strüngmann, Ph.D.; Christian Foerster, M.Sc.[3]	886,785	$ 10,749,976
Entities Affiliated with Biotechnology Value Fund[1]	-	261,803	$ 3,173,697
Dawn Holdco[1]	-	148,932	$ 1,805,424
Entities Affiliated with INCE Capital[1]	-	329,966	$ 3,999,983
Janus Henderson[1]	-	115,678	$ 1,402,300
Redmile Biopharma[1]	-	247,474	$ 2,999,982

(1) Holder of more than 5% of a class of our outstanding capital stock.
(2) Sean Marett, M.B.A. was appointed to our board of directors on December 19, 2024 and served on our board of directors until December 31, 2025.
(3) Thomas Strüngmann, Ph.D. was appointed to our board of directors on January 1, 2026 and resigned from our board of directors on July 7, 2026. Christian Foerster, M.Sc. was elected to our board of directors on July 15, 2026.

Investors' Rights Agreement

We are party to an investors' rights agreement with certain holders of our capital stock, including, among others, entities affiliated with Dr. Shanshan Xu, M.D., Ph.D., M.B.A., our Chief Executive Officer and a member of our board of directors, entities affiliated with RA Capital, RLG, Salvia Investment, entities affiliated with Thomas Strüngmann, Ph.D., entities affiliated with Biotechnology Value Fund, Dawn Holdco, entities affiliated with INCE Capital, Janus Henderson, and Redmile Biopharma. Under our investors' rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Upon the closing of this offering, the investors' rights agreement and the rights and obligations of the parties to the investors' rights agreement will terminate, except for the registration rights set forth therein.

Right of First Refusal

Pursuant to certain of the option agreements and restricted stock agreements under our 2024 Plan and our right of first refusal and co-sale agreement, we or our assignees have a right to purchase shares of our capital stock which stockholders propose to sell to other parties. This right will terminate upon the completion of this offering. Entities affiliated with Dr. Shanshan Xu, M.D., Ph.D., M.B.A., our Chief Executive Officer and a member of our board of directors, entities affiliated with RA Capital, RLG, Salvia Investment, entities affiliated with Thomas Strüngmann, Ph.D., entities affiliated with Biotechnology Value Fund, Dawn Holdco, entities affiliated with INCE Capital, Janus Henderson, and Redmile Biopharma are party to the right of first refusal and co-sale agreement.

Voting Agreement

We are a party to a voting agreement with certain holders of our capital stock, including, among others, entities affiliated with Dr. Shanshan Xu, M.D., Ph.D., M.B.A., our Chief Executive Officer and a member of our board of directors, entities affiliated with RA Capital, RLG, Salvia Investment, entities affiliated with Thomas Strüngmann, Ph.D., entities affiliated with Biotechnology Value Fund, Dawn Holdco, entities affiliated with INCE Capital, Janus Henderson, and Redmile Biopharma. The parties to the voting agreement have agreed, subject to certain conditions,

to vote their shares of our capital stock on certain matters, including with respect to the election of directors. The voting agreement will terminate upon the completion of this offering.

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering generally require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. See the section titled "Management—Limitation of Liability and Indemnification of Officers and Directors" for additional information.

Salvia Loan Agreement

On April 24, 2024, we entered into a loan agreement (the "Salvia Loan Agreement") with Salvia GmbH, a stockholder and an entity controlled by Helmut Jeggle, M.B.A., a member of our board of directors. Pursuant to the Salvia Loan Agreement, Salvia GmbH provided us with a loan in the principal amount of $500,000, which accrued interest at a rate of 3% per annum, with interest accruing daily, payable annually, and compounding on December 31 of the respective year if not repaid. On July 17, 2024, we paid $500,000 in principal and $2,712 in interest to Salvia GmbH, fully repaying the loan.

Founder Stock Issuances

In May 2024, we issued and sold (i) 8,239,199 shares of our common stock to MiNeng, at a price of $0.00001 per share, for an aggregate purchase price of $53.34 (the "MiNeng Shares"), and (ii) 4,119,600 shares of our common stock to Salvia Investment GmbH ("Salvia"), at a price of $0.00001 per share, for an aggregate purchase price of $26.67, in each case, pursuant to a common stock purchase agreement. The common stock purchase agreement with MiNeng was subsequently amended on June 12, 2024 and February 12, 2025. On May 6, 2026, 823,919 of the MiNeng Shares were subsequently transferred to the Xu Trust. Our Chief Executive Officer, Shanshan Xu, M.D., Ph.D., M.B.A., is the sole stockholder of MiNeng and therefore has sole voting and dispositive power with regard to the shares held by MiNeng, and she may be deemed to have voting and dispositive power with regard to the shares held by the Xu Trust. Salvia is an entity affiliated with Helmut Jeggle, a member of our board of directors.

Reserved Share Program

At our request, the underwriters have reserved up to 3.5% of the shares offered by this prospectus, for sale at the initial public offering price in a reserved share program to our directors, officers, employees, distributors, dealers, business associates and related persons.

We do not know if these parties will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Other than the underwriting discount described on the front cover of this prospectus, the underwriters will not be entitled to any commission with respect to shares sold pursuant to the reserved share program. See the section titled "Underwriting—Reserved Share Program" for additional information.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a formal, written policy regarding related person transactions, which will become effective upon the completion of this offering. This written policy regarding related person transactions will provide that a related person transaction is a transaction, arrangement, or relationship, or any series of similar transactions, arrangements, or relationships, in which we are a participant and in which a related person has, had, or will have a direct or indirect material interest and in which the aggregate amount involved exceeds $120,000. Our policy will also provide that a related person means any of our executive officers and directors (including director

nominees), in each case at any time since the beginning of our last fiscal year, or holders of more than 5% of any class of our voting securities and any member of the immediate family of, or person sharing the household with, any of the foregoing persons. Our audit committee will have the primary responsibility for reviewing and approving or disapproving related person transactions. In addition to our policy, our audit committee charter provides that our audit committee shall review and approve or disapprove any related person transactions.

All related person transactions described in this section occurred prior to adoption of the formal, written policy described above, and therefore these transactions were not subject to the approval and review procedures set forth in the policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of October 23, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated, the persons or entities identified in the table have sole voting power and sole investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Section 13(d) and 13(g) of the Exchange Act.

The percentage of beneficial ownership prior to the offering shown in the table is based upon 40,386,875 shares of common stock outstanding as of October 23, 2026, assuming the Preferred Stock Conversion and the Liquidity Event RSU Settlement. The percentage of beneficial ownership after the offering shown in the table is based on 50,942,430 shares of common stock outstanding after the closing of this offering, assuming no exercise of the underwriters' option to purchase additional shares. The table below excludes any potential purchases in this offering by the beneficial owners identified in the table below.

We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of October 23, 2026 to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. In addition, the below table does not reflect any shares that may be purchased in this offering or pursuant to our reserved share program described in the section titled "Underwriting—Reserved Share Program."

Unless otherwise indicated, the address for each person or entity listed in the table is c/o Bambusa Therapeutics, Inc., 22 Boston Wharf Road, Floor 7, Boston, Massachusetts 02210.

	Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering	
Name of Beneficial Owner	Number of Shares	Percentage	Number of Shares	Percentage
Greater than 5% Stockholders:				
Shanshan Xu, M.D., Ph.D., M.B.A.[1]	8,623,812	21.2 %	8,623,812	16.9 %
Salvia Investment[2]	8,889,301	22.0 %	8,889,301	17.4 %
Entities Affiliated with RA Capital[3]	4,475,938	11.1 %	4,475,938	8.8 %
Entities Affiliated with Thomas Strüngmann, Ph.D.[4]	2,849,057	7.1 %	2,849,057	5.6 %
Entities Affiliated with Biotechnology Value Fund[5]	3,239,908	8.0 %	3,239,908	6.4 %
Dawn Holdco[6]	2,469,108	6.1 %	2,469,108	4.8 %
Entities Affiliated with INCE Capital[7]	2,241,919	5.6 %	2,241,919	4.4 %
Named Executive Officers and Directors:				
Shanshan Xu, M.D., Ph.D., M.B.A.[1]	8,623,812	21.2 %	8,623,812	16.9 %
Thang Ho, Ph.D.[8]	228,375	*	228,375	*
Derek DiRocco, Ph.D.	—	—	—	—
Christian Foerster, M.Sc.	—	—	—	—
Helmut Jeggle, M.B.A.[2]	8,889,301	22.0 %	8,889,301	17.4 %
Howard Liang, Ph.D., M.B.A.[9]	21,376	*	21,376	*
All directors and executive officers as a group (seven persons)[10]	17,762,864	43.5 %	17,762,864	34.5 %

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 221,017 shares subject to options held directly by Dr. Shanshan Xu, M.D., Ph.D., M.B.A., exercisable within 60 days of October 23, 2026, (ii) 7,562,518 shares of common stock held of record by MiNeng, Inc. ("MiNeng") and (iii) 840,277 shares of common stock held of record by The Shanshan Xu 2025 Irrevocable Family Trust ("Xu Trust"). Dr. Xu is the President and sole stockholder of MiNeng and therefore has sole voting and dispositive power with regard to the shares held by MiNeng. Dr. Xu may be deemed to share voting and dispositive power with respect to the shares held by the Xu Trust. The address of the Xu Trust is c/o Brian W. Monnich, Trustee, Choate, Hall & Stewart LLP, Two International Place, Boston, MA 02110.

(2) Consists of 8,889,301 shares held by Salvia Investment GmbH ("Salvia"). Helmut Jeggle, M.B.A. is the Managing Director of Salvia GmbH and has sole voting and dispositive power with respect to the shares held by Salvia. Mr. Jeggle disclaims beneficial ownership of such holdings, except to the extent of his pecuniary interest in the shares. The principal business address of the persons and entities listed above is Bergfeldstraße 9, Holzkirchen, 83607, Germany.

(3) Consists of (i) 3,144,858 shares held by RA Capital Healthcare Fund, L.P. ("RACHF") and (ii) 1,331,080 shares held by RA Capital Nexus Fund III, L.P. ("Nexus III"). RA Capital Management, L.P. ("RA Capital Management") is the investment manager of RACHF and Nexus III. The general partner of RA Capital Management is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. Each of RA Capital Management, RA Capital Management GP, LLC, Mr. Kolchinsky, and Mr. Shah may be deemed to have voting and investment power over the shares held by RACHF and Nexus III. RA Capital Management, RA Capital Management GP, LLC, Mr. Kolchinsky, and Mr. Shah each disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The principal business address of the persons and entities listed above is c/o RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(4) Consists of (i) 82,490 shares held by THOMAST GmbH and (ii) 2,766,567 shares held by Salzufer Holding Inc. ("Salzufer"). Thomas Strüngmann, Ph.D. is the sole shareholder and managing director of THOMAST GmbH and therefore has sole voting and dispositive power with regard to the shares held by THOMAS T GmbH. Objektgesellschaft Salzufer 1 GmbH is the sole shareholder of Salzufer, and ATHOS KG ("ATHOS") is the sole shareholder of Objektgesellschaft Salzufer 1 GmbH. Thomas Maier is a general partner (Komplementär) of ATHOS. The limited partners (kommanditisten) of ATHOS are members of the families of Thomas and Andreas Strüngmann. Each of Objektgesellschaft Salzufer 1 GmbH, ATHOS KG, and Thomas Maier may be deemed to share voting and dispositive power over the securities held by Salzufer. Thomas Maier expressly disclaims beneficial ownership of the securities being registered hereby for sale. The principal business address of THOMAST GmbH is Rosenheimer Platz 6, 81669 Munich, Germany. The principal business address of Salzufer is 4918 SW 74th Ct, Miami, FL, 33155.

(5) Consists of (i) 1,692,704 shares held by Biotechnology Value Fund, L.P. ("BVF"), (ii) 1,332,804 shares held by Biotechnology Value Fund II, L.P. ("BVF II"), (iii) 156,746 shares held by Biotechnology Value Trading Fund OS LP ("Trading Fund OS"), and (iv) 57,654 shares held by MSI BVF SPV, LLC ("MSI"). BVF, BVF II, Trading Fund OS and MSI are collectively referred to as the BVF Entities. BVF I GP LLC ("BVF GP"), as the general partner of BVF, may be deemed to share voting and dispositive power over the shares held by BVF. BVF

II GP LLC ("BVF II GP"), as the general partner of BVF II, may be deemed to share voting and dispositive power over the shares held by BVF II. BVF Partners OS Ltd. ("Partners OS"), as the general partner of Trading Fund OS, may be deemed to share voting and dispositive power over the shares held by Trading Fund OS. BVF GP Holdings LLC ("BVF GPH"), as the sole member of each of BVF GP and BVF II GP, may be deemed to share voting and dispositive power over the shares held by BVF and BVF II. BVF Partners L.P. ("Partners") as the investment manager of BVF, BVF II, Trading Fund OS and MSI, and the sole member of Partners OS, may be deemed to share voting and dispositive power over the shares held by BVF, BVF II, Trading Fund OS and MSI. BVF Inc., as the general partner of Partners, may be deemed to share voting and dispositive power over the shares indirectly held by Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to share voting and dispositive power over the shares indirectly held by BVF Inc. Each of BVF GP, BVF II GP, Partners OS, BVF GPH, Partners, BVF Inc., and Mark Lampert disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The principal business address of the persons and entities listed above is 44 Montgomery Street, Suite 4000, San Francisco, CA 94104.

(6) Consists of 2,469,108 shares of common stock held by Dawn Holdco SCSP ("Dawn"), acting through its managing general partner Dawn Holdco GP S.à.r.l.. The principal business address of the persons and entities listed above is 2, rue Edward Steichen, L-2540 Luxembourg, Grand Duchy of Luxembourg, Attn: Iyona Rajkomar.

(7) Consists of 2,241,919 shares held by INCE 227 Limited ("INCE 227"). INCE 227 is wholly owned by INCE Capital Partners II, L.P. ("INCE Capital"), a USD partnership regulated by Cayman Islands Monetary Authority (CIMA) under the Private Funds Act and whose general partner is INCE GP II Ltd. ("INCE GP"). The principal business address of the persons and entities listed above is 1528 W Warm Springs Rd #130, Henderson, NV 89014.

(8) Consists of 228,375 shares subject to outstanding options that are exercisable within 60 days of October 23, 2026.

(9) Consists of 21,376 shares subject to outstanding options that are exercisable within 60 days of October 23, 2026.

(10) Consists of (i) 17,292,096 shares beneficially owned by our executive officers and directors and (ii) 470,768 shares subject to outstanding options held by our executive officers and directors that are exercisable within 60 days of October 23, 2026.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes certain important terms of our capital stock, as they are expected to be in effect upon the closing of this offering. We adopted an amended and restated certificate of incorporation that will be in effect upon the closing of this offering, and amended and restated bylaws that will become effective as of the closing of this offering, and this description summarizes the provisions that are expected to be included in such documents. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this section titled "Description of Capital Stock," you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, and investors' rights agreement, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

Upon the closing of this offering, our authorized capital stock will consist of 1,200,000,000 shares of capital stock, $0.00001 par value per share, consisting of 1,000,000,000 shares of common stock and 200,000,000 shares of preferred stock.

Assuming the automatic conversion of all outstanding shares of our preferred stock into 27,391,561 shares of our common stock and the issuance of 621,192 shares of our common stock pursuant to the Liquidity Event RSU Settlement, as if they had occurred as of June 30, 2026, there were 40,386,875 shares of our common stock outstanding (which includes 2,866,703 shares of unvested restricted common stock), held by 28 stockholders of record, and no shares of our preferred stock outstanding.

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled "Dividend Policy" for more information.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption, or sinking fund provisions.

Voting Rights

Holders of our common stock are entitled to one vote for each share held as of the applicable record date on all matters submitted to a vote of stockholders.

Our stockholders do not have the ability to cumulate votes for the election of directors. As a result, the holders of a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares cast affirmatively or negatively shall be the act of the stockholders (abstentions and broker non-votes are counted for purposes of establishing a quorum but are not treated as votes cast), except as otherwise provided by law, our governing documents, or the rules of the stock exchange on which our securities are listed. The holders of a majority of the voting power of the capital stock issued and outstanding and entitled to vote as of the applicable record date, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only the directors in one class will be elected at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms.

Liquidation Rights

If we become subject to a liquidation, dissolution, or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Fully Paid and Nonassessable

In connection with this offering, our legal counsel will opine that the shares of our common stock to be issued in this offering will be fully paid and non-assessable.

Preferred Stock

Our board of directors will have the authority, subject to limitations prescribed by Delaware law, to issue shares of authorized but unissued preferred stock in one or more series, and to fix the designations, powers, preferences, and rights, and the qualifications, limitations, or restrictions thereof, in each case without further vote or action by our stockholders. These powers, rights, preferences, and privileges could include dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price(s), and liquidation preferences, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of the common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring, or preventing a change in our control or other corporate action. As of the closing of this offering, no shares of preferred stock will be outstanding.

Options

As of June 30, 2026, we had outstanding options to purchase an aggregate of 1,550,428 shares of our common stock, with a weighted-average exercise price of $0.90 per share, under our 2024 Plan.

Registration Rights

Upon the completion of this offering, under our investors' rights agreement, the holders of up to 39,750,360 shares of our common stock or their transferees, will have the right to require us to register the offer and sale of their shares, or to include their shares in any registration statement we file, in each case as described below.

Demand Registration Rights

After the completion of this offering, the holders of up to 39,750,360 shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of at least a majority of the shares having registration rights then outstanding can request that we file a registration statement on Form S-1 to register the offer and sale of their shares. We are only obligated to effect one such registration. The request for registration must cover at least 40% of the shares having registration rights then outstanding. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us to effect such a demand registration, then we have the right to defer such registration, not more than once in any 12-month period (provided we have not already deferred a request for registration on Form S-3, as described under "—Form S-3 Registration Rights", within that period), for a period of not more than 120 days.

Form S-3 Registration Rights

After the completion of this offering, the holders of up to 39,750,360 shares of our common stock will be entitled to certain Form S-3 registration rights. At any time when we are eligible to file a registration statement on

Form S-3, the holders of the shares having these registration rights then outstanding can request that we register the offer and sale of their shares of our common stock on a registration statement on Form S-3 so long as the request covers securities the anticipated aggregate public offering price of which, net of certain selling expenses, is at least $5 million. We are obligated to effect up to two such registrations within any 12-month period. These Form S-3 registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us to effect such a registration, then we have the right to defer such registration, not more than once in any 12-month period (provided we have not already deferred a request for registration on Form S-1, as described under "—Demand Registration Rights", within that period), for a period of not more than 120 days.

Piggyback Registration Rights

After the completion of this offering, the holders of up to 39,750,360 shares of our common stock will be entitled to certain "piggyback" registration rights. If we propose to register the offer and sale of our common stock under the Securities Act, all holders of these shares then outstanding can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration statement under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (1) a registration relating to a stock option, stock purchase, equity incentive, or similar plan, (2) a registration relating to a transaction covered by Rule 145 promulgated under the Securities Act, (3) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable securities, or (4) a registration in which the only stock being registered is common stock issuable upon conversion of debt securities also being registered, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

Expenses of Registration

We will pay the registration expenses (other than underwriting discounts, selling commissions, and stock transfer taxes) of the holders of the shares to be offered and sold pursuant to the registrations described above, including the reasonable fees and disbursements, not to exceed $30,000 per registration, of one counsel chosen by the holders of the shares included in such registrations.

Termination

The registration rights terminate upon the earliest of (1) as to a given holder of registration rights, when such holder of registration rights, together with its affiliates (as defined under SEC Rule 144) holds less than 1% of our outstanding securities and can sell all of such holder's registrable securities without limitation in a three-month period pursuant to Rule 144 promulgated under the Securities Act, (2) immediately prior to the closing of certain liquidation events, and (3) the date that is five years after the closing of this offering.

Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Certificate of Incorporation and Our Bylaws

Certain provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying, deferring, or discouraging another person from acquiring control of us. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We will be governed by the provisions of Section 203 of the DGCL. Subject to certain exceptions, Section 203 of the DGCL generally prohibits a publicly held Delaware corporation from engaging in a "business combination" (as described below) with any "interested stockholder" (defined generally as any person who, together with such person's affiliates and associates, beneficially owns or has the right to acquire 15% or more of the

outstanding voting stock of such corporation) for a period of three years after the time of the transaction in which the person became an interested stockholder of such corporation, unless:

- the business combination or transaction which resulted in the stockholder becoming an interested stockholder was approved by the board of directors prior to the time that the stockholder became an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the time the stockholder became an interested stockholder, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 and 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- mergers or consolidations involving the corporation, or any direct or indirect majority-owned subsidiary of the corporation, and the interested stockholder or any other entity if the merger or consolidation is caused by the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer, or other disposition (in one transaction or a series of transactions), except proportionately as a stockholder of the corporation, involving the interested stockholder of 10% or more of the assets of the corporation or any direct or indirect majority-owned subsidiary of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation, or any direct or indirect majority-owned subsidiary of the corporation, of any stock of the corporation or such subsidiary to the interested stockholder;
- subject to exceptions, any transaction involving the corporation, or any direct or indirect majority-owned subsidiary of the corporation, that has the effect of increasing the proportionate share of the stock of any class or series of the corporation or such subsidiary owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation or any direct or indirect majority-owned subsidiary.

These provisions may have the effect of delaying, deferring, or preventing changes in control of our company.

Certificate of Incorporation and Bylaws Provisions

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws will include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our board of directors or management. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws will:

- permit our board of directors to issue shares of preferred stock, with any powers, rights, and preferences as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;

- provide that all vacancies and newly created directorships, may, except as otherwise required by law, our governing documents or resolution of our board of directors, and subject to the rights of holders of our preferred stock, only be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes, each of which stands for election once every three years;
- for so long as our board of directors is classified, and subject to the rights of holders of our preferred stock, provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also meet specific requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights (therefore allowing the holders of a plurality of the voting power of the shares of our capital stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the board of directors, the chairperson of the board of directors, or our chief executive officer or president; and
- provide that stockholders will be permitted to amend certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws only upon receiving at least two-thirds of the voting power of the then outstanding voting securities, voting together as a single class.

Exclusive Forum

Our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, stockholders, officers, or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws or (4) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware), except for, as to each of (1) through (4) above, any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction. Our amended and restated bylaws will also provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Exchange Act or the Securities Act against any person in connection with any offering of our securities. Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Fidelity Stock Transfer Solutions LLC. The transfer agent and registrar's address is 245 Summer Street, Boston, Massachusetts 02210.

Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “BBTX.”

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Future sales of shares of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices of our common stock prevailing from time to time. As described below, only a limited number of shares of our common stock will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Upon the completion of this offering, based on our shares of our capital stock outstanding as of June 30, 2026, and after giving effect to the Preferred Stock Conversion and the Liquidity Event RSU Settlement, we will have a total of 50,942,430 shares of our common stock outstanding (which includes 2,866,703 shares of unvested restricted common stock). Of these outstanding shares, all 10,555,555 shares of our common stock sold in this offering will be freely tradable, except that (1) any shares purchased in this offering by our "affiliates," as that term is defined in Rule 144 under the Securities Act, would only be able to be sold in compliance with the Rule 144 limitations described below and (2) any shares purchased in our reserved share program by our directors, officers and employees will be subject to the lock-up agreements described below.

The remaining outstanding shares of our common stock will be, and shares subject to stock options will be upon issuance, deemed "restricted securities" as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below. As a result of the lock-up agreements and market standoff provisions described below and subject to the provisions of Rules 144 or 701, shares of our common stock will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all 10,555,555 shares of our common stock sold in this offering (other than shares sold to our directors, officers and employees in our reserved share program) will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, subject to the terms of the lock-up agreements and market standoff provisions described below, all remaining shares will become eligible for sale in the public market, of which 32,568,026 shares will be held by affiliates and subject to the volume and other restrictions of Rule 144 (which number excludes shares sold to our affiliates in our reserved share program), as described below.

Lock-up Agreements and Market Standoff Provisions

We, our directors and officers, and substantially all of the holders of our equity securities have agreed, subject to certain exceptions, not to offer, sell, or transfer any shares of our common stock or securities convertible into or exchangeable or exercisable for our common stock for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Evercore Group L.L.C., as representatives of the several underwriters of this offering. These agreements are described below under the section titled "Underwriting."

After this offering, certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

In addition, our directors and officers and substantially all of the holders of our equity securities have entered into market standoff agreements with us under which they have agreed that, subject to certain exceptions, for a period of up to 180 days after the date of this prospectus, they will not, without the prior written consent of the managing underwriter, lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any

option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or hedge, any shares or any securities convertible into or exchangeable for shares of our common stock.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares of our common stock proposed to be sold for at least six months is entitled to sell those shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares of our common stock on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements and market standoff provisions described above, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 509,424 shares immediately after this offering; and
- the average weekly trading volume of our common stock during the four calendar weeks preceding the date of filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates or persons selling shares of our common stock on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

In general, under Rule 701, a person who purchased shares of our capital stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days may sell these shares in reliance upon Rule 144, but without being required to comply with the notice, manner of sale, or public information requirements or volume limitation provisions of Rule 144. Rule 701 also permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the effective date of this prospectus before selling such shares pursuant to Rule 701.

Registration Rights

Pursuant to our investors' rights agreement, upon the completion of this offering, the holders of up to 39,750,360 shares of our common stock, or certain permitted transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. These registration rights are described under the section titled "Description of Capital Stock—Registration Rights." Upon the effectiveness of a registration statement covering these shares, the shares would become freely tradable without restriction under the Securities Act, subject to the Rule 144 limitations applicable to affiliates, and a large number of shares may be sold into the public market.

Registration Statement on Form S-8

We have filed a registration statement on Form S-8 under the Securities Act to register shares of our common stock subject to options outstanding, as well as reserved for future issuance, under our equity compensation plans. The registration statement on Form S-8 became effective immediately upon filing, and shares covered by the registration statement will then become eligible for sale in the public market, subject to the Rule 144 limitations applicable to affiliates, vesting restrictions and any applicable market standoff provisions and lock-up agreements.

See the section titled “Executive Compensation—Employee Benefit and Stock Plans” for a description of our equity compensation plans.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of material U.S. federal income tax considerations of the ownership and disposition of our common stock acquired in this offering by a "non-U.S. holder" (as defined below) but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, and administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed or be subject to differing interpretations, possibly with retroactive effect, so as to result in U.S. federal income tax considerations different from those set forth below. We have not sought, and do not intend to seek, any ruling from the U.S. Internal Revenue Service (the "IRS") with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary does not address the tax considerations arising under the laws of any U.S. state or local or non-U.S. jurisdiction or under other U.S. federal tax laws, such as gift and estate tax rules, or the effect, if any, of the Medicare contribution tax on net investment income. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts, or other financial institutions;
- persons subject to the alternative minimum tax;
- tax-exempt or governmental organizations;
- pension plans and tax-qualified retirement plans;
- controlled foreign corporations, foreign controlled foreign corporations, passive foreign investment companies, and corporations that accumulate earnings to avoid U.S. federal income tax;
- entities or arrangements treated as partnerships for U.S. federal income tax purposes or other pass-through entities (or owners of such entities or arrangements);
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of tax accounting for their securities holdings;
- persons who own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," or other risk reduction transaction;
- persons who hold or receive our common stock pursuant to the exercise of any option or otherwise as compensation;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment);
- persons deemed to sell our common stock under the constructive sale provisions of the Code; or

- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an "applicable financial statement" as defined in Section 451(b) of the Code.

In addition, if a partnership (or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) or other pass-through entity holds our common stock, the tax treatment of a partner or owner in the partnership or pass-through entity generally will depend on the status of the partner or owner and upon the activities of the partnership or pass-through entity. Partnerships or pass-through entities holding our common stock and the partners or owners in such partnerships or pass-through entities should consult their own tax advisors regarding the U.S. federal income tax considerations applicable to them.

This discussion is for general informational purposes only and does not constitute legal or tax advice. You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax considerations of the purchase, ownership, and disposition of our common stock arising under the U.S. federal gift or estate tax rules or under the laws of any U.S. state or local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a "non-U.S. holder" if you are a beneficial owner of our common stock that, for U.S. federal income tax purposes, is neither a partnership nor:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized under the laws of the United States or any state or political subdivision thereof, or otherwise treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and that has one or more "United States persons" (as defined in Section 7701(a)(30) of the Code) who have the authority to control all substantial decisions of the trust or (y) that has made a valid election under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy," we have never declared or paid cash dividends on our common stock, and we do not anticipate paying any such dividends on our common stock following the completion of this offering. However, if we do make cash distributions (or distributions of property other than certain distributions of our common stock) on our common stock, those distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your adjusted tax basis in our common stock, but not below zero, and then will be treated as capital gain from the sale of our common stock as described below under "—Gain on Disposition of Common Stock."

Subject to the discussions below regarding effectively connected income, backup withholding, and the Foreign Account Tax Compliance Act ("FATCA"), any dividend paid to you generally will be subject to U.S. federal withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. In order to receive a reduced treaty rate, you must provide us or the applicable withholding agent with an IRS Form W-8BEN or W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. If you hold our common stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or the applicable withholding agent, either directly or through other intermediaries.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, that are attributable to a permanent establishment or fixed base maintained by you in the United States) are generally exempt from the 30% U.S. federal withholding tax, subject to the discussions below regarding backup withholding and FATCA withholding. In order to obtain this exemption, you must provide us or the applicable withholding agent with a properly executed IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to U.S. federal withholding tax, generally are taxed at the U.S. federal income tax rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. You should consult your tax advisor regarding the tax consequences of the receipt of distributions on our common stock, including the application of any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussions below regarding backup withholding and FATCA withholding, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation" ("USRPHC") for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our U.S. and worldwide real property interests plus our other assets used or held for use in a trade or business, there can be no assurance that we currently are not a USRPHC or will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is "regularly traded" on an "established securities market", each as defined by applicable Treasury Regulations, your common stock will be treated as U.S. real property interests only if you actually (directly or indirectly) and/or constructively hold more than five percent of our common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

Gain described in the first bullet above generally will be subject to U.S. federal income tax rates applicable to U.S. persons. A corporate non-U.S. holder also may be subject to the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to U.S. federal income tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale or other disposition, which gain may be offset by U.S. source capital losses for the year, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult your tax advisor regarding any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS any distributions on our common stock paid to you, your name and address, and the amount of tax withheld, if any, regardless of whether such distributions constitute dividends. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock within the United States or conducted through certain U.S.-related brokers made to you may be subject to backup withholding at the applicable statutory rate unless you certify your non-U.S. status, for example, by properly certifying your non-U.S. status on a properly completed IRS Form W-8BEN or W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or the applicable withholding agent has actual knowledge, or reason to know, that you are a United States person. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Additional Withholding Requirements under the Foreign Account Tax Compliance Act

FATCA, including Sections 1471 through 1474 of the Code and the Treasury Regulations and other official IRS guidance issued thereunder, generally imposes a U.S. federal withholding tax of 30% on dividends on, and (subject to the proposed Treasury Regulations discussed in this section) the gross proceeds from a sale or other disposition of, our common stock, paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the accounts of such institution held by certain "specified United States persons" or "United States owned foreign entities" (each as specially defined under these rules) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on, and (subject to the proposed Treasury Regulations discussed in this section) the gross proceeds from a sale or other disposition of, our common stock paid to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent with a certification identifying the "substantial United States owners" (as specially defined under these rules) of the entity, certifies that it does not have any substantial United States owners, or otherwise establishes an exemption. However, proposed Treasury Regulations eliminate FATCA withholding on gross proceeds of the sale or other disposition of our common stock (but not on payments of dividends). They may be relied upon by taxpayers until final Treasury Regulations are issued or until such proposed Treasury Regulations are rescinded. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States may be subject to different rules. You should consult with your own tax advisors regarding the application of FATCA withholding to your investment in, and ownership and disposition of, our common stock.

The preceding discussion of material U.S. federal income tax considerations is for general information only. It is not tax advice to investors in their particular circumstances. You should consult your own tax advisor regarding the particular U.S. federal, state, and local and non-U.S. tax considerations of purchasing, owning, and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

BofA Securities, Inc., Evercore Group L.L.C., UBS Securities LLC and Cantor Fitzgerald & Co. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	3,430,555
Evercore Group L.L.C.	2,902,778
UBS Securities LLC	2,111,111
Cantor Fitzgerald & Co.	2,111,111
Total	10,555,555

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel, or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $0.672 per share. After the initial offering, the public offering price, concession, or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discounts and commissions, and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$ 16.00	$ 168,888,880	$ 194,222,208
Underwriting discounts and commissions	$ 1.12	$ 11,822,222	$ 13,595,555
Proceeds, before expenses, to us	$ 14.88	$ 157,066,658	$ 180,626,653

The expenses of the offering, not including the underwriting discount, are estimated at $4.6 million and are payable by us. We have agreed to reimburse the underwriters for certain of their expenses up to $40,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,583,333 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting

agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers, directors, and holders of substantially all of our capital stock and securities convertible into or exchangeable for our common stock have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Evercore Group L.L.C. Specifically, we and these other persons have agreed, with certain exceptions, not to directly or indirectly:

- offer, pledge, sell, or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right, or warrant for the sale of any common stock;
- lend or otherwise dispose of or transfer any common stock;
- request or demand that we file or make a confidential submission of a registration statement related to the common stock; or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The restrictions described above and contained in the lock-up agreement between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including transfers of lock-up securities:

- as a bona fide gift or gifts, including, without limitation, gifts to a trust, charitable organization or educational institution, or for bona fide estate planning purposes;
- by will, testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the lock-up signatory;
- by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement;
- pursuant to an order of a court or regulatory agency having jurisdiction over the lock-up signatory;
- to any corporation, partnership, limited liability company or other entity of which the lock-up signatory or the immediate family of the lock-up signatory are the legal and beneficial owner of all of the outstanding equity securities or similar interests;
- to a nominee or custodian of a person or entity to whom a transfer would be permissible under the preceding bullets;
- to any immediate family member or any trust, partnership, limited liability company or other entity for the direct or indirect benefit of the lock-up signatory or one or more immediate family members of the lock-up

signatory, or if the lock-up signatory is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust;

- if the lock-up signatory is a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up signatory, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up signatory or affiliates of the lock-up signatory, or (B) as part of a distribution to partners, members, managers or stockholders of the lock-up signatory or holders of similar equity interests in the lock-up signatory;
- to us upon the lock-up signatory's death, disability or termination of employment or other service relationship with us;
- to us upon the exercise, vesting or settlement of any equity award granted under any equity incentive plan or stock purchase plan, or any warrants or other securities convertible into or exercisable or exchangeable for shares of common stock, in each case that is disclosed in this prospectus (including in each case on a "net" or "cashless" basis), including for the payment of tax withholdings or remittance payments, including estimated taxes, due as a result of such exercise, vesting or settlement, provided that (A) any such shares of common stock received upon such vesting or exercise shall be subject to the terms of the lock-up agreement, (B) any filing under the Exchange Act made during the lock-up period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described above, as applicable, and (C) the lock-up signatory does not otherwise voluntarily effect any other public filings or reports regarding such transfers during the lock-up period; or
- the establishment or amendment of a trading plan under Rule 10b5-1 under the Exchange Act, provided that no sales of lock-up securities are made under such plan during the lock-up period.

The restrictions described above do not apply to us with respect to certain transactions, including in connection with:

- the sale of our common stock to the underwriters pursuant to the underwriting agreement;
- the issuance of any shares of common stock by us upon the exercise of an option or other equity incentive awards, settlement of other equity awards, or conversion of a security outstanding on the date of the underwriting agreement and referred to in this prospectus;
- the issuance of any shares of common stock or granting of options to purchase common stock pursuant to our employee benefit plans referred to in this prospectus;
- the issuance of any shares of common stock pursuant to any non-employee director compensation plan or program or dividend reinvestment plan referred to in this prospectus;
- the reacquisition or withholding of all or a portion of shares of common stock subject to a stock option or other equity incentive award to satisfy the purchase price or exercise price of such stock award and/or for the payment of related tax withholdings or remittance payments;
- our filing of a registration statement on Form S-8 or any successor form thereto with respect to the registration of securities to be offered under any of our employee benefit or equity incentive plans referred to in this prospectus; and
- the issuance of common stock or other securities issued in connection with (A) the acquisition of securities, businesses, properties or other assets or pursuant to any employee benefit plan assumed in connection with any such acquisition, (B) joint ventures, (C) collaboration, licensing, or commercial relationships, or (D) other strategic transactions with a bona fide business purpose; provided, that the aggregate number of shares of common stock or other securities issued pursuant to the foregoing shall not exceed 5% of the total number of issued and outstanding shares of common stock immediately following the issuance and sale of the securities upon the closing of this offering pursuant to the underwriting agreement; provided further that

each recipient of any such shares of common stock or securities issued pursuant to the foregoing agrees to be bound by the terms of the lock-up agreement or shall enter into a lock-up agreement.

BofA Securities, Inc. and Evercore Group L.L.C., in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

Listing

The shares have been approved for listing on Nasdaq under the symbol "BBTX."

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix, or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales, and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that

might otherwise exist in the open market. The underwriters may conduct these transactions on Nasdaq, in the over-the-counter market, or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Reserved Share Program

At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 3.5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. If these persons purchase reserved shares it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area (each a "Relevant State"), no shares of common stock have been offered or will be offered pursuant to the offering of shares to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(a) to any qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation, supplement a prospectus pursuant to Article 23 of the Prospectus Regulation or publish an Annex IX document pursuant to Article 1(4) of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

No shares of common stock have been offered or will be offered pursuant to the offering of shares to the public in the United Kingdom except that the shares may be offered to the public in the United Kingdom at any time:

(a) where the offer is conditional on the admission of the shares to trading on the London Stock Exchange plc's main market (in reliance on the exception in paragraph 6(a) of Schedule 1 of the United Kingdom Public Offers and Admissions to Trading Regulations 2024 ("POATR"));

(b) to any qualified investor as defined under paragraph 15 of Schedule 1 of the POATR;

(c) to fewer than 150 persons (other than qualified investors as defined under paragraph 15 of Schedule 1 of the POATR), subject to obtaining the prior consent of the representatives for any such offer; or

(d) in any other circumstances falling within Part 1 of Schedule 1 of the POATR.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares of common stock in the United Kingdom means the communication to any person which presents sufficient information on: (a) the shares of common stock to be offered; and (b) the terms on which they are to be offered, to enable an investor to decide to buy or subscribe for the shares.

Notice to Prospective Investors in Switzerland

This prospectus does not constitute an offer to the public or a solicitation to purchase or invest in any shares of common stock. No shares of common stock have been offered or will be offered to the public in Switzerland, except that offers of shares of common stock may be made to the public in Switzerland at any time under the following exemptions under the Swiss Financial Services Act ("FinSA"):

(a) to any person which is a professional client as defined under the FinSA;

(b) to fewer than 500 persons (other than professional clients as defined under the FinSA), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 36 FinSA in connection with Article 44 of the Swiss Financial Services Ordinance,

provided that no such offer of shares of common stock shall require the Company or any investment bank to publish a prospectus pursuant to Article 35 FinSA.

The shares of common stock have not been and will not be listed or admitted to trading on a trading venue in Switzerland. Neither this document nor any other offering or marketing material relating to the shares of common stock constitutes a prospectus as such term is understood pursuant to the FinSA and neither this document nor any other offering or marketing material relating to the shares of common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an exempt offer which is not subject to any form of regulation or approval by the Dubai Financial Services Authority (the "DFSA"). The DFSA has not approved this prospectus nor has any responsibility for reviewing or verifying any document or other documents in connection with the offering of shares of common stock. Accordingly, the DFSA has not approved this prospectus or any other associated documents nor taken any steps to verify the information set out in this prospectus, and has no responsibility for it.

