Filed pursuant to Rule 424(b)(4)
Registration Statement No. 333-299018

Prospectus

8,333,334 Shares



Common Stock

This is TRex Bio, Inc.'s initial public offering. We are selling 8,333,334 shares of our common stock.

The initial public offering price is $14.00 per share. Our common stock has been approved for listing on The Nasdaq Global Select Market ("Nasdaq") under the symbol "TRXB."

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 reporting requirements in this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 11 of this prospectus.

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

	Per Share	Total
Initial public offering price	$ 14.00	$ 116,666,676
Underwriting discounts and commissions[(1)]	$ 0.98	$ 8,166,667
Proceeds, before expenses, to us	$ 13.02	$ 108,500,009

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

The underwriters may also exercise their option to purchase up to an additional 1,250,000 shares from us, at the initial public offering price, less underwriting discounts and commissions, for 30 days after the date of this prospectus.

The underwriters expect to deliver the shares of our common stock on or about October 13, 2026.

Eli Lilly and Company ("Lilly") has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount, when combined with shares of common stock beneficially owned by Lilly prior to the initial public offering, that will not exceed 19.9% of the number of shares of common stock issued and outstanding after this offering. Because this indication of interest is not a binding agreement or commitment to purchase, Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Lilly. The underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by Lilly as it will from any other shares of common stock sold to the public in this offering. The number of shares of common stock available for sale to the public will be reduced to the extent that Lilly purchases shares of common stock in the offering.

J.P. Morgan **Evercore ISI** **Cantor** **Stifel** **Wedbush PacGrow**

The date of this prospectus is October 8, 2026.

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Through and including the 25th day after the date of this prospectus, all dealers that effect transactions in these shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligations to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary highlights selected information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Except where the context otherwise requires or where otherwise indicated, the terms "TRexBio," "we," "us," "our," "our company," "the company" and "our business" refer to TRex Bio, Inc. and its subsidiary.

Overview

We are a clinical-stage biopharmaceutical company focused on tissue Treg biology for the discovery and development of immunoregulatory medicines designed to restore immune balance and promote tissue repair to address unmet needs of patients with autoimmune and inflammatory diseases. TRexBio was built on a pivotal scientific insight: that regulatory T cells ("Tregs") in human tissue are not merely passive suppressors of inflammation, but active orchestrators of tissue immune homeostasis and repair. Leveraging our Deep Biology drug discovery and design platform, we integrate tissue-level insights into human biology and Treg function to identify and characterize novel targets and approaches for therapeutic intervention. Our tissue-first conviction and unique insights in Treg biology are the foundation of our pipeline of therapeutic candidates aimed at restoring immune balance and promoting tissue repair for more durable disease control.

Our pipeline is focused on augmenting tissue Tregs to address critical treatment gaps in autoimmune and inflammatory diseases. Our most advanced wholly-owned product candidate, TRB-061, is an investigational tumor necrosis factor receptor 2 ("TNFR2") agonist designed to expand and activate Tregs in inflamed tissues. We believe TRB-061 has broad, multi-indication potential, and are currently conducting a Phase 1a/b clinical trial of TRB-061 in healthy volunteers and patients with moderate-to-severe atopic dermatitis ("AD"). We expect to announce topline data from the Phase 1b portion of the TRB-061 trial in patients with moderate-to-severe AD in mid-2027. Our second wholly-owned product candidate, TRB-071, is an investigational TNF receptor superfamily member 8, better known as TNFRSF8 (or "CD30") agonist designed to both augment tissue Tregs and block immune system inflammatory signaling axes. Genetic studies support the involvement of CD30 and its ligand in inflammatory bowel disease ("IBD"). TRB-071 is currently in IND-enabling studies and, subject to regulatory allowance to proceed, is expected to enter a Phase 1 trial in the first half of 2027. We believe TRB-071 has the potential to address the significant unmet need in IBD by directly targeting the immune system dysfunction in the gut barrier that drives disease pathology.

We believe each of our two lead product candidates has the potential to treat a range of autoimmune and inflammatory diseases with high unmet need, including AD, alopecia areata ("AA") and IBD. Beyond our lead product candidates, we are advancing multiple preclinical-stage programs focused on differentiated aspects of Treg biology with the goal of transforming the lives of patients affected by autoimmune and inflammatory diseases. We believe our Deep Biology platform, built on a proprietary database of healthy and diseased tissue samples, is key to achieving this goal. Our platform is designed to decode Treg functionality in human tissue, mapping key drivers of immune dysregulation and uncovering novel targets and insights that inform our drug discovery and translational efforts.