The shares of common stock have not been offered and will not be offered to any persons in the DIFC except on the basis that an offer is:

(a) an "Exempt Offer" in accordance with the Markets Rules ("MKT") Module of the DFSA Rulebook; and

(b) made only to persons who meet the "Deemed Professional Client" criteria set out in Rule 2.3.4 of the Conduct of Business ("COB") module of the DFSA Rulebook, who are not natural persons.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement, or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement, or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement, or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act), or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation, or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives, and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation, or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares of common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations, and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the

relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares of common stock were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of common stock, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares of common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares of common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* ("NI 33-105"), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Korea

The shares of common stock have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the shares of common stock have been and will be offered in Korea as a private placement under the FSCMA. None of the shares of common stock may be offered, sold, or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). Furthermore, the purchaser of the shares of common stock shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares of common stock. By the purchase of the shares of common stock, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares of common stock pursuant to the applicable laws and regulations of Korea.

Notice to Prospective Investors in Brazil

The offer and sale of the shares of common stock have not been and will not be registered with the Brazilian Securities Commission ("Comissão de Valores Mobiliários", or "CVM") and, therefore, will not be carried out by any means that would constitute a public offering in Brazil under CVM Resolution No 160, dated 13 July 2022, as amended, or unauthorized distribution under Brazilian laws and regulations. The shares of common may only be offered to Brazilian professional investors (as defined by applicable CVM Regulation), who may only acquire the shares of common stock through a non-Brazilian account, with settlement outside Brazil in non-Brazilian currency. The trading of these shares of common on regulated securities markets in Brazil is prohibited.

Notice to Prospective Investors in Israel

The shares of common stock offered by this prospectus have not been approved or disapproved by the Israel Securities Authority (the "ISA"), nor have such shares of common stock been registered for sale in Israel. The shares of common stock may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus that has been approved by the ISA. The ISA has not issued permits, approvals, or licenses in connection with this offering or publishing this document, nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the shares of common stock being offered.

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the "Israeli Securities Law"), and has not been filed with or approved by the ISA. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum (the "Addendum") to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million, and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same, and agree to it.

LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation, Boston, Massachusetts, which has acted as our counsel in connection with this offering, will pass upon the validity of the shares of our common stock being offered by this prospectus. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2025 and December 31, 2024 and for the year ended December 31, 2025, and for the period from March 14, 2024 (Inception) through December 31, 2024 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus constitutes only a part of the registration statement. Some items are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or document referred to are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an Internet website at *www.sec.gov* that contains reports, proxy and information statements, and other information about issuers, like us, that file electronically with the SEC.

Immediately upon the effectiveness of the registration statement of which this prospectus forms a part, we became subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. We also maintain a website at www.bambusatx.com. Upon the effectiveness of the registration statement of which this prospectus forms a part, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessed through, our website is not a part of, and is not incorporated by reference into, this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Bambusa Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Bambusa Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and December 31, 2024, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' deficit and of cash flows for the year ended December 31, 2025 and for the period from March 14, 2024 (Inception) to December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2025 and for the period from March 14, 2024 (Inception) to December 31, 2024 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses and negative operating cash flows since its inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
August 3, 2026, except for the effects of the stock split discussed in Note 17 to the consolidated financial statements, as to which the date is October 26, 2026

We have served as the Company's auditor since 2026.

BAMBUSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 50,643	$ 9,362
Marketable securities	39,984	—
Prepaid expenses and other current assets	3,505	402
Total current assets	94,132	9,764
Other assets	1,581	—
Total assets	$ 95,713	$ 9,764
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,905	$ 13
Accrued expenses and other current liabilities	7,743	9,303
Total current liabilities	9,648	9,316
Commitments and contingencies (Note 14)		
Series Seed convertible preferred stock, $0.00001 par value; 5,329,588 shares authorized, 5,329,584 shares issued and outstanding; liquidation preference of $5,100 as of December 31, 2025 and 2024	5,066	5,066
Series Seed Plus convertible preferred stock, $0.00001 par value; 3,740,043 shares authorized, 3,740,038 shares issued and outstanding; liquidation preference of $9,000 as of December 31, 2025 and 2024	8,930	8,930
Series A-1 convertible preferred stock, $0.00001 par value; 15,593,922 and zero shares authorized, 15,593,907 and zero shares issued and outstanding as of December 31, 2025 and 2024, respectively; liquidation preference of $88,880 and zero as of December 31, 2025 and 2024, respectively	89,232	—
Series A-2 convertible preferred stock, $0.00001 par value; 2,728,039 and zero shares authorized, 2,645,542 and zero shares issued and outstanding as of December 31, 2025 and 2024, respectively; liquidation preference of $32,070 and zero as of December 31, 2025 and 2024, respectively	32,007	—
Stockholders' deficit:		
Common stock, $0.00001 par value; 46,346,000 and 25,181,055 shares authorized as of December 31, 2025 and 2024, respectively; 12,374,122 and 12,358,799 shares issued and outstanding as of December 31, 2025, and 2024, respectively	—	—
Additional paid-in capital	5,598	193
Accumulated other comprehensive income	60	—
Accumulated deficit	(54,828)	(13,741)
Total stockholders' deficit	$ (49,170)	$ (13,548)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 95,713	$ 9,764

The accompanying notes are an integral part of these consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024
Operating Expenses:		
Research and development	$ 38,096	$ 13,025
General and administrative	5,910	855
Total operating expenses	44,006	13,880
Loss from operations	(44,006)	(13,880)
Other income (expense):		
Interest income	2,171	131
Research and development incentive	3,310	—
Change in fair value of preferred stock tranche right obligation	(454)	—
Other income, net	125	8
Total other income, net	5,152	139
Loss before income taxes	(38,854)	(13,741)
Income tax provision	2,233	—
Net loss	$ (41,087)	$ (13,741)
Comprehensive loss:		
Net loss	$ (41,087)	$ (13,741)
Unrealized gains on marketable securities	60	—
Comprehensive loss	$ (41,027)	$ (13,741)
Net loss attributable to common stockholders[(1)]	$ (39,332)	N/A
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (6.08)	N/A
Weighted-average common shares outstanding, basic and diluted[(1)]	6,474,305	N/A

(1) Represents net loss per share of common stock and weighted-average shares of common stock outstanding for the period from February 12, 2025 to December 31, 2025. See Note 2—Summary of Significant Accounting Policies and Note 15—Net Loss Per Share.

The accompanying notes are an integral part of these consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
March 14, 2024 (Inception)	—	$ —	—	$ —	$ —	$ —	$ —	$ —
Issuance of restricted common stock	—	—	12,358,799	—	—	—	—	—
Issuance of Series Seed preferred stock, net of issuance costs of $34	5,329,584	5,066	—	—	—	—	—	—
Issuance of Series Seed Plus preferred stock, net of issuance costs of $70	3,740,038	8,930	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	193	—	—	193
Net loss	—	—	—	—	—	—	(13,741)	(13,741)
Balances at December 31, 2024	9,069,622	13,996	12,358,799	—	193	—	(13,741)	(13,548)
Issuance of Series A-1 preferred stock, inclusive of issuance and settlement of preferred stock tranche right obligation, net of issuance costs of $101	15,593,907	89,232	—	—	—	—	—	—
Issuance of Series A-2 preferred stock, net of issuance costs of $64	2,645,542	32,007	—	—	—	—	—	—
Issuance of common stock	—	—	15,323	—	28	—	—	28
Stock-based compensation expense	—	—	—	—	5,377	—	—	5,377
Unrealized gain on marketable securities	—	—	—	—	—	60	—	60
Net loss	—	—	—	—	—	—	(41,087)	(41,087)
Balances at December 31, 2025	27,309,071	$ 135,235	12,374,122	$ —	$ 5,598	$ 60	$ (54,828)	$ (49,170)

The accompanying notes are an integral part of these consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024
Cash flows from operating activities:		
Net loss	$ (41,087)	$ (13,741)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,377	193
Change in fair value of preferred stock tranche right obligation	454	—
Accretion of discount on marketable securities	(196)	—
Unrealized gain on foreign currency transactions	(71)	(8)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,063)	(394)
Other assets	(1,567)	—
Accounts payable	1,906	13
Accrued expenses and other current liabilities	(1,557)	9,303
Net cash used in operating activities	(39,804)	(4,634)
Cash flows from investing activities:		
Purchases of marketable securities	(47,228)	—
Maturities of marketable securities	7,500	—
Net cash used in investing activities	(39,728)	—
Cash flows from financing activities:		
Proceeds from issuance of common stock	28	—
Proceeds from issuance of Series Seed convertible preferred stock, net of issuance costs paid of $34[(1)]	—	5,066
Proceeds from issuance of Series Seed Plus convertible preferred stock, net of issuance costs paid of $70[(2)]	—	8,930
Proceeds from issuance of Series A-1 convertible preferred stock, including tranche obligation, net of issuance costs paid of $101[(3)]	88,778	—
Proceeds from issuance of Series A-2 convertible preferred stock, net of issuance costs paid of $64[(4)]	32,007	—
Net cash provided by financing activities	120,813	13,996
Net increase in cash and cash equivalents	41,281	9,362
Cash and cash equivalents:		
Beginning of period	9,362	—
End of period	$ 50,643	$ 9,362
Supplemental disclosure of noncash investing and financing activities		
Settlement of Series A-1 preferred stock tranche right obligation	$ 2,271	$ —

(1) Includes related party amount of $3.7 million (see Note 16).
(2) Includes related party amounts of $0.1 million (see Note 16).
(3) Includes related party amounts of $9.1 million (see Note 16).
(4) Includes related party amounts of $2.3 million (see Note 16).

The accompanying notes are an integral part of these consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
Notes to Consolidated Financial Statements

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Bambusa Therapeutics, Inc. and its consolidated subsidiaries (the "Company" or "Bambusa"), is a clinical-stage therapeutics company focused on developing innovative bispecific antibodies for immunological and inflammatory ("I&I") disorders. The Company was incorporated on March 14, 2024 in the state of Delaware, and its principal offices are in Boston, Massachusetts.

As used in the accompanying consolidated financial statements, unless the context otherwise requires, references to the "Company" or "Bambusa" refer to Bambusa Therapeutics, Inc. and its wholly owned subsidiaries Bambusa Securities Corporation, Bambusa Therapeutics Pty. Ltd (Australia), and Bambusa (Beijing) Therapeutics Co., Ltd.

Basis of presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") and in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). These consolidated financial statements include the accounts of Bambusa Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Risks and uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including but not limited to, successful completion of preclinical studies and clinical trials, obtaining regulatory approvals for product candidates, new technological innovations, protection of proprietary technology, competition, dependence on key personnel, compliance with government regulations, reliance on third-party organizations for the discovery, manufacturing, and preclinical and clinical support of its product candidates, managing growth and expansion of the Company, and the ability to secure capital necessary to fund operations. Product candidates currently under development will require significant additional research and development efforts, including manufacturing, preclinical and clinical development, and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities.

There can be no assurance that the Company's research and development efforts will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Going concern

Management has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements were available to be issued.

Since inception, the Company has devoted the majority of its resources to research and development of its product candidates, including by conducting clinical trials and preclinical studies, raising capital, and recruiting management and technical staff to support these operations. To date, the Company has not generated any revenue from product sales as none of its product candidates have been approved for commercialization. The Company has

historically financed its operations primarily through the sale of convertible preferred stock. The Company has incurred recurring losses and negative operating cash flows since its inception. As of December 31, 2025, the Company had an accumulated deficit of $54.8 million. The Company expects to continue to generate operating losses and negative cash flows for the foreseeable future as the Company continues to develop its product candidates. The Company's future operations will be dependent on its ability to raise additional capital to finance such operations.

As of August 3, 2026, the date these consolidated financial statements were available to be issued, the Company expects that its cash and cash equivalents and marketable securities on hand will not be sufficient to fund its operations for at least 12 months from the date these consolidated financial statements were available to be issued. Accordingly, the Company determined there is substantial doubt about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Significant additional funding is necessary to maintain current operations and to advance the Company's research and development activities. The Company plans to seek additional funding through equity offerings or debt financings, credit or loan facilities, strategic alliances, and licensing arrangements. The Company's ability to access capital when and in the amount needed is not assured. The terms of any future financing may adversely affect the holdings or the rights of the Company's current stockholders.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the completion of a qualified public offering on specified terms, the Company's outstanding convertible preferred stock will be automatically converted into shares of common stock (see Note 7). If the Company is unable to complete its IPO or obtain other funding, it could be forced to delay, reduce, or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or it may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all or that any proceeds would be sufficient to support the Company's operating plans for at least the next 12 months from the date these consolidated financial statements were available to be issued.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of estimates

The preparation of consolidated financial statements in accordance with U.S. GAAP requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period presented. Management bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Management evaluates its estimates and assumptions on an ongoing basis. Changes in estimates are recorded in the period in which they become known. Significant estimates and assumptions relied upon in preparing these consolidated financial statements include, but are not limited to, accrued research and development expenses, the valuation of common stock used in the determination of stock-based compensation expense, and the valuation of the preferred stock tranche right obligation. Actual results may differ from the estimates under different assumptions or conditions.

Concentrations of risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and marketable securities. The Company maintains its cash and cash equivalent balances

with financial institutions believed to be of high credit quality and, consequently, the Company believes that such funds are subject to minimal credit risk. At times, the Company's cash and cash equivalents may be uninsured or in deposit accounts that exceed Federal Deposit Insurance Corporation limits. The Company's cash equivalents and marketable securities are comprised of money market funds and U.S. Treasury securities, respectively.

The Company is dependent on the third-party contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") with whom they do business. In particular, the Company relies and expects to continue to rely on a small number of CMOs to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities on its programs. The Company also relies on a limited number of CROs to perform research and development activities on its behalf. The Company's clinical development programs could be adversely affected by significant interruption from these providers.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Assets and liabilities carried at fair value are classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2—Inputs other than Level 1 quoted prices that are either directly or indirectly observable.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. An asset and liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Foreign currency

The Company's reporting currency is the U.S. dollar. The consolidated financial statements of the Company's foreign subsidiaries are measured using the U.S. dollar as the functional currency. The Company remeasures monetary assets and liabilities using exchange rates in effect at the balance sheet date and non-monetary assets and liabilities at historical rates and records resulting exchange gains or losses in other income (expense) in the consolidated statements of operations and comprehensive loss. We translate income statement amounts at average rates for the period. Transaction gains and losses are recorded in other income (expense) in the consolidated statements of operations and comprehensive loss.

Comprehensive loss

Comprehensive loss consists of net loss plus other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the year ended December 31, 2025, other comprehensive loss consisted of changes in unrealized gains on marketable securities. For the period from March 14, 2024 (Inception) to December 31, 2024, there was no difference between net loss and comprehensive loss.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. The Company invests excess cash primarily in overnight cash sweeps and money

market funds which are highly liquid and have high credit ratings. Such investments are subject to minimal credit and market risks. Cash equivalents are carried at fair value.

Marketable securities

The Company also invests excess cash in marketable debt securities, which are comprised of U.S. Treasury securities. All debt securities are classified as available-for-sale at the time of purchase based on management's intent. Available-for-sale debt securities are classified as current assets on the balance sheet due to their highly liquid nature and because they are considered available for use in current operations. In addition, marketable securities are reported at fair market value using quoted prices in active markets for similar securities.

Unrealized gains and losses on available-for-sale marketable debt securities that are not related to credit losses are included in other comprehensive income in the consolidated statements of operations and comprehensive loss. Amortization of premium or accretion of discount, along with interest income earned on debt securities, is included in interest income in the consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, are included in other income, net, and the cost of securities sold is determined using the specific-identification method.

The Company assesses its available-for-sale securities under the available-for-sale debt security impairment model as of each reporting date in order to determine if a portion of any decline in fair value below carrying value recognized on its available-for-sale debt securities is the result of a credit loss. For any available-for-sale debt securities that may be in an unrealized net loss position, the Company does not intend to sell, and it is not more likely than not that the Company will be required to sell, such securities before recovery of their amortized cost bases. As of the balance sheet date, the Company evaluates its debt securities in an unrealized loss position to determine the extent of the loss, if any, that is attributable to expected credit losses. Expected credit losses on debt securities are recorded as an allowance on the balance sheet, with an offsetting amount recognized in other income, net, in the consolidated statements of operations and comprehensive loss. To date, the Company has not recorded any credit losses on its marketable debt securities.

Convertible preferred stock

The Company has classified convertible preferred stock as temporary equity on the Company's consolidated balance sheets due to terms that allow for redemption of the shares in cash upon the occurrence of deemed liquidation events that are not solely within the control of the Company (see Note 7). The Company initially recorded its convertible preferred stock at fair value, net of preferred stock tranche right obligations, if applicable, and issuance costs. The Company has not adjusted the carrying values of the convertible preferred stock to the redemption amount of such shares because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the redemption amount to holders of shares of convertible preferred stock. Subsequent adjustments of the carrying values of the convertible preferred stock will be made only when a deemed liquidation event becomes probable.

Preferred stock tranche right obligation

The Company's Series A-1 convertible preferred stock agreement obligated the Company to issue additional shares of Series A-1 convertible preferred stock in a subsequent closing upon the satisfaction of certain conditions (refer to Note 7, *Convertible Preferred Stoc*k). At issuance, the Company classified the preferred stock tranche right obligation as a liability on its consolidated balance sheets as the preferred stock tranche right obligation was determined to be a freestanding financial instrument that may have required the Company to transfer assets to settle its obligation upon events outside of its control. The preferred stock tranche right obligation was initially recorded at fair value upon the initial issuance date and was subsequently remeasured to fair value at each reporting date and immediately prior to being settled. Changes in fair value of the preferred stock tranche right obligation were recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. Upon settlement of the preferred stock tranche right obligation, the Company derecognized the related liability and stopped recognizing changes in the fair value of the preferred stock tranche right obligation.

Research and development costs

Research and development, or R&D, costs are recognized as expense as incurred. Such costs consist of costs incurred in performing R&D activities, including personnel related expenses, stock-based compensation, facilities and information and technology ("IT") costs, third-party license fees, and external costs to outside vendors engaged to conduct clinical and nonclinical activities as well as to manufacture research and development materials.

The Company is required to estimate its accrued R&D costs as of the end of the reporting period. In accruing R&D costs, the Company estimates the period over which services will be performed or goods will be provided and the level of effort to be performed in each period. The financial terms of the R&D contracts vary and may result in payments that do not match the periods over which the goods or services are provided. The Company accrues costs under its contracts based on analyzing the work performed and amounts paid. In circumstances where amounts have been paid in advance of costs incurred, the Company records the advanced payments as a prepaid expense or other assets. Such amounts are recognized as an expense as the goods are delivered or the related services are performed or until it is no longer expected that the goods will be delivered or the services rendered. If the actual timing of the performance of services varies from the estimate, then the Company adjusts the amount of the accrued expense or the prepaid expense accordingly. The Company has not recorded any material adjustments to its accrued or prepaid R&D expenses.

General and administrative costs

General and administrative expenses include personnel related expenses, stock-based compensation, facility and IT costs, costs to secure and defend patents, professional service fees, and other general overhead costs to support other general and administrative functions.

Patent and trademark costs

All patent- and trademark-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent- and trademark-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss.

Asset acquisition and acquired in-process research and development expenses

In determining whether an acquisition should be accounted for as a business combination or asset acquisition, the Company first determines whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the single identifiable asset or the group of similar assets is not deemed to be a business and is instead deemed to be an asset acquisition (see Note 11). Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in-process research and development ("IPR&D"). Acquired IPR&D that has no alternative future use as of the acquisition date is recognized as research and development expense as of the acquisition date.

The Company will recognize additional research and development expenses in the future or capitalize such amounts for completed technology if and when it becomes probable the Company is obligated to make contingent milestone payments under the terms of the agreements by which it acquired the IPR&D assets.

Contingent consideration in asset acquisitions is measured and recognized when payment becomes probable and reasonably estimable. Subsequent changes in the accrued amount of contingent consideration are measured and recognized at the end of each reporting period and upon settlement as an adjustment to the cost basis of the acquired asset or group of assets, or, if related to IPR&D with no alternative future use, charged to expense.