Our approach is to fundamentally rethink the approaches historically utilized in autoimmune disease drug development. Current therapies in this space rely on broad immunosuppression or focus on inhibiting one or more of the pathways that drive inflammation and often leave patients with chronic residual disease or disease progression. Many patients do not achieve lasting, durable remission, and, given these limitations, a significant number of patients remain untreated or fail to continue treatment with current therapeutic options. By moving away from systemic immunosuppression to immunoregulation, we believe Treg augmentation has the potential to represent a transformative shift in treating and maintaining durable remission of immune-mediated diseases.

Tregs are master regulators of immune tolerance and mediators of tissue regeneration. The quantitative insufficiency, functional impairment, and phenotypic instability of Tregs in inflamed tissues are increasingly recognized as critical contributors to the pathogenesis of autoimmune and chronic inflammatory diseases. By studying Tregs in human tissues at high resolution, we better understand how those regulatory pathways affect other tissue immune and stromal cells, and how the failure of Treg-mediated tissue homeostasis drives chronic, self-perpetuating inflammatory cycles. Our approach is designed to address disease at its source—in the tissue—by developing medicines focused on tissue immune homeostasis that we believe have the potential to provide a durable clinical benefit.

Our most advanced wholly-owned product candidate, TRB-061, is a fragment crystallizable-fusion, or Fc-fusion, protein designed to agonize TNFR2, selectively, without activation of proinflammatory cells. TNFR2 is a member of the TNF receptor superfamily, a family of cytokine receptors that regulate immune responses and inflammation, and is enriched on tissue Tregs, including in the skin and gut. Our platform identified TNFR2 as a key node in tissue Treg regulatory pathways. Evidence from

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our preclinical and Phase 1a clinical trial in healthy participants has shown activation and expansion of a highly active subpopulation of Tregs in the tissue following administration of TRB-061, which function to promote restoration of immune balance, forkhead box P3 ("FOXP3") epigenetic stabilization, and a tissue-reparative phenotype that we believe can address barrier dysfunction. TRB-061 is currently in Phase 1b clinical development in patients with moderate-to-severe AD, and we expect to announce topline data in mid-2027. In addition, we are exploring expanding development of TRB-061 into other autoimmune and inflammatory diseases, including AA, based on data from our platform and published evidence supporting TNFR2 agonism or Treg augmentation as a therapeutic strategy in these conditions.

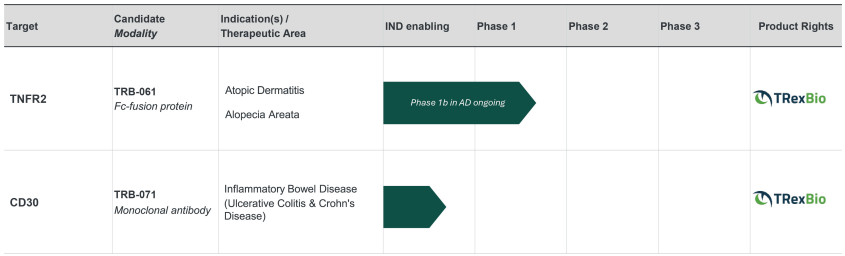
We are also developing TRB-071, an investigational monoclonal antibody designed to leverage the biology of CD30 and its associated ligand ("CD30L") by agonizing CD30 to drive Treg activation, expansion and enhanced immune-regulatory capacity, while modulating the inflammatory pathway of CD30L. CD30 is a member of the TNF superfamily highly expressed on tissue Tregs. Human genetic studies have associated variants in both CD30 and CD30L with IBD susceptibility. In *in vivo* colitis models we saw reduced inflammation following treatment with TRB-071, and in our preclinical non-human primate studies, following administration of TRB-071 we observed Treg activation and expansion. We believe this dual mechanism, activating Tregs to restore immune balance while simultaneously modulating inflammatory signaling, has the potential to address underlying immune dysregulation in immune-mediated diseases such as IBD. We are currently conducting a three-month Good Laboratory Practice ("GLP") toxicology study of TRB-071 in cynomolgus monkeys and, subject to regulatory allowance to proceed, expect to initiate a Phase 1 clinical trial in the first half of 2027.