Australia research and development incentive

The Company is eligible to obtain certain research and development incentives, refundable in cash, through its wholly owned Australian subsidiary, Bambusa Therapeutics Pty. Ltd., as part of a program administered by the Australian Tax Office ("ATO"). The Company recognizes amounts earned as under the Australian research and

development program when it is deemed probable the applicable conditions have been met and the incentive will be received. The Company recognizes research and development incentive as income within other income, net within the consolidated statements of operations and comprehensive loss as the qualifying research expense is incurred, and a corresponding receivable within prepaid and other current assets on its consolidated balance sheets. The Company recorded research and development incentive receivables of $1.1 million and $0 as of December 31, 2025 and 2024, respectively, and other income from Australia research and development incentives of $3.3 million and $0 for the year ended December 31, 2025 and the period from March 14, 2024 ("Inception") to December 31, 2024, respectively. During the year ended December 31, 2025, the Company applied $2.2 million of its Australia research and development incentives earned to offset income tax liabilities arising from taxable income at the Company's Australian subsidiary.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company has one operating and reportable segment, which is the business of advancing multiple next generation, bi-specific antibody programs. The Company's CODM, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources and assessing performance. All of the Company's long-lived assets are held in the United States.

Stock-based compensation

The Company measures the fair value of stock-based awards on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period during which an employee provides service in exchange for the award. Compensation expense for awards to non-employees is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. The Company accounts for forfeitures as they occur. For awards that vest solely based on a service condition, the Company recognizes expense on a straight-line basis over the requisite service period.

Certain of the Company's stock-based awards include performance conditions based on the achievement of specified clinical development milestones. Because the achievement of these milestones involves inherent risks and uncertainties, management's determination of when achievement of each performance condition is probable requires significant judgment. The Company begins to recognize the value of these stock-based awards when management determines that achievement of the applicable performance condition is deemed probable. At the probable date, the Company records a cumulative catch-up adjustment for compensation expense attributable to the requisite service completed to date and recognizes any remaining compensation expense over the remaining requisite service period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. The fair value of each restricted stock award granted in the form of founder shares is based on the difference, if any, between the purchase price per share of the award and fair value of the Company's common stock on the date of grant (see Note 8).

Given the absence of an active market for the Company's common stock, the estimated fair value of common stock was determined by the Company's board of directors (the "Board") at the time of each grant of a stock-based award, with inputs from management, considering the Company's most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly-traded peer companies. The expected term of the Company's stock options has been determined utilizing the simplified method for awards that qualify as "plain-vanilla" options, which is presumed to be the midpoint between the vesting date and the end of the contractual term. If vesting is subject to a performance condition, the expected term is based on the mid-point between the explicit service period and the contractual term of the option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant

for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

Value appreciation rights

The Company has issued value appreciation rights ("VARs") to employees and nonemployees in exchange for services. The VARs contain both service-based and performance-based vesting conditions. Upon a change in control of the Company, any VARs that have achieved the respective service-based and other performance-based conditions, if applicable, vest and become payable. To the extent the service-based vesting condition has not been fully met at the time of a public listing or change in control for the Company, such VARs will continue to vest in accordance with the applicable service vesting conditions. The Company recognizes compensation expense for the VARs when the achievement of the performance condition(s) becomes probable and over the requisite service period applicable to the award. The VARs are classified as liabilities as the VARs are settleable in cash. In the periods prior to becoming a public company, the Company has elected to measure the fair value of the VARs at their intrinsic value which is the difference between the grant-date price and the fair value of the Company's common stock.

The Company remeasures the fair value of the VARs at each reporting date and, to the extent the performance conditions associated with the awards are met or considered probable, recognizes compensation expense based on changes in fair value. At December 31, 2025, no amounts have been recorded in the consolidated financial statements as the related performance conditions are not considered probable (see Note 10).

Income taxes

The Company recognizes income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are recognized based on differences between the financial reporting and tax basis of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is recorded through a charge to income tax expense.

The Company recognizes the benefit of a tax position only when it is more likely than not that the position will be sustained upon examination by the relevant taxing authority based on the technical merits of the position. For tax positions that meet this recognition threshold, the Company measures the benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. The evaluation of tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity, and changes in facts or circumstances related to a tax position. The Company accrues interest and penalties related to unrecognized tax benefits in income tax expense. As of December 31, 2025 and 2024, the Company has not identified any uncertain tax positions.

Deferred offering costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the convertible preferred stock or in stockholders' deficit as a reduction of additional paid-in capital. Should the planned equity financing be abandoned, the deferred offering costs are

expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company had no deferred offering costs as of December 31, 2025 and 2024.

Net loss per share

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of shares of the Company's common stock and participating securities. The Company's Preferred Stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of shares of common stock included in the computation of diluted net loss gives effect to all potentially dilutive common stock equivalent shares, including outstanding stock options and preferred stock, to the extent their effect is dilutive.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Prior to February 12, 2025, there were no outstanding shares of the Company for accounting purposes. As such, only net loss per share for the period from February 12, 2025 to December 31, 2025 is presented based on net losses attributable to common stockholders during this period (see Note 15).

Recently issued accounting pronouncements not yet adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition period related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company will adopt the new or revised standard at the time non-public companies adopt the new or revised standard unless early adoption is permitted and the Company elects to early adopt. The Company will continue to use such extended transition period until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt new or revised accounting standards whenever such early adoption is permitted for non-public companies.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)*: *Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires public business entities to disaggregate, on both an interim and annual basis, each relevant expense caption presented on the face of the income statement into specific expense categories. Additionally, entities are required to provide a qualitative description of amounts remaining in relevant expense captions that are not separately disaggregated quantitatively, as well as disclosure of the total amount of selling expenses and, in annual reporting periods, an entity's definition of selling expenses. The amendments in ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact that ASU 2024-03 will have on its disclosures in the consolidated financial statements.

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state, and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. The Company early adopted this standard for the year ended December 31, 2025 and applied the disclosure requirements on a retrospective basis for all periods presented. The adoption did not have a material impact on the Company's consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606)* ("ASU 2025-07"), which refines the scope of Topic 815 by clarifying which contracts are subject to derivative accounting and expands the scope exception for certain contracts not traded on an exchange to include contracts for which settlement is based on operations or activities specific to one of the parties to the contract. The guidance also provides clarification under Topic 606 for share-based payments from a customer in a revenue contract. The Company early adopted this standard for the year ended December 31, 2025 and applied it on a retrospective basis for all periods presented. The adoption did not have a material impact on the Company's consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities* ("ASU 2025-10"), which adds guidance to ASC 832 on the recognition, measurement, and presentation of government grants. In developing the ASU's recognition and measurement framework, the FASB largely leveraged the guidance in International Accounting Standards 20, *Accounting for Government Grants and Disclosure of Government Assistance*, to which many for-profit entities that apply U.S. GAAP have historically analogized when accounting for government grants. The ASU is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years. The guidance can be applied on a modified prospective basis, a modified retrospective basis, or a full retrospective basis. Early adoption is permitted. The Company early adopted ASU 2025-10 on a full retrospective basis for all periods presented. The adoption did not have a material impact on the Company's consolidated financial statements.

3. MARKETABLE SECURITIES

Investments in marketable securities are summarized as follows (in thousands):

	December 31, 2025			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
U.S. Treasury securities	$ 39,924	$ 60	$ —	$ 39,984
Total marketable securities	$ 39,924	$ 60	$ —	$ 39,984

As of December 31, 2025, all marketable securities had contractual maturities within one year. The Company held no marketable securities as of December 31, 2024.

4. FAIR VALUE MEASUREMENTS

The following tables present, within the fair value hierarchy, information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 36,779	$ —	$ —	$ 36,779
Marketable securities:				
U.S. Treasury securities	—	39,984	—	39,984
Total financial assets	$ 36,779	$ 39,984	$ —	$ 76,763

As of December 31, 2025, the Company had cash equivalents consisting of money market funds classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment. As of December 31, 2025, the Company has marketable securities consisting of U.S. treasuries which are classified as Level 2 instruments. The Company estimates the fair value of the investments by using observable market inputs, including quoted prices for similar securities, benchmark yields, reported trades, broker/ dealer quotes, and other market-based pricing sources with reasonable price transparency. As of December 31, 2024, the Company had no financial assets or liabilities that required fair value measurement.

During the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024, there were no transfers or reclassifications between fair value measurement levels of assets or liabilities. The carrying values of other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Preferred stock tranche right obligation

The Company determined that its obligation to issue, and the Company's investors' obligation to purchase, additional shares of convertible preferred stock at a fixed price (i.e. the issuance price) in subsequent tranche following the initial closing of the Series A-1 convertible preferred stock financing represented a freestanding financial instrument (the "preferred stock tranche right obligation"). The freestanding financial instrument was classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value, with changes in fair value recognized in other income (expense) in the consolidated statement of operations and comprehensive loss.

In connection with the Company's initial issuance of Series A-1 Preferred Stock in February 2025 (see Note 7) the Company recognized the preferred stock tranche right obligation at fair value, which was determined based on significant unobservable inputs, which represented a Level 3 measurement within the fair value hierarchy.

The preferred stock tranche right obligation was determined using the binomial pricing model, which takes into account various significant assumptions, including the fair value of the Company's Series A-1 Preferred Stock, and the probability and expected timing of the achievement of a clinical milestone event as of the measurement dates or the failure to achieve such milestone. The Company determined the fair value per share of the underlying Series A-1 Preferred Stock by taking into consideration the most recent sales of its Series A-1 Preferred Stock, results obtained from third-party valuations, and additional factors the Company deemed relevant. An increase or decrease in these assumptions will result in an increase or decrease in the fair value of the preferred stock tranche right obligation and such changes could be material.

The following reflects the significant quantitative assumptions used in the valuation of the preferred stock tranche right obligation at issuance date:

Series A-1 Preferred Stock present value	$5.5055
Estimated future value of Series A-1 Preferred Stock	$3.2716 - $6.0639
Probability of tranche closing	20% - 80%

In June 2025, the Board approved the achievement of the milestone associated with the tranche and issued 6,237,556 shares of Series A-1 Preferred Stock (see Note 7). Upon settlement, the fair value of the preferred stock tranche right obligation was determined based on the difference between the estimated fair value of the Series A-1 Preferred Stock, or $6.0639 per share, and its contractual purchase price, or $5.6997 per share.

The following table sets forth a summary of changes in the fair value of the Company's preferred stock tranche right obligation for which fair value was determined by Level 3 inputs (in thousands)

Balance at December 31, 2024	$ —
Issuance of preferred stock tranche right obligation	1,817
Change in fair value of preferred stock tranche right obligation	454
Settlement of the preferred stock tranche right obligation	(2,271)
Balance at December 31, 2025	$ —

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following as of December 31, 2025, and 2024, (in thousands):

	December 31,	
	2025	2024
Prepaid research and development	$ 1,040	$ 275
Research and development incentive receivable	1,097	—
Goods and services tax receivable	785	33
Other	583	94
Total prepaid expenses and other current assets	$ 3,505	$ 402

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following as of December 31, 2025, and 2024, (in thousands):

	December 31,	
	2025	2024
Accrued employee compensation and benefits	$ 789	$ 209
Accrued legal and professional fees	170	141
Accrued research and development costs	6,716	4,953
Accrued IPR&D	—	4,000
Accrued other	68	—
Total accrued expenses and other current liabilities	$ 7,743	$ 9,303

7. CONVERTIBLE PREFERRED STOCK

The Company has issued Series Seed convertible preferred stock ("Series Seed Preferred Stock"), Series Seed Plus convertible preferred stock ("Series Seed Plus Preferred Stock"), Series A-1 convertible preferred stock

("Series A-1 Preferred Stock), and Series A-2 convertible preferred stock ("Series A-2 Preferred Stock and together with Series A-1 Preferred Stock, "Series A Preferred Stock"), (collectively, the "Preferred Stock").

Series Seed Preferred Stock

In June 2024, the Company entered into a preferred stock agreement with investors pursuant to which the Company authorized, issued, and sold 5,329,584 shares of Series Seed Preferred Stock for a purchase price of $0.9570 per share, resulting in gross aggregate proceeds of approximately $5.1 million. Total issuance costs were $34 thousand.

Series Seed Plus Preferred Stock

In August 2024, the Company entered into a preferred stock agreement with investors pursuant to which the Company authorized, issued, and sold 3,740,038 shares of Series Seed Plus Preferred Stock for a purchase price of $2.4064 per share, resulting in gross aggregate proceeds of approximately $9.0 million. Total issuance costs were $70 thousand.

Series A-1 Preferred Stock

In February 2025, the Company authorized the sale and issuance of up to 15,593,922 shares of Series A convertible preferred stock, which were subsequently reclassified to Series A-1 Preferred Stock in October 2025 in connection with the sale of our Series A-2 Preferred Stock, and entered into a preferred stock agreement with investors structured to close in two closings. In connection with the initial closing in February 2025, the Company issued and sold 9,355,299 shares of Series A-1 Preferred Stock for a purchase price of $5.6997 per share, resulting in gross aggregate proceeds of approximately $53.3 million. The Company incurred issuance costs of $85 thousand.

Upon the initial closing of the Series A-1 Preferred Stock, the Company recorded a preferred stock tranche right obligation at its estimated fair value of $1.8 million and a corresponding reduction to the carrying value of the Series A-1 Preferred Stock. The fair value of the preferred stock tranche right obligation was allocated from the gross cash proceeds of $53.3 million of the Series A-1 Preferred Stock, with the remainder of the cash proceeds allocated to the Series A-1 Preferred Stock.

The second closing was contingent upon the achievement of a clinical milestone. The milestone was achieved in June 2025, and the Company issued 6,237,556 shares of Series A-1 Preferred Stock for a purchase price of $5.6997 per share, resulting in gross aggregate $35.6 million. As a result of this issuance, the preferred stock tranche right obligation of $2.2 million was settled and the Series A-1 Preferred Stock was recorded at its fair value of $37.8 million. The Company incurred issuance costs of $15 thousand.

Series A-2 Preferred Stock

In October 2025, the Company authorized the sale and issuance of up to 2,728,039 shares Series A-2 Preferred Stock. In October 2025, the Company entered into a preferred stock agreement with investors pursuant to which the Company issued and sold 2,645,542 shares of Series A-2 Preferred Stock for a purchase price of $12.1225 per share, resulting in gross proceeds of approximately $32.1 million. Total issuance costs were $64 thousand.

In January 2026, the Company entered into a preferred stock agreement with an investor pursuant to which the Company issued and sold an additional 82,490 shares of Series A-2 Preferred Stock for a purchase price of $12.1225 per share, resulting in gross aggregate proceeds of approximately $1.0 million.

As of December 31, 2025, and 2024, Preferred Stock consisted of the following (in thousands, except for share and per share data):

As of December 31, 2025	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Original Issuance Price	Liquidation Preference	Shares Issuable Upon Conversion
Series Seed	5,329,588	5,329,584	$ 5,066	$ 0.9570	$ 5,100	5,329,584
Series Seed Plus	3,740,043	3,740,038	8,930	$ 2.4064	9,000	3,740,038
Series A-1	15,593,922	15,593,907	89,232	$ 5.6997	88,880	15,593,907
Series A-2	2,728,039	2,645,542	32,007	$ 12.1225	32,070	2,645,542
Total	27,391,592	27,309,071	$ 135,235		$ 135,050	27,309,071

As of December 31, 2024	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Original Issuance Price	Liquidation Preference	Shares Issuable Upon Conversion
Series Seed	5,329,588	5,329,584	$ 5,066	$ 0.9570	$ 5,100	5,329,584
Series Seed Plus	3,740,043	3,740,038	8,930	$ 2.4064	9,000	3,740,038
Total	9,069,631	9,069,622	$ 13,996		$ 14,100	9,069,622

The following is a summary of rights, privileges and preferences of the Preferred Stock as of December 31, 2025.

Dividends—Holders of the Preferred Stock are entitled to receive dividends on a pari passu basis, prior and in preference to any other class or series of capital stock, calculated on an as-if-converted basis (meaning conversion of Preferred Stock into the particular series on which the dividend is being declared) when and if dividends are declared by the Company. If the Company declares dividends on more than one class of share, each series of Preferred Stock shall receive the dividend amount that results in the highest dividend. No dividends were declared through December 31, 2025.

Liquidation Rights—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company including a deemed liquidation event, the holders of the Preferred Stock are entitled to be paid out of the assets of the Company on a pari passu basis, prior and in preference to any distribution or payment of any of the assets or surplus funds of the Company to the holders of common stock, an amount equal to the greater of: (i) the original purchase price of the Preferred Stock, plus all declared, but unpaid dividends or (ii) amount per share as would have been payable, if all shares of Preferred Stock had been converted into common stock immediately prior to such liquidation or deemed liquidation event. If the assets of the Company are insufficient to make payment in full to all holders of Preferred Stock, then the assets or consideration will be distributed ratably among such preferred stockholders in proportion to the full liquidation preference amounts to which the preferred stockholders would otherwise be entitled. After the payment of the full liquidation preference to holders of Preferred Stock the remaining assets of the Company shall be distributed among the holders of shares of common stock, pro rata based on the number of shares of common stock held by each such holder.

A deemed liquidation event shall include a merger, consolidation, statutory conversion, transfer of corporation, domestication, or continuance or sale, lease, transfer, exclusive license, or other disposition of substantially all of the assets of the Company.

Conversion—Each outstanding share of Preferred Stock is convertible at the option of the holder and at any time into common stock as determined by dividing the Preferred Stock original issue price by the Preferred Stock Conversion Price. “Conversion Price” is defined as initially the applicable original issue price for the applicable series of Preferred Stock, subject to certain adjustments in the event of any down round, stock dividend, stock split, combination, or other similar recapitalization. The Preferred Stock will also be converted automatically into shares of common stock (a) immediately prior to the closing of the sale of shares of common stock to the public at a price of at least $8.5496 per share in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to the Company and in connection with such offering the shares of common stock are listed for trading on the Nasdaq

Stock Market, the New York Stock Exchange, or another exchange or marketplace approved by the Board (b) at any time upon the affirmative election of the holders of a majority of the outstanding shares of Preferred Stock, voting together as a single class on an as-if-converted to common stock basis (the "Requisite Holders"), or with respect to automatic conversion of the Series A Preferred Stock, upon the affirmative election of the holders of a majority of the outstanding shares of Series A Preferred Stock, voting as a single class on an as-if-converted to common stock basis, provided that such majority must include stockholders holding at least 2,193,116 shares of Series A-1 Preferred Stock and Series A-2 Preferred Stock who do not hold any shares of Series Seed Preferred Stock or Series Seed Plus Preferred Stock.

Voting Rights—Each holder has the right to one vote, on each matter submitted to a vote at any meeting of stockholders, for each share of common stock into which such series of Preferred Stock could be converted. Preferred Stockholders and common stockholders vote together as a single class.

In addition, the holders of shares of Series Seed Preferred Stock, exclusively and voting together as a separate class on an as-converted to common stock basis, are entitled to elect one director of the Company. The holders of shares of Series A-1 Preferred Stock, exclusively and voting together as a separate class on an as-converted to common stock basis, are entitled to elect one director of the Company. The holders of shares of Common Stock, exclusively and voting together as a separate class, are entitled to elect two directors of the Company. The holders of shares of common stock and any other class or series of voting stock (including Preferred Stock), exclusively and voting together as a single class, are entitled to elect the balance of the total number of directors of the Company.

Redemption— The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a deemed liquidation event.

8. COMMON STOCK

The voting, dividend, and liquidation rights of the holders of the Company's common stock are subject to the rights, powers, and preferences of the holders of the Preferred Stock set forth above. Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock, on each matter submitted to a vote at any meeting of stockholders. Common stockholders are entitled to receive dividends, subject to the preferential dividend rights of the preferred stock. Through December 31, 2025, no cash dividends have been declared or paid.

Founders' Shares

In May 2024, the Company entered into Common Stock Purchase Agreements (each, a "CSPA") with related party entities controlled by certain of its co-founders (see Note 16) pursuant to which the Company authorized, issued, and sold 12,358,799 shares of common stock ("Founders' Shares") at an original purchase price of $0.00001 per share and an aggregate fair value of $5.6 million. The CSPAs stipulate that in the event of the voluntary or involuntary termination of the controlling founder's continuous service status, the Company has the option ("Repurchase Option") to repurchase all or any portion of the respective shares as of the termination date which have not yet been released from the Repurchase Option at the original purchase price. Subject to continuous employment, shares are released from the Repurchase Option as follows: (i) 5,149,499 upon the closing of the Series A-1 Preferred Stock and (ii) 7,209,300 in equal monthly installments over a three-year period subsequent to the closing of the Series A-1 Preferred Stock. The release of the Repurchase Option is subject to future acceleration upon the closing of an initial public offering or a change in control. For accounting purposes, the Founders' Shares subject to the Company's Repurchase Option are treated as unvested restricted common stock and are not considered outstanding until the applicable shares are released from the Repurchase Option.

The Founders' Shares are considered compensatory for which expense is recorded based on the fair value of the common stock less original purchase price at the date of issuance, with expense being recognized in the consolidated statements of operations and comprehensive loss over the period which the Repurchase Option is released. Compensation expense recognized for the Founders' Shares was $5.0 million and $0, for the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024, respectively. Forfeitures are recognized as they occur. The CSPA for one of the co-founders was subsequently amended in June 2024 and February 2025. The amendments did not result in incremental compensation expense.

The following table summarizes Founder's Shares activity for the period from March 14, 2024 (Inception) to December 31, 2024 and for the year ended December 31, 2025:

	Shares	Weighted-average fair value per share
Unvested at March 14, 2024 (Inception)	—	$ —
Granted	12,358,799	$ 0.46
Unvested at December 31, 2024	12,358,799	$ 0.46
Vested	(7,863,623)	$ 0.46
Unvested at December 31, 2025	4,495,176	$ 0.46

As of December 31, 2025, there were 4,495,176 Founders Shares subject to repurchase with $0.6 million in unrecognized compensation expense, which is expected to be recognized over a period of 2.1 years. To date, there have been no forfeitures of Founders' Shares.

The number of shares of common stock that have been reserved for the potential conversion of Preferred Stock, outstanding stock options granted, and stock options available for grant under the 2024 Plan as of December 31, 2025, and 2024, are as follows:

	December 31,	
	2025	2024
Conversion of Series Seed	5,329,584	5,329,584
Conversion of Series Seed Plus	3,740,038	3,740,038
Conversion of Series A-1	15,593,907	—
Conversion of Series A-2	2,645,542	—
Outstanding common stock options	1,526,912	1,040,928
Unvested restricted common stock	4,495,176	12,358,799
Common stock options available for grant	2,681,427	2,048,772
Total	36,012,586	24,518,121

9. STOCK-COMPENSATION EXPENSE

2024 Stock Plan

The Company maintains the 2024 Stock Plan ("2024 Plan"), which provides for the grant of incentive stock options, non-statutory stock options, restricted stock, and other awards (including restricted stock units) to employees, directors, and consultants of the Company. The 2024 Plan is administered by the Board, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price, and the vesting schedule. The aggregate number of shares of common stock available for issuance under the 2024 Plan is 4,208,339 shares. Shares that are expired, terminated, surrendered, or canceled under the 2024 Plan without having been fully exercised or that are retained upon exercise in order to satisfy the exercise or purchase price of the award or withholding taxes due with respect to such award will be available for future awards. As of December 31, 2025, the Company has reserved 2,681,427 shares of common stock for issuance under the 2024 Plan.

Stock options granted under the 2024 Plan generally have a contractual term of ten years and typically vest ratably over a four-year period ("time-based options"). Certain stock options vest based on the achievement of specified milestones ("performance options"). Upon achievement of the applicable milestone, the performance options begin vesting over the requisite service period, subject to continued service, typically over a four-year period. The exercise price of each stock option may not be less than 100% of the fair market value of the Company's common stock on the grant date.

The following table summarizes stock option activity under the 2024 Plan for the year ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	1,040,928	$ 0.35	8.77	$ —
Granted	672,883	1.84		
Exercised	—	—		
Forfeited	(171,576)	1.84		
Expired	(15,323)	0.34		
Outstanding at December 31, 2025	1,526,912	$ 0.84	8.38	$ 6,076
Options exercisable at December 31, 2025	359,942	$ 0.35	7.62	$ 1,609
Options vested and expected to vest at December 31, 2025	1,279,671	$ 0.93	8.26	$ 4,971

The Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options issued under the 2024 Plan on each grant date. The following table presents the ranges of assumptions used by the Company during the years ended:

	December 31,	
	2025	2024
Expected term (in years)	5.96 – 8.10	3.22 – 7.39
Risk free interest rate	3.85% - 4.16%	4.36% - 4.52%
Volatility	107.43% - 122.61%	85.71% - 124.41%
Dividend yield	0.00%	0.00%

Based in part on retrospective valuations performed for accounting purposes, the weighted-average grant-date fair value of time-based options granted during the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024 were $2.52 and $0.94 per share, respectively. Based in part on retrospective valuations performed for accounting purposes, the weighted-average grant-date fair value of performance-based options granted during the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024 was $2.40 and $1.04 per share, respectively. As of December 31, 2025, no stock options had been exercised.

As of December 31, 2025, there was $1.7 million in unrecognized stock-based compensation expense associated with stock options with only service conditions, which is expected to be recognized over a weighted-average period of 2.9 years. As of December 31, 2025, there was $47 thousand in unrecognized stock-based compensation expense associated with issued and outstanding performance-based stock options, which is expected to be recognized over a weighted-average period of 3.3 years.

Stock-Based Compensation Expense

Total stock-based compensation expense for the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024 was $5.4 million and $0.2 million, respectively, inclusive of stock-based

compensation expense for the Founders' Shares (see Note 8). The following table represents stock-based compensation expense recorded in the consolidated statements of operations and comprehensive loss (in thousands):

	December 31,	
	2025	2024
Research and development	$ 2,691	$ 132
General and administrative	2,686	61
Total	$ 5,377	$ 193

10. VALUE APPRECIATION RIGHTS

The Company granted incentive awards to employees and non-employees as value appreciation rights ("VARs"). The VARs were issued separately from the Company's 2024 Plan. Each VAR represents the right to receive an amount in cash or other consideration equal to the excess, if any, of the fair value of the common stock on the applicable payment date over the grant-date price, multiplied by the number of VARs vested. The VARs do not provide stockholder rights. As of December 31, 2025, the Company expected all VARs to be settled in cash. The VARs have a ten-year contractual term.

All VARs contain both service conditions and performance conditions, including a company liquidity event and the achievement of clinical or transactional milestones in certain cases. The VARs vest over a period of two to four years from the achievement of the requisite performance condition(s). In addition, the VARs become payable only if a liquidity event occurs, i.e., a change of control or public listing of the Company, before the expiration date and while the participant remains in continuous service. The VARs may be settled in cash or other consideration with payment due within 60 days following the liquidity event, or if later, the applicable vesting date following the liquidity event.

The following table summarizes VAR activity for the year ended December 31, 2025:

	Number of VARs	Weighted Average Grant-Date Price (per share)	Weighted Average Remaining Contract Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	63,820	$ 0.34	9.97	$ —
Granted	806,363	1.84		
Outstanding at December 31, 2025	870,183	$ 1.73	9.35	$ 2,682
Vested and expected to vest at December 31, 2025	—	$ —	—	$ —

No VARs were vested, settled, cancelled, or forfeited during the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024.

As of December 31, 2025, the performance conditions contingent were not deemed probable of achievement. As such, the Company has not recognized any expense for the VARs during the year ended December 31, 2025, and the period from March 14, 2024 (Inception) to December 31, 2024.

11. LICENSE AGREEMENTS

BioNTech Zhuhai Assignment Agreement

In March 2024, the Company entered into an assignment agreement, which was amended and restated in its entirety in December 2024 (the "BioNTech Zhuhai Assignment Agreement") with BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"). Pursuant to the BioNTech Zhuhai Assignment Agreement, the Company obtained from BioNTech Zhuhai certain intellectual property rights, and related research materials and data packages, for two bispecific antibody programs, which the Company has designated BBT001 and BBT002 (together, the "Assigned Programs"). The BioNTech Zhuhai

Assignment Agreement also included a sublicense to use certain antibody platform technology owned by BioNTech Zhuhai's upstream licensor Alloy Therapeutics, LLC ("Alloy") to develop and commercialize products comprising antibodies generated from the Assigned Programs.

Under the BioNTech Zhuhai Assignment Agreement, the consideration included (i) a $4.0 million cash payment to BioNTech Zhuhai; (ii) annual platform fees of $7,500 per Assigned Program to BioNTech Zhuhai; (iii) annual partner antibody fees of $50,000 per Assigned Program to Alloy, and (iv) development milestones of up to approximately $1.8 million per Assigned Program and maximum aggregate commercial and sales milestones of up to $11.0 million per Assigned Program to Alloy.

The BioNTech Zhuhai Assignment Agreement will continue in full force until terminated. Either the Company or BioNTech Zhuhai may terminate the BioNTech Zhuhai Assignment Agreement in the event of the other party's material breach, subject to certain notice and cure periods, and BioNTech Zhuhai may also terminate in the event of the Company's bankruptcy or failure to make any due payment within a certain period.

The partner antibody fees are payable on an Assigned Program-by-Assigned Program basis for so long as the applicable Assigned Program remains active and the relevant rights have not been terminated or abandoned before the applicable anniversary date.

During the period from March 14, 2024 (Inception) to December 31, 2024, the Company recognized the $4.0 million upfront fee as IPR&D expense within research and development expense, which the Company subsequently paid in 2025, and $0.2 million in annual fees in effect and paid prior to the December 2024 amendment for the Assigned Programs.

During the year ended December 31, 2025, the Company recorded $0.1 million in annual platform and partnered antibody fees and $0.5 million in development milestone payments under the BioNTech Zhuhai Assignment Agreement.

Research Collaboration and Option Agreement

In April 2024, the Company entered into a research collaboration and option agreement with BioNTech Zhuhai (the "BioNTech Zhuhai Option Agreement") pursuant to which the Company may nominate certain bispecific antibody target combinations, subject to mutual agreement (each a "Selected Target Combination"). BioNTech Zhuhai agreed to design, identify, generate, and develop development candidates for the Selected Target Combinations through the execution of research programs, each inclusive of one or more development candidates. Each research program follows a research plan which is approved by a Joint Steering Committee ("JSC"). The JSC is comprised of equal members representing both parties.

At the culmination of each research program, BioNTech Zhuhai determines if the related development candidate(s) meet the appropriate criteria, as established and agreed to by both parties, to become a lead development candidate ("Lead Development Candidate"). The JSC reviews and determines if a Lead Development Candidate meets the applicable criteria to be an optioned (an "Option Compound"). For any Lead Development Candidates that do not meet the applicable criteria to be an Option Compound, the Company may terminate the research program or request rework to develop an additional Lead Development Candidate. For any Lead Development Candidate that meets the applicable criteria to be an Option Compound, the Company has the exclusive option, on a research program-by-research program basis, to obtain an exclusive license (the "License Option"), with the right to grant sublicenses through multiple tiers to optimize, develop, make, use, offer for sale, sell, import, and export the Option Compound for such research program, subject to a 12-month Option Period. Within 60 days of the Company's exercise of the License Option (the "License Negotiation Period"), the parties may negotiate the terms and conditions of a definitive license agreement on an exclusive basis (a "License Agreement"). Upon the execution of a License Agreement, the Selected Target Combination and associated selected compound(s) shall each become a licensed target combination and licensed compound(s), respectively.

The BioNTech Zhuhai Option Agreement applies on a research program-by-research program basis and, unless earlier terminated, remains in effect for three years, subject to renewal. During the term of the research program, License Option Period (if applicable), and License Negotiation Period (if applicable) with respect to a given research

program, BioNTech Zhuhai may not independently develop, commercialize, license, assign, transfer, or otherwise exploit products or rights directed to the applicable Selected Target Combination in the specified field and territory without prior written consent from the Company. Upon the termination of a research program or expiration of the License Option Period or License Negotiation Period, the Selected Target Combination and associated Development Candidates for such research program shall each become an "Abandoned Target Combination" and "Abandoned Compound(s)" which may be exploited by BioNTech Zhuhai.

Under the terms of the BioNTech Zhuhai Option Agreement, the Company is required to pay BioNTech Zhuhai a research fee of $0.5 million for each research program. On a research program-by-research program basis, to the extent that the Company requests and BioNTech Zhuhai agrees to perform any additional research or development activities not set forth in the research plan, the Parties shall discuss in good faith the financial considerations for such additional research or development activities. For any products containing or comprising an Abandoned Compound, Target Combination(s) and "Abandoned Compound(s)", BioNTech Zhuhai shall pay the Company an amount of revenue sharing determined as the greater of: (i) at a rate of mid-single-digit to low teen-digit percentage of net licensing proceeds, or (ii) a fixed amount of $0.2 million, dependent on the clinical status of the product and the relative portion of the Abandoned Compound comprising the product.

As of December 31, 2025, the Company has entered into two research programs with aggregate research fees of $1.0 million. During the year ended December 31, 2025 and the period from March 14, 2024 (Inception) to December 31, 2024, the Company recorded $0.5 million and $0.3 million, respectively, in research and development expense under the BioNTech Zhuhai Option Agreement. The Company has paid $1.0 million and $0 under the BioNTech Zhuhai Option Agreement as of December 31, 2025, and December 31, 2024, respectively.

License Agreement

In September 2025 and pursuant to the BioNTech Zhuhai Option Agreement, the Company entered into a definitive license agreement with BioNTech Zhuhai whereby BioNTech Zhuhai granted the Company an exclusive, worldwide, royalty-bearing license to further develop, manufacture, commercialize, or otherwise exploit certain Licensed Compounds and Licensed Products covered by patent rights and a Licensed Compound owned by BioNTech Zhuhai under the BBT003 research program directed to specified bispecific antibodies. The Company has the right to grant sublicenses, with consent from BioNTech Zhuhai in certain circumstances, under the BioNTech Zhuhai License Agreement (the "BioNTech Zhuhai License Agreement"). The term of the BioNTech Zhuhai License Agreement is from execution through the end of the applicable royalty term.

Under the terms of the BioNTech Zhuhai License Agreement, the Company paid BioNTech Zhuhai aggregate upfront fees of $1.0 million. In addition, the Company is required to pay an annual license fee of $57,500 until the first commercial sale of the first licensed product. The BioNTech Zhuhai License Agreement also provides maximum aggregate development milestone payments of $6.9 million, first commercial sale milestone payments of $57.5 million, and sales milestone payments of $217.5 million, as well as low single-digit royalties on net sales.

During the year ended December 31, 2025, the Company recorded and paid $1.0 million in expense under the BioNTech Zhuhai License Agreement. As of December 31, 2025, no amounts were outstanding under the BioNTech Zhuhai License Agreement.

Triparty Payment Agreement

In September 2025, the Company entered into a Triparty Payment Agreement with BioNTech Zhuhai and Adimab LLC ("Adimab") under which BioNTech Zhuhai exercised its option for use of certain Adimab intellectual property for the purposes of development and commercialization of BBT003, and became obligated to pay for a sublicense under the development and commercialization license granted by Adimab to BioNTech Zhuhai with respect to such compounds.

Under the terms of the Triparty Payment Agreement, the Company paid Adimab a license fee of $0.5 million. In addition, the Company is required to pay maximum aggregate development milestone payments of $3.0 million and marketing approval milestone payments of $3.0 million, as well as low single-digit royalties on net sales.

During the year ended December 31, 2025, the Company recorded and paid $0.5 million in expense under the Triparty Payment Agreement. As of December 31, 2025, no amounts were outstanding under the Triparty Payment Agreement.

12. INCOME TAXES

The following table summarizes the components of loss before income taxes by jurisdiction for the periods indicated: (in thousands):

	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024
Domestic	$ (43,300)	$ (13,765)
Foreign	4,446	24
Loss before income taxes	$ (38,854)	$ (13,741)

The Company recorded a $2.2 million tax expense in 2025 with respect to its operations in Australia where the Company generates taxable income under a transfer pricing arrangement. No provision (benefit) for income taxes was recorded for the year ended December 31, 2025 and the period from March 14, 2024 (Inception) to December 31, 2024 for the U.S. due to the Company incurring net losses and maintaining a full valuation allowance against its net deferred tax assets.

The reconciliation of the income taxes at the U.S. federal statutory rate to the effective tax rate pursuant to the disclosure requirements of ASU 2023-09 is as follows (in thousands):

	Year Ended December 31, 2025		Period from March 14, 2024 (Inception) to December 31, 2024	
	Percent	Amount	Percent	Amount
Tax at U.S. federal statutory income tax rate	21.0 %	$ (8,159)	21.0 %	$ (2,886)
State and local income taxes, net of federal tax effect	0.0 %	—	0.0 %	—
Foreign tax effects				
Australia:				
Effects of R&D incentive	(2.3)%	903	0.0 %	—
Foreign rate differential	(0.9)%	365	0.0 %	—
Other foreign jurisdictions:				
Foreign rate differential	(0.1)%	32	0.0 %	—
Effect of cross-border tax laws:				
Global intangible low-taxed income	(1.3)%	496	0.0 %	5
Nontaxable and nondeductible items:				
Stock based compensation	(2.8)%	1,099	0.0 %	4
Other	(0.2)%	94	0.0 %	(5)
Change in valuation allowance	(19.1)%	7,403	(21.0)%	2,882
Effective tax rate and income tax expense	(5.7)%	$ 2,233	0.0 %	$ —

There were no income taxes paid (net of refunds received) for the year ended December 31, 2025 and period from March 14 (Inception) to December 31, 2024.

The components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 3,489	$ 434
Capitalized research and development expenditures	8,011	1,977
Capitalized licenses	903	943
Accruals and reserves	192	50
Other	115	79
Total deferred tax assets	12,710	3,483
Valuation allowance	(12,710)	(3,483)
Net deferred tax assets	$ —	$ —

Activity in the deferred tax assets valuation allowance is summarized as follows (in thousands):

	As of December 31,	
	2025	2024
Beginning balance	$ 3,483	$ —
Additions	9,227	3,483
Ending balance	$ 12,710	$ 3,483

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. The Company considered its history of cumulative net losses incurred since inception and has concluded that it is more-likely-than-not that it will not realize the benefits of the deferred tax assets. Accordingly, a valuation allowance has been established against the deferred tax assets as of December 31, 2025 and 2024 that are not expected to be realized. The Company reevaluates the positive and negative evidence at each reporting period. During the year ended December 31, 2025, the valuation allowance increased by $9.2 million primarily due to the increase in the Company's capitalized research and development expenditures and federal net operating loss during the period.

As of December 31, 2025, the Company had $13.3 million and $11.1 million of federal and state operating loss carryforwards, respectively. U.S. federal NOLs have an indefinite carryforward period, but can only offset 80% of U.S. federal taxable income in a given year. State NOLs begin to expire in 2044. As of December 31, 2025, the Company also had state research and development tax credit carryforwards of approximately $78,000, that will begin to expire in 2039.

Utilization of the Company's NOL carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Internal Revenue Code Section 382 ("Section 382") as well as similar state provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings could result in a change of control as defined by Section 382. The Company has not yet conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2025, would limit or otherwise restrict its ability to utilize its NOL and research and development credit carryforwards. In addition, future changes in ownership occurring after December 31, 2025 could affect the limitation in future years, and any

limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization.

On July 4, 2025, the U.S. government enacted The One Big Beautiful Bill Act of 2025 ("OBBBA") which includes, among other provisions, changes to the U.S. corporate income tax system. Key corporate tax provisions include the restoration of 100% bonus depreciation, immediate expensing for domestic research and experimental expenditures, changes to Section 163(j) interest limitations, updates to GILTI and FDII rules, amendments to energy credits, and expanded Section 162(m) aggregation requirements. In accordance with ASC 740, the Company recognized the effects of the new tax law in the period that includes the enactment date. While OBBBA did not have a material impact on the Company's consolidated financial statements as of and for year ended December 31, 2025, the Company will continue to assess the changes. However, the Company does not expect such changes will have a material effect on its consolidated financial statements in future periods.

The Company had no unrecognized tax benefits or related interest and penalties accrued as of December 31, 2025 and 2024. The Company's accounting policy is to recognize any interest and penalties related to uncertain tax positions as components of income tax expense.