A central principle of our approach is the ability to connect human disease biology to Treg mechanism of action. Leveraging our proprietary Deep Biology platform, we analyze gene expression, pathway activity and cellular states in disease-relevant human tissues to identify where Treg function is disrupted, whether through impaired activation, instability, altered trafficking, or loss of tissue-reparative programs. These insights inform our target selection process and our design of translational strategies to align with the underlying disease biology. By linking target biology, Treg functional programs, and disease-specific immune dysregulation, we aim to establish a coherent framework that enables rational clinical development and early demonstration of biological activity in patients. Our platform is built on three integrated pillars: (1) Deep tissue biology and computational mapping to pinpoint disease-relevant biology with speed and precision; (2) our Treg Atlas, which recreates human tissue-specific Treg states *in vitro*; and (3) our Functional Assay Cascade, that interrogates multiple dimensions of Treg biology. Together, we believe these capabilities give us unique access to immune-mediated disease pathology, targets, and insights into how to approach the validation and development of therapeutic candidates in relevant target indications.

In addition to our own pipeline of product candidates, we believe the translational power and proprietary ability to discover novel ways to augment Treg biology through our Deep Biology platform have been validated through strategic target-discovery collaborations with global pharmaceutical leaders. We have an ongoing collaboration with Lilly which is advancing a clinical product candidate first identified and developed utilizing our platform.

Our Pipeline

We are leveraging our Deep Biology platform to discover and develop product candidates for the treatment of a wide range of immune-mediated diseases. Our therapeutic product candidates are summarized in the table below:



We have an ongoing collaboration with Lilly for TRB-051, a modulator of immune effector cells, first identified and advanced under a multi-year discovery collaboration leveraging our platform. In June 2024, we announced that Lilly had initiated a Phase 1 first-in-human study for TRB-051. In June 2026, we announced that Lilly intends to move TRB-051 into a Phase 2a clinical trial in lupus with cutaneous involvement in the second half of 2026.

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TRB-061: A TNFR2 agonist

Our most advanced wholly-owned clinical-stage product candidate, TRB-061, is a novel, selective TNFR2 agonist Fc-fusion protein designed to activate and expand Tregs in inflamed tissues and restore immune balance without stimulating unwanted immune cells. We are developing TRB-061 for a variety of autoimmune and inflammatory diseases, with an initial focus on patients with AD. We initiated a Phase 1a clinical trial in healthy volunteers in June 2025. Based on the safety and biomarker data supporting proof-of-mechanism from the Phase 1a portion of this trial, the Phase 1b portion of this clinical trial in patients with moderate-to-severe AD began in April 2026, and we expect to announce topline data in mid-2027. In addition to evaluating safety and pharmacokinetics ("PK"), the Phase 1b part of this study includes pharmacodynamic ("PD") biomarkers from skin and includes exploratory clinical efficacy endpoints.

AD is a chronic, relapsing, intensely itchy inflammatory skin disease that can cause severe disruption to daily life and affects approximately 16 million American adults and an estimated 225 million individuals globally. Available treatments for AD are often limited by contraindications, side effects, and lack of efficacy, and are commonly associated with disease rebound when patients stop treatment. No approved therapies have been shown to induce durable remission independent of ongoing treatment, highlighting an unmet medical need for safer, more effective treatment options that address the underlying pathophysiology of AD.

TRB-071: A CD30 agonist

TRB-071 is an investigational agonist monoclonal antibody targeting CD30, a TNF receptor superfamily selectively enriched on a subset of tissue Tregs. TRB-071 is designed to induce expansion and increase immune-regulatory activity in Tregs and additionally block the inflammatory action of CD30L. Blocking CD30L has been shown to inhibit disease in third-party colitis models. Human genetic studies have associated variants in both CD30 and CD30L with IBD susceptibility. Together with our findings on tissue Treg biology, these data suggest that the CD30/CD30L axes contribute to both immune regulation and inflammatory responses. In our preclinical studies in non-human primates, we observed Treg activation and expansion following administration of TRB-071, and in *in vivo* colitis models we observed reduced inflammation after administration of TRB-071. We believe this dual mechanism of activating Tregs to restore immune balance while simultaneously modulating inflammatory signaling, has the potential to address underlying immune dysregulation in immune-mediated diseases such as IBD. IND-enabling activities for TRB-071 are ongoing, and, subject to regulatory allowance to proceed, we expect to initiate a Phase 1 clinical trial in the first half of 2027.