Undistributed earnings of the Company's foreign subsidiaries are indefinitely invested outside the United States. The majority of the Company's cash flow is generated from domestic operations, and the Company is not dependent on foreign cash or earnings to meet funding requirements, nor does the Company intend to repatriate these undistributed foreign earnings to fund U.S. operations. As a result, the Company has not provided U.S. deferred taxes on these undistributed earnings because it intends that such earnings will remain indefinitely reinvested outside of the United States and, therefore unavailable for use in funding U.S. operations. The Company estimates the income taxes that would be payable on the repatriation of the unremitted earnings would not be material.

The Company is subject to taxation in the United States and Australia. At December 31, 2025, the Company is subject to examination by taxing authorities in the United States and Australia for the year ended December 31, 2025 and the period from March 14, 2024 (Inception) to December 31, 2024. Currently, no federal or state income tax returns are under examination by the respective taxing authorities. All tax years remain open to examination by these jurisdictions, as carryforward attributes generated in past years may be adjusted in a future period.

13. SEGMENTS

The Company manages its operations as a single operating and reportable segment that is engaged in research and development activities aimed at advancing multiple next generation, bi-specific antibody programs. The Company's chief operating decision maker ("CODM") is the chief executive officer ("CEO"). The CODM manages the Company's operations on a consolidated basis. Consolidated net loss is used by the CODM to make key operating decisions, such as the determination of the program-level spending and the allocation of capital between research and development activities and general and administrative support functions. The CODM also assesses financial performance and allocates resources based on cash resources and operating expense projections.

The following table presents selected financial information with respect to the Company's single operating segment (in thousands):

	Year Ended December 31, 2025	Period from March 14, 2024 (Inception) to December 31, 2024
Operating expenses:		
External research and development expense - BBT001	$ 15,519	$ 6,165
External research and development expense - BBT002	12,979	5,063
Other research and development expenses[1]	3,064	626
Personnel-related research and development expenses[1]	3,844	1,039
External general & administrative expenses[1]	2,018	703
Personnel-related general and administrative expenses[1]	1,205	91
Stock-based compensation expense	5,377	193
Other segment items[2]	(2,919)	(139)
Consolidated net loss	$ 41,087	$ 13,741

(1) Amounts exclude employee and non-employee stock-based compensation.
(2) Other segment items consist of interest income, research and development incentive income, change in fair value of preferred stock tranche right obligation, other income, net, and income tax provision.

The measure of segment assets is reported on the consolidated balance sheets as total assets. The CODM additionally reviews cash and cash equivalents and marketable securities when reviewing segment assets. As of December 31, 2025, the Company's cash and cash equivalents and marketable securities were $90.6 million. The Company does not provide its CODM with any more detailed segment asset information than what is included on the Company's consolidated balance sheets.

14. COMMITMENTS AND CONTINGENCIES

Legal matters

The Company, from time to time, may be involved with lawsuits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the consolidated balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2025 and 2024, the Company was not a party to any material legal proceedings or claims.

Guarantees and indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 and 2024.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

License and other agreements

The Company is obligated to make fixed and contingent payments under the BioNTech Zhuhai Assignment Agreement, Research and Collaboration and Option Agreement, and the BioNTech Zhuhai License Agreement (see Note 11).

The Company maintains its headquarters through a membership agreement that provides access to shared office space and does not otherwise lease office or laboratory space.

401(k) Plan

The Company has a defined-contribution savings plan under Section 401(k) of the IRC (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax or post-tax basis. The Company makes contributions of up to 3.5% of each employee's annual compensation, consisting of a 100% match on the first 1% contributed and a 50% match on the next 5% contributed, subject to employee contributions and annual safe harbor limits. The Company has expensed $89,000 and $23,000 in 401(k) contributions for the year ended December 31, 2025 and period from March 14, 2024 (Inception) to December 31, 2024, respectively.

15. NET LOSS PER SHARE

Basic and diluted net loss per share is calculated as follows (in thousands except share and per share amounts):

	Period from February 12, 2025 to December 31, 2025
Net loss attributable to common stockholders	$ (39,332)
Net loss per share attributable to common stockholders, basic and diluted	$ (6.08)
Weighted-average shares outstanding, basic and diluted	6,474,305

The computation of basic and diluted weighted-average common shares outstanding excludes unvested Founders' Shares as such shares are subject to a repurchase option and therefore not considered outstanding for accounting purposes. There was no common stock outstanding for accounting purposes until February 12, 2025 with the closing of the Series A-1 Preferred Stock and the release of the Repurchase Option for a portion of the Founders' Shares. Refer to Note 8 for more information.

As there was no common stock outstanding for accounting purposes during the period from March 14, 2024 (Inception) to December 31, 2024, there is no net loss per share for the period from March 14, 2024 (Inception) to December 31, 2024. Further, as there was no common stock outstanding for accounting purposes until February 12, 2025, the Company has computed net loss attributable to common stockholders and weighted-average shares outstanding, basic and diluted, for the period from February 12, 2025 to December 31, 2025.

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect is antidilutive:

	As of December 31, 2025
Unvested restricted common stock	4,495,176
Outstanding stock options	1,279,671
Series Seed Preferred Stock (as converted to common stock)	5,329,584
Series Seed Plus Preferred Stock (as converted to common stock)	3,740,038
Series A-1 Preferred Stock (as converted to common stock)	15,593,907
Series A-2 Preferred Stock (as converted to common stock)	2,645,542
Total	33,083,918

The amount of outstanding stock options in the table above for the year ended December 31, 2025 exclude 247,241 of potentially dilutive securities as these outstanding stock options relate to contingently issuable shares for which the performance condition was not satisfied as of period end.

16. RELATED PARTIES

The Company's Chief Executive Officer and co-founder, Dr. Shanshan Xu, controls MiNeng, Inc. ("MiNeng"). In addition, the Company's co-founder and director, Helmut Jeggle, controls Salvia Investment GmbH ("Salvia").

In May 2024, MiNeng and Salvia entered into CSPAs with the Company for the purchase of Founders' Shares. Refer to Note 8 for more information.

In April 2024, the Company entered into a loan agreement with Salvia in an amount of $0.5 million (the "Salvia Loan Agreement"). The Salvia Loan Agreement was unsecured and bore simple interest at a fixed rate per annum of 3% and was designated to finance the operations of the Company. The Company repaid the loan in July 2024.

In addition, the Company issued and sold shares of its Preferred Stock to certain of the Company's management, MiNeng, and Salvia during the following periods (in thousands, except shares):

	Year Ended December 31, 2025		Period From March 14, 2024 (Inception) to December 31, 2024	
	Shares	Total Aggregate Purchase Price	Shares	Total Aggregate Purchase Price
Series Seed Preferred Stock	—	$ —	3,866,562	$ 3,700
Series Seed Plus Preferred Stock	—	—	41,554	100
Series A-1 Preferred Stock	1,596,583	9,100	—	—
Series A-2 Preferred Stock	185,604	2,250	—	—
Total	1,782,187	$ 11,350	3,908,116	$ 3,800

17. SUBSEQUENT EVENTS

The Company evaluated subsequent events through August 3, 2026, the date the consolidated financial statements were available to be issued and, with respect to the stock split discussed below, through October 26, 2026, the date the consolidated financial statements were available to be reissued, for events requiring recording or disclosure in the consolidated financial statements for the year ended December 31, 2025.

Grants of VARs and Stock Options

In April 2026, the Company issued to employees 39,994 VARs at a grant date price of $4.81. In June 2026, 8,748 VARs were forfeited. Subsequently, in June 2026, the Company modified 159,639 of the VARs outstanding

as of December 31, 2025 and those granted in April 2026 to refine the definition of a liquidity event to include only a change in control of the Company.

In April 2026, the Company granted options for the purchase of an aggregate of 552,957 shares of common stock to employees at an exercise price of $4.81 per share, of which 527,688 were subsequently forfeited. In July 2026, the Company granted options for the purchase of an aggregate of 268,093 shares of common stock to employees at an exercise price of $8.04 per share.

In May 2026, BioNTech Zhuhai discontinued the sublicense with Alloy (see Note 11). The Company has been released of its obligation to pay the associated annual platform fee.

In July 2026, the Company issued 18,963 VARs at a grant date price of $8.04 per share.

Stock Split

On October 23, 2026, the Company effected a 1.54485-for-1 forward stock split of its issued and outstanding shares of common stock and preferred stock (see Note 7). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split. As the number, issuance price, and conversion price of all outstanding preferred stock were adjusted, the conversion ratios for each series of the Company's preferred stock were unchanged.

Events Subsequent to Original Issuance of Financial Statements (Unaudited)

In connection with the reissuance of the consolidated financial statements, the Company has evaluated subsequent events through October 26, 2026, the date the financial statements were available to be reissued.

BAMBUSA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 46,534	$ 50,643
Marketable securities	24,941	39,984
Prepaid expenses and other current assets	3,824	3,505
Total current assets	75,299	94,132
Deferred offering costs	1,744	—
Other assets	453	1,581
Total assets	$ 77,496	$ 95,713
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,614	$ 1,905
Accrued expenses and other current liabilities	10,609	7,743
Total current liabilities	12,223	9,648
Commitments and contingencies (Note 13)		
Series Seed convertible preferred stock, $0.00001 par value; 5,329,588 shares authorized, 5,329,584 shares issued and outstanding; liquidation preference of $5,100 as of June 30, 2026 and December 31, 2025	5,066	5,066
Series Seed Plus convertible preferred stock, $0.00001 par value; 3,740,043 shares authorized, 3,740,038 shares issued and outstanding; liquidation preference of $9,000 as of June 30, 2026 and December 31, 2025	8,930	8,930
Series A-1 convertible preferred stock, $0.00001 par value; 15,593,922 shares authorized, 15,593,907 shares issued and outstanding; liquidation preference of $88,880 as of June 30, 2026 and December 31, 2025	89,232	89,232
Series A-2 convertible preferred stock, $0.00001 par value; 2,728,039 shares authorized, 2,728,032 and 2,645,542 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively; liquidation preference of $33,070 and $32,070 as of June 30, 2026 and December 31, 2025, respectively	33,003	32,007
Stockholders' deficit:		
Common stock, $0.00001 par value; 46,346,000 shares authorized, 12,374,122 shares issued and outstanding as of June 30, 2026 and December 31, 2025	—	—
Additional paid-in capital	6,249	5,598
Accumulated other comprehensive (loss) income	(19)	60
Accumulated deficit	(77,188)	(54,828)
Total stockholders' deficit	$ (70,958)	$ (49,170)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 77,496	$ 95,713

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Six months ended June 30, 2026	Six months ended June 30, 2025
Operating Expenses:		
Research and development	$ 20,646	$ 11,892
General and administrative	3,413	3,556
Total operating expenses	24,059	15,448
Loss from operations	(24,059)	(15,448)
Other income (expense):		
Interest income	1,313	732
Research and development incentive	1,513	1,236
Change in fair value of preferred stock tranche right obligation	—	(454)
Other income, net	67	37
Total other income, net	2,893	1,551
Loss before income taxes	(21,166)	(13,897)
Income tax provision	1,194	850
Net loss	$ (22,360)	$ (14,747)
Comprehensive loss:		
Net loss	$ (22,360)	$ (14,747)
Unrealized (losses) gains on marketable securities	(79)	60
Comprehensive loss	$ (22,439)	$ (14,687)
Net loss attributable to common stockholders[(1)]	$ (22,360)	$ (12,989)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (2.56)	$ (2.30)
Weighted-average common shares outstanding, basic and diluted[(1)]	8,727,671	5,657,176

(1) With respect to the six months ended June 30, 2025, represents net loss per share of common stock and weighted-average shares of common stock outstanding for the period from February 12, 2025 to June 30, 2025. See Note 2—Summary of Significant Accounting Policies and Note 14—Net Loss Per Share.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at January 1, 2025	9,069,622	$ 13,996	12,358,799	$ —	$ 193	$ —	$ (13,741)	$ (13,548)
Issuance of Series A-1 preferred stock, inclusive of issuance and settlement of preferred stock tranche right obligation, net of issuance costs of $85	15,593,907	89,248	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	4,486	—	—	4,486
Unrealized gain on marketable securities	—	—	—	—	—	60	—	60
Net loss	—	—	—	—	—	—	(14,747)	(14,747)
Balances at June 30, 2025	24,663,529	$ 103,244	12,358,799	$ —	$ 4,679	$ 60	$ (28,488)	$ (23,749)
Balances at January 1, 2026	27,309,071	$ 135,235	12,374,122	$ —	$ 5,598	$ 60	$ (54,828)	$ (49,170)
Issuance of Series A-2 preferred stock, net of issuance costs of $4	82,490	996	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	651	—	—	651
Unrealized loss on marketable securities	—	—	—	—	—	(79)	—	(79)
Net loss	—	—	—	—	—	—	(22,360)	(22,360)
Balances at June 30, 2026	27,391,561	$ 136,231	12,374,122	$ —	$ 6,249	$ (19)	$ (77,188)	$ (70,958)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Six months ended June 30, 2026	Six months ended June 30, 2025
Cash flows from operating activities:		
Net loss	$ (22,360)	$ (14,747)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	651	4,486
Change in fair value of preferred stock tranche right obligation	—	454
Accretion of discount on marketable securities	(68)	—
Unrealized (loss) gain on foreign currency transactions	(18)	72
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(312)	(1,518)
Other assets	1,129	(749)
Accounts payable	(337)	69
Accrued expenses and other current liabilities	1,178	(7,107)
Net cash used in operating activities	(20,137)	(19,040)
Cash flows from investing activities:		
Purchases of marketable securities	(14,968)	—
Maturities of marketable securities	30,000	—
Net cash provided by investing activities	15,032	—
Cash flows from financing activities:		
Proceeds from issuance of Series A-1 convertible preferred stock, including tranche obligation, net of issuance costs paid of $85[(1)]	—	88,794
Proceeds from issuance of Series A-2 convertible preferred stock, net of issuance costs paid of $4[(2)]	996	—
Net cash provided by financing activities	996	88,794
Net (decrease) increase in cash and cash equivalents	(4,109)	69,754
Cash and cash equivalents:		
Beginning of period	50,643	9,362
End of period	$ 46,534	$ 79,116
Supplemental disclosure of noncash investing and financing activities		
Deferred offering costs in accounts payable and accrued expenses	$ 1,744	$ —
Settlement of Series A-1 preferred stock tranche right obligation	$ —	$ 2,271

(1) Includes related party amounts of $9.1 million (see Note 15).
(2) Includes related party amounts of $1.0 million (see Note 15).

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BAMBUSA THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Bambusa Therapeutics, Inc. and its consolidated subsidiaries (the "Company" or "Bambusa"), is a clinical-stage therapeutics company focused on developing innovative bispecific antibodies for immunological and inflammatory ("I&I") disorders. The Company was incorporated on March 14, 2024 in the state of Delaware, and its principal offices are in Boston, Massachusetts.

As used in the accompanying unaudited condensed consolidated financial statements, unless the context otherwise requires, references to the "Company" or "Bambusa" refer to Bambusa Therapeutics, Inc. and its wholly owned subsidiaries Bambusa Securities Corporation, Bambusa Therapeutics Pty. Ltd (Australia), and Bambusa (Beijing) Therapeutics Co., Ltd.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") and in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim reporting and as required by Regulation S-X, Rule 10-01. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). These unaudited condensed consolidated financial statements include the accounts of Bambusa Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of June 30, 2026, and the results of its operations and cash flows for the six months ended June 30, 2026 and 2025. The unaudited condensed consolidated balance sheet as of December 31, 2025 was derived from audited annual financial statements but does not include all disclosures required by GAAP. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2026, any other interim periods, or any future year or period.

Risks and uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including but not limited to, successful completion of preclinical studies and clinical trials, obtaining regulatory approvals for product candidates, new technological innovations, protection of proprietary technology, competition, dependence on key personnel, compliance with government regulations, reliance on third-party organizations for the discovery, manufacturing, and preclinical and clinical support of its product candidates, managing growth and expansion of the Company, and the ability to secure capital necessary to fund operations. Product candidates currently under development will require significant additional research and development efforts, including manufacturing, preclinical and clinical development, and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities.

There can be no assurance that the Company's research and development efforts will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Going concern

Management has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements were available to be issued.

Since inception, the Company has devoted the majority of its resources to research and development of its product candidates, including by conducting clinical trials and preclinical studies, raising capital, and recruiting management and technical staff to support these operations. To date, the Company has not generated any revenue from product sales as none of its product candidates have been approved for commercialization. The Company has historically financed its operations primarily through the sale of convertible preferred stock. The Company has incurred recurring losses and negative operating cash flows since its inception. As of June 30, 2026, the Company had an accumulated deficit of $77.2 million. The Company expects to continue to generate operating losses and negative cash flows for the foreseeable future as the Company continues to develop its product candidates. The Company's future operations will be dependent on its ability to raise additional capital to finance such operations.

As of September 14, 2026, the date these condensed consolidated financial statements were available to be issued, the Company expects that its cash and cash equivalents and marketable securities on hand will not be sufficient to fund its operations for at least 12 months from the date these condensed consolidated financial statements were available to be issued. Accordingly, the Company determined there is substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Significant additional funding is necessary to maintain current operations and to advance the Company's research and development activities. The Company plans to seek additional funding through equity offerings or debt financings, credit or loan facilities, strategic alliances, and licensing arrangements. The Company's ability to access capital when and in the amount needed is not assured. The terms of any future financing may adversely affect the holdings or the rights of the Company's current stockholders.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the completion of a qualified public offering on specified terms, the Company's outstanding convertible preferred stock will be automatically converted into shares of common stock (see Note 7). If the Company is unable to complete its IPO or obtain other funding, it could be forced to delay, reduce, or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or it may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all or that any proceeds would be sufficient to support the Company's operating plans for at least the next 12 months from the date these condensed consolidated financial statements were available to be issued.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited annual financial statements included elsewhere in the Company's Registration Statement on Form S-1. During the six months ended June 30, 2026, there were no material changes to the Company's significant accounting policies.

Use of estimates

The preparation of condensed consolidated financial statements in accordance with U.S. GAAP requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and

liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period presented. Management bases its estimates on historical experience and various other assumptions that management believes to be reasonable under the circumstances. Management evaluates its estimates and assumptions on an ongoing basis. Changes in estimates are recorded in the period in which they become known. Significant estimates and assumptions relied upon in preparing these condensed consolidated financial statements include, but are not limited to, accrued research and development expenses, the valuation of common stock used in the determination of stock-based compensation expense, and the valuation of the preferred stock tranche right obligation. Actual results may differ from the estimates under different assumptions or conditions.

Concentrations of risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and marketable securities. The Company maintains its cash and cash equivalent balances with financial institutions believed to be of high credit quality and, consequently, the Company believes that such funds are subject to minimal credit risk. At times, the Company's cash and cash equivalents may be uninsured or in deposit accounts that exceed Federal Deposit Insurance Corporation limits. The Company's cash equivalents and marketable securities are comprised of money market funds and U.S. Treasury securities, respectively.

The Company is dependent on the third-party contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") with whom they do business. In particular, the Company relies and expects to continue to rely on a small number of CMOs to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities on its programs. The Company also relies on a limited number of CROs to perform research and development activities on its behalf. The Company's clinical development programs could be adversely affected by significant interruption from these providers.

Convertible preferred stock

The Company has classified convertible preferred stock as temporary equity on the Company's condensed consolidated balance sheets due to terms that allow for redemption of the shares in cash upon the occurrence of deemed liquidation events that are not solely within the control of the Company (see Note 7). The Company initially recorded its convertible preferred stock at fair value, net of preferred stock tranche right obligations, if applicable, and issuance costs. The Company has not adjusted the carrying values of the convertible preferred stock to the redemption amount of such shares because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the redemption amount to holders of shares of convertible preferred stock. Subsequent adjustments of the carrying values of the convertible preferred stock will be made only when a deemed liquidation event becomes probable.

Australia research and development incentive

The Company is eligible to obtain certain research and development incentives, refundable in cash, through its wholly owned Australian subsidiary, Bambusa Therapeutics Pty. Ltd., as part of a program administered by the Australian Tax Office ("ATO"). The Company recognizes amounts earned under the Australian research and development program when it is deemed probable the applicable conditions have been met and the incentive will be received. The Company recognizes research and development incentive as income within other income, net within the condensed consolidated statements of operations and comprehensive loss as the qualifying research expense is incurred, and a corresponding receivable within prepaid and other current assets on its condensed consolidated balance sheets. The Company recorded research and development incentive receivables of $1.0 million and $1.1 million as of June 30, 2026 and December 31, 2025, respectively, and income from Australia research and development incentives of $1.5 million and $1.2 million for the six months ended June 30, 2026 and 2025, respectively.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company has one operating and reportable segment, which is the business of advancing multiple next generation, bispecific antibody programs. The Company's CODM, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources and assessing performance. All of the Company's long-lived assets are held in the United States.

Stock-based compensation

The Company measures the fair value of stock-based awards on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period during which an employee provides service in exchange for the award. Compensation expense for awards to non-employees is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. The Company accounts for forfeitures as they occur. For awards that vest solely based on a service condition, the Company recognizes expense on a straight-line basis over the requisite service period.

Certain of the Company's stock-based awards include performance conditions based on the achievement of specified clinical development milestones. Because the achievement of these milestones involves inherent risks and uncertainties, management's determination of when achievement of each performance condition is probable requires significant judgment. The Company begins to recognize the value of these stock-based awards when management determines that achievement of the applicable performance condition is deemed probable. At the probable date, the Company records a cumulative catch-up adjustment for compensation expense attributable to the requisite service completed to date and recognizes any remaining compensation expense over the remaining requisite service period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. The fair value of each restricted stock award granted in the form of founder shares is based on the difference, if any, between the purchase price per share of the award and fair value of the Company's common stock on the date of grant (see Note 8).

Given the absence of an active market for the Company's common stock, the estimated fair value of common stock was determined by the Company's board of directors (the "Board") at the time of each grant of a stock-based award, with inputs from management, considering the Company's most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. The Company is a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly-traded peer companies. The expected term of the Company's stock options has been determined utilizing the simplified method for awards that qualify as "plain-vanilla" options, which is presumed to be the midpoint between the vesting date and the end of the contractual term. If vesting is subject to a performance condition, the expected term is based on the mid-point between the explicit service period and the contractual term of the option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

Value appreciation rights

The Company has issued value appreciation rights ("VARs") to employees and nonemployees in exchange for services. The VARs contain both service-based and performance-based vesting conditions. Upon a change in control

of the Company, any VARs that have achieved the respective service-based and other performance-based conditions, if applicable, vest and become payable. To the extent the service-based vesting condition has not been fully met at the time of a public listing or change in control for the Company, such VARs will continue to vest in accordance with the applicable service vesting conditions. The Company recognizes compensation expense for the VARs when the achievement of the performance condition(s) becomes probable and over the requisite service period applicable to the award. The VARs are classified as liabilities as the VARs are settleable in cash. In the periods prior to becoming a public company, the Company has elected to measure the fair value of the VARs at their intrinsic value which is the difference between the grant-date price and the fair value of the Company's common stock.

The Company remeasures the fair value of the VARs at each reporting date and, to the extent the performance conditions associated with the awards are met or considered probable, recognizes compensation expense based on changes in fair value. At June 30, 2026, no amounts have been recorded in the condensed consolidated financial statements as the related performance conditions are not considered probable (see Note 10).

Deferred offering costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the convertible preferred stock or in stockholders' deficit as a reduction of additional paid-in capital. Should the planned equity financing be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. As of June 30, 2026, the Company had deferred offering costs of $1.7 million. The Company had no deferred offering costs as of December 31, 2025.

Net loss per share

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of shares of the Company's common stock and participating securities. The Company's Preferred Stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-average number of shares of common stock included in the computation of diluted net loss gives effect to all potentially dilutive common stock equivalent shares, including outstanding stock options and preferred stock, to the extent their effect is dilutive.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Prior to February 12, 2025, there were no outstanding shares of the Company for accounting purposes. As such, only net loss per share for the period from February 12, 2025 to June 30, 2025 is presented based on net losses attributable to common stockholders during this period (see Note 14).

Recently issued accounting pronouncements not yet adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the

extended transition period related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company will adopt the new or revised standard at the time non-public companies adopt the new or revised standard unless early adoption is permitted and the Company elects to early adopt. The Company will continue to use such extended transition period until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt new or revised accounting standards whenever such early adoption is permitted for non-public companies.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)*: *Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires public business entities to disaggregate, on both an interim and annual basis, each relevant expense caption presented on the face of the income statement into specific expense categories. Additionally, entities are required to provide a qualitative description of amounts remaining in relevant expense captions that are not separately disaggregated quantitatively, as well as disclosure of the total amount of selling expenses and, in annual reporting periods, an entity's definition of selling expenses. The amendments in ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact that ASU 2024-03 will have on its disclosures in the condensed consolidated financial statements.

3. MARKETABLE SECURITIES

Marketable securities are summarized as follows (in thousands):

	June 30, 2026			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
U.S. Treasury securities	$ 24,960	$ 1	$ (20)	$ 24,941
Total marketable securities	$ 24,960	$ 1	$ (20)	$ 24,941

	December 31, 2025			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
U.S. Treasury securities	$ 39,924	$ 60	$ —	$ 39,984
Total marketable securities	$ 39,924	$ 60	$ —	$ 39,984

As of June 30, 2026 and December 31, 2025, all marketable securities had contractual maturities within one year.

4. FAIR VALUE MEASUREMENTS

The following tables present, within the fair value hierarchy, information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	June 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 38,541	$ —	$ —	$ 38,541
Marketable securities:				
U.S. Treasury securities	—	24,941	—	24,941
Total financial assets	$ 38,541	$ 24,941	$ —	$ 63,482

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 36,779	$ —	$ —	$ 36,779
Marketable securities:				
U.S. Treasury securities	—	39,984	—	39,984
Total financial assets	$ 36,779	$ 39,984	$ —	$ 76,763

As of June 30, 2026 and December 31, 2025, the Company had cash equivalents consisting of money market funds classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment. As of June 30, 2026 and December 31, 2025, the Company has marketable securities consisting of U.S. Treasury securities which are classified as Level 2 instruments. The Company estimates the fair value of its marketable securities by using observable market inputs, including quoted prices for similar securities, benchmark yields, reported trades, broker/ dealer quotes, and other market-based pricing sources with reasonable price transparency.

During the six months ended June 30, 2026 and 2025, there were no transfers or reclassifications between fair value measurement levels of assets or liabilities. The carrying values of other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Preferred stock tranche right obligation

The Company determined that its obligation to issue, and the Company's investors' obligation to purchase, additional shares of convertible preferred stock at a fixed price (i.e. the issuance price) in subsequent tranche following the initial closing of the Series A-1 convertible preferred stock financing represented a freestanding financial instrument (the "preferred stock tranche right obligation"). The freestanding financial instrument was classified as a liability on the Company's consolidated balance sheets and initially recorded at fair value, with changes in fair value recognized in other income (expense) in the condensed consolidated statement of operations and comprehensive loss.

In connection with the Company's initial issuance of Series A-1 Preferred Stock in February 2025 the Company recognized the preferred stock tranche right obligation at fair value, which was determined based on significant unobservable inputs, which represented a Level 3 measurement within the fair value hierarchy.

The preferred stock tranche right obligation was determined using the binomial pricing model, which takes into account various significant assumptions, including the fair value of the Company's Series A-1 Preferred Stock, and the probability and expected timing of the achievement of a clinical milestone event as of the measurement dates or the failure to achieve such milestone. The Company determined the fair value per share of the underlying Series A-1 Preferred Stock by taking into consideration the most recent sales of its Series A-1 Preferred Stock, results obtained from third-party valuations, and additional factors the Company deemed relevant. An increase or decrease in these assumptions will result in an increase or decrease in the fair value of the preferred stock tranche right obligation and such changes could be material.

The following reflects the significant quantitative assumptions used in the valuation of the preferred stock tranche right obligation at issuance date:

Series A-1 Preferred Stock present value	$5.5055
Estimated future value of Series A-1 Preferred Stock	$3.2716 - $6.0639
Probability of tranche closing	20% - 80%

In June 2025, the Board approved the achievement of the milestone associated with the tranche and issued 6,237,556 shares of Series A-1 Preferred Stock. Upon settlement, the fair value of the preferred stock tranche right

obligation was determined based on the difference between the estimated fair value of the Series A-1 Preferred Stock, or $6.0639 per share, and its contractual purchase price, or $5.6997 per share.

The following table sets forth a summary of changes in the fair value of the Company's preferred stock tranche right obligation for which fair value was determined by Level 3 inputs (in thousands):

Balance at December 31, 2024	$ —
Issuance of preferred stock tranche right obligation	1,817
Change in fair value of preferred stock tranche right obligation	454
Settlement of the preferred stock tranche right obligation	(2,271)
Balance at June 30, 2025	$ —

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Prepaid research and development	$ 2,233	$ 1,040
Research and development incentive receivable	1,026	1,097
Goods and services tax receivable	200	785
Other	365	583
Total prepaid expenses and other current assets	$ 3,824	$ 3,505

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following (in thousands):

	June 30, 2026	December 31, 2025
Accrued research and development costs	$ 7,101	$ 6,716
Accrued legal and professional fees	2,398	170
Accrued employee compensation and benefits	879	789
Accrued other	231	68
Total accrued expenses and other current liabilities	$ 10,609	$ 7,743

7. CONVERTIBLE PREFERRED STOCK

The Company has issued Series Seed convertible preferred stock ("Series Seed Preferred Stock"), Series Seed Plus convertible preferred stock ("Series Seed Plus Preferred Stock"), Series A-1 convertible preferred stock ("Series A-1 Preferred Stock), and Series A-2 convertible preferred stock ("Series A-2 Preferred Stock and together with Series A-1 Preferred Stock, "Series A Preferred Stock"), (collectively, the "Preferred Stock").

In January 2026, the Company entered into a preferred stock agreement with an investor pursuant to which the Company issued and sold an additional 82,490 shares of Series A-2 Preferred Stock for a purchase price of $12.1225 per share, resulting in gross aggregate proceeds of approximately $1.0 million.

Preferred Stock consisted of the following (in thousands, except for share and per share data):

As of June 30, 2026	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Original Issuance Price	Liquidation Preference	Shares Issuable Upon Conversion
Series Seed	5,329,588	5,329,584	$ 5,066	$ 0.9570	$ 5,100	5,329,584
Series Seed Plus	3,740,043	3,740,038	8,930	$ 2.4064	9,000	3,740,038
Series A-1	15,593,922	15,593,907	89,232	$ 5.6997	88,880	15,593,907
Series A-2	2,728,039	2,728,032	33,003	$12.1225	33,070	2,728,032
Total	27,391,592	27,391,561	$ 136,231		$ 136,050	27,391,561

As of December 31, 2025	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Original Issuance Price	Liquidation Preference	Shares Issuable Upon Conversion
Series Seed	5,329,588	5,329,584	$ 5,066	$ 0.9570	$ 5,100	5,329,584
Series Seed Plus	3,740,043	3,740,038	8,930	$ 2.4064	9,000	3,740,038
Series A-1	15,593,922	15,593,907	89,232	$ 5.6997	88,880	15,593,907
Series A-2	2,728,039	2,645,542	32,007	$ 12.1225	32,070	2,645,542
Total	27,391,592	27,309,071	$ 135,235		$ 135,050	27,309,071

The following is a summary of rights, privileges and preferences of the Preferred Stock as of June 30, 2026.

Dividends—Holders of the Preferred Stock are entitled to receive dividends on a pari passu basis, prior and in preference to any other class or series of capital stock, calculated on an as-if-converted basis (meaning conversion of Preferred Stock into the particular series on which the dividend is being declared) when and if dividends are declared by the Company. If the Company declares dividends on more than one class of share, each series of Preferred Stock shall receive the dividend amount that results in the highest dividend. No dividends were declared through June 30, 2026.

Liquidation Rights—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company including a deemed liquidation event, the holders of the Preferred Stock are entitled to be paid out of the assets of the Company on a pari passu basis, prior and in preference to any distribution or payment of any of the assets or surplus funds of the Company to the holders of common stock, an amount equal to the greater of: (i) the original purchase price of the Preferred Stock, plus all declared, but unpaid dividends or (ii) amount per share as would have been payable, if all shares of Preferred Stock had been converted into common stock immediately prior to such liquidation or deemed liquidation event. If the assets of the Company are insufficient to make payment in full to all holders of Preferred Stock, then the assets or consideration will be distributed ratably among such preferred stockholders in proportion to the full liquidation preference amounts to which the preferred stockholders would otherwise be entitled. After the payment of the full liquidation preference to holders of Preferred Stock the remaining assets of the Company shall be distributed among the holders of shares of common stock, pro rata based on the number of shares of common stock held by each such holder.

A deemed liquidation event shall include a merger, consolidation, statutory conversion, transfer of corporation, domestication, or continuance or sale, lease, transfer, exclusive license, or other disposition of substantially all of the assets of the Company.

Conversion—Each outstanding share of Preferred Stock is convertible at the option of the holder and at any time into common stock as determined by dividing the Preferred Stock original issue price by the Preferred Stock Conversion Price. “Conversion Price” is defined as initially the applicable original issue price for the applicable series of Preferred Stock, subject to certain adjustments in the event of any down round, stock dividend, stock split, combination, or other similar recapitalization. The Preferred Stock will also be converted automatically into shares of common stock (a) immediately prior to the closing of the sale of shares of common stock to the public at a price of at least $8.5496 per share in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to the

Company and in connection with such offering the shares of common stock are listed for trading on the Nasdaq Stock Market, the New York Stock Exchange, or another exchange or marketplace approved by the Board (b) at any time upon the affirmative election of the holders of a majority of the outstanding shares of Preferred Stock, voting together as a single class on an as-if-converted to common stock basis (the "Requisite Holders"), or with respect to automatic conversion of the Series A Preferred Stock, upon the affirmative election of the holders of a majority of the outstanding shares of Series A Preferred Stock, voting as a single class on an as-if-converted to common stock basis, provided that such majority must include stockholders holding at least 2,193,116 shares of Series A-1 Preferred Stock and Series A-2 Preferred Stock who do not hold any shares of Series Seed Preferred Stock or Series Seed Plus Preferred Stock.

Voting Rights—Each holder has the right to one vote, on each matter submitted to a vote at any meeting of stockholders, for each share of common stock into which such series of Preferred Stock could be converted. Preferred Stockholders and common stockholders vote together as a single class.

In addition, the holders of shares of Series Seed Preferred Stock, exclusively and voting together as a separate class on an as-converted to common stock basis, are entitled to elect one director of the Company. The holders of shares of Series A-1 Preferred Stock, exclusively and voting together as a separate class on an as-converted to common stock basis, are entitled to elect one director of the Company. The holders of shares of Common Stock, exclusively and voting together as a separate class, are entitled to elect two directors of the Company. The holders of shares of common stock and any other class or series of voting stock (including Preferred Stock), exclusively and voting together as a single class, are entitled to elect the balance of the total number of directors of the Company.

Redemption— The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a deemed liquidation event.

8. COMMON STOCK

The voting, dividend, and liquidation rights of the holders of the Company's common stock are subject to the rights, powers, and preferences of the holders of the Preferred Stock set forth above. Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock, on each matter submitted to a vote at any meeting of stockholders. Common stockholders are entitled to receive dividends, subject to the preferential dividend rights of the preferred stock. Through June 30, 2026, no cash dividends have been declared or paid.

Founders' Shares

In May 2024, the Company entered into Common Stock Purchase Agreements (each, a "CSPA") with related party entities controlled by certain of its co-founders pursuant to which the Company authorized, issued, and sold 12,358,799 shares of common stock ("Founders' Shares") at an original purchase price of $0.00001 per share and an aggregate fair value of $5.6 million. The CSPAs stipulate that in the event of the voluntary or involuntary termination of the controlling founder's continuous service status, the Company has the option ("Repurchase Option") to repurchase all or any portion of the respective shares as of the termination date which have not yet been released from the Repurchase Option at the original purchase price. Subject to continuous employment, shares are released from the Repurchase Option as follows: (i) 5,149,499 upon the closing of the Series A-1 Preferred Stock and (ii) 7,209,300 in equal monthly installments over a three-year period subsequent to the closing of the Series A-1 Preferred Stock. The release of the Repurchase Option is subject to future acceleration upon the closing of an initial public offering or a change in control. For accounting purposes, the Founders' Shares subject to the Company's Repurchase Option are treated as unvested restricted common stock and are not considered outstanding until the applicable shares are released from the Repurchase Option.

The Founders' Shares are considered compensatory for which expense is recorded based on the fair value of the common stock less original purchase price at the date of issuance, with expense being recognized in the condensed consolidated statements of operations and comprehensive loss over the period which the Repurchase Option is released. Compensation expense recognized for the Founders' Shares was $0.4 million and $4.4 million, for the six months ended June 30, 2026 and 2025, respectively. Forfeitures are recognized as they occur.

The following table summarizes Founders' Shares activity:

	Shares	Weighted-average fair value per share
Unvested at December 31, 2025	4,495,176	$ 0.46
Vested	(1,628,473)	$ 0.46
Unvested at June 30, 2026	2,866,703	$ 0.46

As of June 30, 2026, there were 2,866,703 Founders' Shares subject to repurchase with $0.2 million in unrecognized compensation expense, which is expected to be recognized over a period of 1.6 years. To date, there have been no forfeitures of Founders' Shares.

The number of shares of common stock that have been reserved for the potential conversion of Preferred Stock, outstanding stock options granted, and stock options available for grant under the 2024 Plan are as follows:

	June 30, 2026	December 31, 2025
Conversion of Series Seed	5,329,584	5,329,584
Conversion of Series Seed Plus	3,740,038	3,740,038
Conversion of Series A-1	15,593,907	15,593,907
Conversion of Series A-2	2,728,032	2,645,542
Outstanding common stock options	1,550,428	1,526,912
Unvested restricted common stock	2,866,703	4,495,176
Common stock options available for grant	2,657,911	2,681,427
Total	34,466,603	36,012,586

9. STOCK-COMPENSATION EXPENSE

2024 Stock Plan

The Company maintains the 2024 Stock Plan ("2024 Plan"), which provides for the grant of incentive stock options, non-statutory stock options, restricted stock, and other awards (including restricted stock units) to employees, directors, and consultants of the Company. The 2024 Plan is administered by the Board, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price, and the vesting schedule. The aggregate number of shares of common stock available for issuance under the 2024 Plan is 4,208,339 shares. Shares that are expired, terminated, surrendered, or canceled under the 2024 Plan without having been fully exercised or that are retained upon exercise in order to satisfy the exercise or purchase price of the award or withholding taxes due with respect to such award will be available for future awards. As of June 30, 2026, the Company has reserved 2,657,911 shares of common stock for future issuance under the 2024 Plan.

Stock options granted under the 2024 Plan generally have a contractual term of ten years and typically vest ratably over a four-year period ("time-based options"). Certain stock options vest based on the achievement of specified milestones ("performance options"). Upon achievement of the applicable milestone, the performance options begin vesting over the requisite service period, subject to continued service, typically over a four-year period. The exercise price of each stock option may not be less than 100% of the fair market value of the Company's common stock on the grant date.

The following table summarizes stock option activity under the 2024 Plan:

	Number of Options	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	1,526,912	$ 0.84		
Granted	552,957	4.81		
Exercised	—	—		
Forfeited	(529,441)	4.80		
Expired	—	—		
Outstanding at June 30, 2026	1,550,428	$ 0.90	7.91	$ 11,078
Options exercisable at June 30, 2026	566,098	$ 0.68	7.49	$ 4,173
Options vested and expected to vest at June 30, 2026	1,305,247	$ 1.01	7.81	$ 9,175

The Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options issued under the 2024 Plan on each grant date. The following table presents the ranges of assumptions used by the Company:

	Six Months Ended June 30,	
	2026	2025
Expected term (in years)	5.82 – 7.25	5.96 – 7.25
Risk free interest rate	4.09% - 4.22%	4.00% - 4.16%
Volatility	85.89% - 108.51%	112.84% - 122.61%
Dividend yield	0.00%	0.00%

Based in part on retrospective valuations performed for accounting purposes, the weighted-average grant-date fair value of time-based options granted during the six months ended June 30, 2026 and 2025 were $6.45 and $2.14 per share, respectively. Based in part on retrospective valuations performed for accounting purposes, the weighted-average grant-date fair value of performance-based options granted during the periods ended June 30, 2026 and 2025 was $6.16 and $2.25 per share, respectively. As of June 30, 2026, no stock options have been exercised.

As of June 30, 2026, there was $1.3 million in unrecognized stock-based compensation expense associated with stock options with only service conditions, which is expected to be recognized over a weighted-average period of 2.4 years.

Stock-Based Compensation Expense

Total stock-based compensation expense for the six months ended June 30, 2026 and 2025 was $0.7 million and $4.5 million, respectively, inclusive of stock-based compensation expense for the Founders' Shares (see Note 8). The following table represents stock-based compensation expense recorded in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Six Months Ended June 30,	
	2026	2025
Research and development	$ 363	$ 2,217
General and administrative	288	2,269
Total	$ 651	$ 4,486

10. VALUE APPRECIATION RIGHTS

The Company granted incentive awards to employees and non-employees as value appreciation rights ("VARs"). The VARs were issued separately from the Company's 2024 Plan. Each VAR represents the right to receive an amount in cash or other consideration equal to the excess, if any, of the fair value of the common stock on the applicable payment date over the grant-date price, multiplied by the number of VARs vested. The VARs do not provide stockholder rights. As of June 30, 2026, the Company expected all VARs to be settled in cash. The VARs have a ten-year contractual term.

All VARs contain both service conditions and performance conditions, including a company liquidity event and the achievement of clinical or transactional milestones in certain cases. The VARs vest over a period of two to four years from the achievement of the requisite performance condition(s). The VARs granted prior to June 2026 became payable only if a liquidity event occurred, defined as a change of control or public listing of the Company, before the expiration date and while the participant remained in continuous service. In June 2026, the Company modified 199,633 of the then-outstanding VARs to change the definition of a liquidity event to include only a change in control of the Company. Of the VARs modified, 159,639 were outstanding as of December 31, 2025 and 39,994 were granted in April 2026. The modification did not have an impact on the Company's condensed consolidated financial statements as of and for the six months ended June 30, 2026. The VARs may be settled in cash or other consideration with payment due within 60 days following the liquidity event, or if later, the applicable vesting date following the liquidity event.

The following table summarizes VAR activity:

	Number of VARs	Weighted Average Grant-Date Price (per share)	Weighted Average Remaining Contract Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	870,183	$ 1.73		
Granted	39,994	$ 4.81		
Forfeited	(8,748)	$ 1.84		
Outstanding at June 30, 2026	901,429	$ 1.87	8.89	$ 5,567
Vested and expected to vest at June 30, 2026	—	$ —	—	$ —

No VARs were vested or settled during the six months ended June 30, 2026 and 2025.

As of June 30, 2026, the performance conditions were not deemed probable of achievement. As such, the Company has not recognized any expense for the VARs during the six months ended June 30, 2026 and 2025.

11. LICENSE AGREEMENTS

BioNTech Zhuhai Assignment Agreement

In March 2024, the Company entered into an assignment agreement, which was amended and restated in its entirety in December 2024 (the "BioNTech Zhuhai Assignment Agreement") with BioNTech (Zhuhai) Pharmaceuticals R&D, a subsidiary of BioNTech then known as Biotheus ("BioNTech Zhuhai"). Pursuant to the BioNTech Zhuhai Assignment Agreement, the Company obtained from BioNTech Zhuhai certain intellectual property rights, and related research materials and data packages, for two bispecific antibody programs, which the Company has designated BBT001 and BBT002 (together, the "Assigned Programs"). The BioNTech Zhuhai Assignment Agreement also included a sublicense to use certain antibody platform technology owned by BioNTech Zhuhai's upstream licensor Alloy Therapeutics, LLC ("Alloy") to develop and commercialize products comprising antibodies generated from the Assigned Programs.

Under the BioNTech Zhuhai Assignment Agreement, the consideration included (i) a $4.0 million cash payment to BioNTech Zhuhai; (ii) annual platform fees of $7,500 per Assigned Program to BioNTech Zhuhai; (iii) annual partner antibody fees of $50,000 per Assigned Program to Alloy, and (iv) development milestones of up to

approximately $1.8 million per Assigned Program and maximum aggregate commercial and sales milestones of up to $11.0 million per Assigned Program to Alloy.

The BioNTech Zhuhai Assignment Agreement will continue in full force until terminated. Either the Company or BioNTech Zhuhai may terminate the BioNTech Zhuhai Assignment Agreement in the event of the other party's material breach, subject to certain notice and cure periods, and BioNTech Zhuhai may also terminate in the event of the Company's bankruptcy or failure to make any due payment within a certain period.

The partner antibody fees are payable on an Assigned Program-by-Assigned Program basis for so long as the applicable Assigned Program remains active and the relevant rights have not been terminated or abandoned before the applicable anniversary date. In May 2026, BioNTech Zhuhai did not renew its license with Alloy. As a result, the Company was released from its obligation to pay the associated annual platform fee of $7,500 per Assigned Program. The remaining rights and obligations remain in full effect.

During the six months ended June 30, 2025, the Company recognized $0.5 million of research and development expense under the BioNTech Zhuhai Assignment Agreement primarily attributable to the filing of investigational new drug ("IND") applications for the Assigned Programs and paid $4.5 million for such costs and the settlement of $4.0 million in previously accrued IPR&D expense. During the six months ended June 30, 2026, there were no costs incurred or paid related to the BioNTech Zhuhai Assignment Agreement. As of June 30, 2026 and December 31, 2025, no amounts were due or accrued under the BioNTech Zhuhai Assignment Agreement. In addition, no additional contingent milestone payments were accrued as no additional development, commercial or sales milestones had occurred or were considered probable.

Research Collaboration and Option Agreement

In April 2024, the Company entered into a research collaboration and option agreement with BioNTech Zhuhai (the "BioNTech Zhuhai Option Agreement") pursuant to which the Company may nominate certain bispecific antibody target combinations, subject to mutual agreement (each a "Selected Target Combination"). BioNTech Zhuhai agreed to design, identify, generate, and develop development candidates for the Selected Target Combinations through the execution of research programs, each inclusive of one or more development candidates. Each research program follows a research plan which is approved by a Joint Steering Committee ("JSC"). The JSC is comprised of equal members representing both parties.

At the culmination of each research program, BioNTech Zhuhai determines if the related development candidate(s) meet the appropriate criteria, as established and agreed to by both parties, to become a lead development candidate ("Lead Development Candidate"). The JSC reviews and determines if a Lead Development Candidate meets the applicable criteria to be an optioned (an "Option Compound"). For any Lead Development Candidates that do not meet the applicable criteria to be an Option Compound, the Company may terminate the research program or request rework to develop an additional Lead Development Candidate. For any Lead Development Candidate that meets the applicable criteria to be an Option Compound, the Company has the exclusive option, on a research program-by-research program basis, to obtain an exclusive license (the "License Option"), with the right to grant sublicenses through multiple tiers to optimize, develop, make, use, offer for sale, sell, import, and export the Option Compound for such research program, subject to a 12-month Option Period. Within 60 days of the Company's exercise of the License Option (the "License Negotiation Period"), the parties may negotiate the terms and conditions of a definitive license agreement on an exclusive basis (a "License Agreement"). Upon the execution of a License Agreement, the Selected Target Combination and associated selected compound(s) shall each become a licensed target combination and licensed compound(s), respectively.

The BioNTech Zhuhai Option Agreement applies on a research program-by-research program basis and, unless earlier terminated, remains in effect for three years, subject to renewal. During the term of the research program, License Option Period (if applicable), and License Negotiation Period (if applicable) with respect to a given research program, BioNTech Zhuhai may not independently develop, commercialize, license, assign, transfer, or otherwise exploit products or rights directed to the applicable Selected Target Combination in the specified field and territory without prior written consent from the Company. Upon the termination of a research program or expiration of the License Option Period or License Negotiation Period, the Selected Target Combination and associated Development

Candidates for such research program shall each become an “Abandoned Target Combination” and “Abandoned Compound(s)” which may be exploited by BioNTech Zhuhai.

Under the terms of the BioNTech Zhuhai Option Agreement, the Company is required to pay BioNTech Zhuhai a research fee of $0.5 million for each research program. On a research program-by-research program basis, to the extent that the Company requests and BioNTech Zhuhai agrees to perform any additional research or development activities not set forth in the research plan, the parties shall discuss in good faith the financial considerations for such additional research or development activities. For any products containing or comprising an Abandoned Compound, Target Combination(s) and “Abandoned Compound(s)”, BioNTech Zhuhai shall pay the Company an amount of revenue sharing determined as the greater of: (i) at a rate of mid-single-digit to low teen-digit percentage of net licensing proceeds, or (ii) a fixed amount of $0.2 million, dependent on the clinical status of the product and the relative portion of the Abandoned Compound comprising the product.

As of June 30, 2026, the Company has entered into two research programs with aggregate research fees of $1.0 million. During the six months ended June 30, 2026 and 2025, the Company recorded $0.2 million and $0.4 million, respectively, in research and development expense under the BioNTech Zhuhai Option Agreement. As of June 30, 2026 and December 31, 2025, no amounts were due or accrued under the BioNTech Zhuhai Option Agreement.

License Agreement

In September 2025 and pursuant to the BioNTech Zhuhai Option Agreement, the Company entered into a definitive license agreement with BioNTech Zhuhai whereby BioNTech Zhuhai granted the Company an exclusive, worldwide, royalty-bearing license to further develop, manufacture, commercialize, or otherwise exploit certain Licensed Compounds and Licensed Products covered by patent rights and a Licensed Compound owned by BioNTech Zhuhai under the BBT003 research program directed to specified bispecific antibodies. The Company has the right to grant sublicenses, with consent from BioNTech Zhuhai in certain circumstances, under the BioNTech Zhuhai License Agreement (the “BioNTech Zhuhai License Agreement”). The term of the BioNTech Zhuhai License Agreement is from execution through the end of the applicable royalty term.

Under the terms of the BioNTech Zhuhai License Agreement, the Company paid BioNTech Zhuhai aggregate upfront fees of $1.0 million. In addition, the Company is required to pay an annual license fee of $57,500 until the first commercial sale of the first licensed product. The BioNTech Zhuhai License Agreement also provides maximum aggregate development milestone payments of $6.9 million, first commercial sale milestone payments of $57.5 million, and sales milestone payments of $217.5 million, as well as low single-digit royalties on net sales.

During the six months ended June 30, 2026, the Company incurred and paid $0.1 million in research and development expense under the BioNTech Zhuhai License Agreement for annual license fees. As of June 30, 2026 and December 31, 2025, no amounts were due or accrued under the BioNTech Zhuhai License Agreement. In addition, no contingent milestone payments were accrued as no development, first commercial sale or sales milestones had occurred or were considered probable.

Triparty Payment Agreement

In September 2025, the Company entered into a Triparty Payment Agreement with BioNTech Zhuhai and Adimab LLC (“Adimab”) under which BioNTech Zhuhai exercised its option for use of certain Adimab intellectual property for the purposes of development and commercialization of BBT003, and became obligated to pay for a sublicense under the development and commercialization license granted by Adimab to BioNTech Zhuhai with respect to such compounds.

Under the terms of the Triparty Payment Agreement, the Company paid Adimab a license fee of $0.5 million. In addition, the Company is required to pay maximum aggregate development milestone payments of $3.0 million and marketing approval milestone payments of $3.0 million, as well as low single-digit royalties on net sales.

During the six months ended June 30, 2026, the Company did not record or pay any costs under the Triparty Payment Agreement. As of June 30, 2026 and December 31, 2025, no amounts were due or accrued under the

Triparty Payment Agreement. In addition, no contingent milestone payments were accrued as no development or marketing approval milestones had occurred or were considered probable.

12. SEGMENTS

The Company manages its operations as a single operating and reportable segment that is engaged in research and development activities aimed at advancing multiple next generation, bispecific antibody programs. The Company's chief operating decision maker ("CODM") is the chief executive officer ("CEO"). The CODM manages the Company's operations on a consolidated basis. Consolidated net loss is used by the CODM to make key operating decisions, such as the determination of the program-level spending and the allocation of capital between research and development activities and general and administrative support functions. The CODM also assesses financial performance and allocates resources based on cash resources and operating expense projections.

The following table presents selected financial information with respect to the Company's single operating segment (in thousands):

	Six Months Ended June 30,	
	2026	2025
Operating expenses:		
External research and development expense - BBT001	$ 6,636	$ 3,950
External research and development expense - BBT002	5,073	3,097
External research and development expense - early programs	5,368	448
Other research and development expenses[1]	141	659
Personnel-related research and development expenses[1]	3,065	1,520
External general & administrative expenses[1]	2,017	819
Personnel-related general and administrative expenses[1]	1,108	469
Stock-based compensation expense	651	4,486
Other segment items[2]	(1,699)	(701)
Consolidated net loss	$ 22,360	$ 14,747

(1) Amounts exclude employee and non-employee stock-based compensation.
(2) Other segment items consist of interest income, research and development incentive income, change in fair value of preferred stock tranche right obligation, other income, net, and income tax provision.

The measure of segment assets is reported on the condensed consolidated balance sheets as total assets. The CODM additionally reviews cash and cash equivalents and marketable securities when reviewing segment assets. As of June 30, 2026, the Company's cash and cash equivalents and marketable securities were $71.5 million. The Company does not provide its CODM with any more detailed segment asset information than what is included on the Company's condensed consolidated balance sheets.

13. COMMITMENTS AND CONTINGENCIES

Legal matters

The Company, from time to time, may be involved with lawsuits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the consolidated balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. Legal fees and other costs associated with such proceedings are expensed as incurred. As of June 30, 2026 and December 31, 2025, the Company was not a party to any material legal proceedings or claims.

Guarantees and indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2026 and December 31, 2025.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

License and other agreements

The Company is obligated to make fixed and contingent payments under the BioNTech Zhuhai Assignment Agreement, Research Collaboration and Option Agreement, and the BioNTech Zhuhai License Agreement (see Note 11).

The Company maintains its headquarters through a membership agreement that provides access to shared office space and does not otherwise lease office or laboratory space.

14. NET LOSS PER SHARE

Basic and diluted net loss per share is calculated as follows (in thousands except share and per share amounts):

	Six Months Ended June 30, 2026	Period from February 12, 2025 to June 30, 2025
Net loss attributable to common stockholders	$ (22,360)	$ (12,989)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.56)	$ (2.30)
Weighted-average shares outstanding, basic and diluted	8,727,671	5,657,176

The computation of basic and diluted weighted-average common shares outstanding excludes unvested Founders' Shares as such shares are subject to a repurchase option and therefore not considered outstanding for accounting purposes. There was no common stock outstanding for accounting purposes until February 12, 2025 with the closing of the Series A-1 Preferred Stock and the release of the Repurchase Option for a portion of the Founders' Shares (see Note 8 for more information). As there was no common stock outstanding for accounting purposes until February 12, 2025, the Company has computed net loss attributable to common stockholders and weighted-average shares outstanding, basic and diluted, for the period from February 12, 2025 to June 30, 2025.

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect is antidilutive:

	Six Months Ended June 30, 2026	Period from February 12, 2025 to June 30, 2025
Unvested restricted common stock	2,866,703	6,123,651
Outstanding stock options	1,305,247	839,704
Series Seed Preferred Stock (as converted to common stock)	5,329,584	5,329,584
Series Seed Plus Preferred Stock (as converted to common stock)	3,740,038	3,740,038
Series A-1 Preferred Stock (as converted to common stock)	15,593,907	15,593,907
Series A-2 Preferred Stock (as converted to common stock)	2,728,032	—
Total	31,563,511	31,626,884

The amount of outstanding stock options in the table above for the six months ended June 30, 2026 and the period from February 12, 2025 to June 30, 2025 exclude 245,181 and 279,043 of potentially dilutive securities, respectively, as these outstanding stock options relate to contingently issuable shares for which the performance condition was not satisfied as of period end.

15. RELATED PARTIES

The Company issued and sold shares of its Preferred Stock to certain of the Company's management, MiNeng, and Salvia (in thousands, except shares):

	Six Months Ended June 30,			
	2026		2025	
	Shares	Total Aggregate Purchase Price	Shares	Total Aggregate Purchase Price
Series A-1 Preferred Stock	—	$ —	1,596,583	$ 9,100
Series A-2 Preferred Stock	82,490	1,000	—	—
Total	82,490	$ 1,000	1,596,583	$ 9,100

16. SUBSEQUENT EVENTS

The Company evaluated subsequent events through September 14, 2026, the date the condensed consolidated financial statements were available to be issued, and through October 26, 2026, the date the condensed consolidated financial statements were available to be reissued, for events requiring recording or disclosure in the condensed consolidated financial statements for the six months ended June 30, 2026:

Grants of VARs and Stock Options

In July 2026, the Company granted options for the purchase of an aggregate of 268,093 shares of common stock to employees at an exercise price of $8.04 per share.

In July 2026, the Company issued 18,963 VARs at a grant-date price of $8.04 per share. These VARs become payable only if a liquidity event occurs, defined as a change of control of the Company, before the expiration date and while the participant remains in continuous service (see Note 10).

In September 2026, the Company granted options for the purchase of an aggregate of 1,353,356 shares of common stock to employees at an exercise price of $13.57 per share and 39,237 VARs at a grant-date price of $13.57 per share.

Stock Split

On October 23, 2026, the Company effected a 1.54485-for-1 forward stock split of its issued and outstanding shares of common stock and preferred stock (see Note 7). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split. As the number, issuance price, and conversion price of all outstanding preferred stock were adjusted, the conversion ratios for each series of the Company's preferred stock were unchanged.

2026 Equity Incentive Plan

On October 19, 2026, the Company's Board of Directors adopted, and its stockholders approved, the 2026 Equity Incentive Plan ("2026 Plan"), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement related to the Company's IPO. The 2026 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, and other stock-based awards. The number of shares of common stock authorized and reserved for issuance under the 2026 Plan is 5,560,163 shares. In addition, the shares reserved for issuance under the 2026 Plan will include (i) shares that remained available for grant under the 2024 Plan as of the business day immediately prior to the effective date of the registration statement and (ii) shares of common stock subject to or issued pursuant to awards granted under the 2024 Plan that, on or after the effective date of the registration statement, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by us for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by the Company due to failure to vest (provided that the maximum number of shares that may be added to the 2026 Plan pursuant to (i) and (ii) is 4,208,339 shares). The number of shares of common stock reserved for issuance under the 2026 Plan will automatically increase on the first day of each fiscal year for a period of ten years, beginning with the 2027 fiscal year, in an amount equal to the lesser of: (i) 5.0% of the total number of shares of the Company's fully-diluted common stock outstanding on the last day of the immediately preceding fiscal year and (ii) such other number of shares as the administrator of the 2026 Plan may determine. No further grants will be made under the 2024 Plan.

2026 ESPP

In October 2026, the Company's Board of Directors adopted, and its stockholders approved, the 2026 Employee Stock Purchase Plan ("ESPP"), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement related to the Company's IPO. A total of 505,469 shares of common stock were initially reserved for sale under the ESPP. The ESPP provides that the number of shares reserved and available for sale will automatically increase on the first day of each fiscal year for a period of ten years, beginning with fiscal year 2027, by the lesser of (i) 1,516,407 shares of common stock, (ii) 1% of the total number of shares of the Company's fully diluted common stock (as defined in the ESPP) outstanding on the last day of the immediately preceding fiscal year, or (iii) such other number of shares as determined by the administrator of the ESPP. No offering period or purchase period under the ESPP will begin unless and until determined by the Board of Directors.

Cancellation of VARs and Issuance of Restricted Stock Units

In October 2026, the Company cancelled VARs which were payable upon a liquidity event, defined as a change in control or public listing, and granted 701,797 restricted stock units ("RSUs") which contain both a performance condition (including a public listing) and a service condition. The total RSUs eligible to vest will be calculated based on the volume-weighted average price of the Company's common stock in the 20-day trading period immediately following the effectiveness of such public listing. A significant portion of the RSUs are expected to vest following a public listing pursuant to an initial public offering with the remainder vesting over time, subject to continued service, and will result in additional compensation expense in the period the RSUs vest.

Through and including November 23, 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

10,555,555 Shares



Common Stock

BofA Securities

Evercore ISI

UBS Investment Bank

Cantor

October 29, 2026