IBD, including Crohn's disease ("CD") and ulcerative colitis ("UC"), currently affects approximately 3 million Americans and is expected to affect more than 10 million patients worldwide by 2032, with its highest prevalence found in North America and Europe. Approved systemic treatments for IBD often carry safety concerns, including infections, cardiovascular events, malignancies, gastrointestinal perforations, and progressive multifocal leukoencephalopathy, among others, suggesting a meaningful gap in adequate patient care and therapeutic benefit. Development of additional therapies with novel mechanisms of action is imperative as patients often progress through existing advanced therapies. Considering the significant unmet medical need and treatment burden, we have identified IBD as an initial priority disease area for exploration.

Collaboration and Early Research and Discovery Pipeline

We are also advancing multiple preclinical-stage programs addressing differentiated aspects of tissue Treg biology informed by our proprietary Deep Biology platform. We believe the scientific depth and translational value of our platform have been independently validated by multi-year, de novo target-discovery and selection collaborations with global pharmaceutical companies. We have an ongoing collaboration with Lilly for a therapeutic candidate that we call TRB-051. TRB-051 is a modulator of immune effector cells, first identified and advanced under a multi-year discovery collaboration leveraging our platform. In June 2024, we announced that Lilly had initiated a Phase 1 first-in-human study for TRB-051. In June 2026, we announced that Lilly intends to move TRB-051 into a Phase 2a clinical trial in lupus with cutaneous involvement in the second half of 2026.

Our Team

We have assembled an experienced management team and board of directors with decades of experience in the foundational areas of immunology, Treg biology, and drug development. M. Johnston Erwin, Jr., our Chief Executive Officer, spent over 35 years at Lilly in leadership roles across regulatory, clinical, and corporate development. We are also guided by our board of directors, and scientific advisors who are key opinion leaders in Treg biology, dermatology, and gastroenterology.

TRexBio has been built with the support of a syndicate of leading healthcare investors who share our conviction in the transformative potential of tissue Treg focused immunology. We have raised approximately $220 million in aggregate equity financing to date. Our investor syndicate includes SV Health, Pfizer Ventures, Janus Henderson, Alexandria Ventures, Delos Capital, and Polaris Partners. Notably, we established pharmaceutical collaborations with each of Lilly and Janssen Pharmaceutica NV ("Janssen"), an affiliate of Johnson & Johnson Innovation—JJDC, Inc ("JJDC"). Lilly and JJDC are also

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each equity holders in TRexBio, reflecting their belief in both the scientific productivity of our Deep Biology platform and the long-term strategic value of our approach to Treg-biology-informed drug discovery. Notwithstanding the foregoing, these collaborations and equity investments should not be viewed as guarantees of future success, continued investment, or the achievement of any particular milestones or commercial outcomes. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering. See "Certain Relationships and Related Person Transactions" for more information.

Our Strategy

Our goal is to become the leading company in Treg biology for restoration of immune balance and tissue repair by developing medicines that achieve durable, disease-modifying benefit by addressing autoimmune and inflammatory disease where they occur. Our deep understanding of human tissue immune biology and our expertise in how Tregs function in health and disease in specific tissue compartments are both our scientific foundation and our competitive advantage. The key tenets of our business strategy to achieve our goal of becoming the preeminent leader in Treg biology and drug development are as follows:

- Establish clinical proof-of-concept that targeting Treg-mediated immunoregulation in the tissue can improve disease outcomes;
- Maximize the potential of TRB-061 in a broad range of chronic autoimmune and inflammatory diseases;
- Advance our preclinical pipeline of product candidates, including TRB-071, for additional autoimmune and inflammatory diseases into clinical trials;
- Grow and sustain the world's leading tissue Treg biology organization, built on the foundation of our Deep Biology platform; and
- Selectively evaluate strategic collaborations to maximize the reach and value of our technology platform in a capital efficient manner.

Risk Factors Summary

Our business is subject to a number of risks of which you should be aware before making an investment decision regarding shares of our common stock. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. Some of the most significant challenges and risks we face include the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale; we have incurred substantial losses since our inception, and we anticipate incurring substantial and increasing losses for the foreseeable future;
- Even if this offering is successful, we will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, would cause us to delay, limit, reduce or terminate our product development efforts;
- Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, imposing restrictions on our operations or require us to relinquish rights to our product candidates;
- Clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our current product candidates or any future product candidates;
- Delays or difficulties in the enrollment and dosing of patients in clinical trials delay or prevent receipt of necessary regulatory approvals;
- Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any;
- We face potential competition from different sources that have made substantial investments into the rapid development of novel treatments for autoimmune and inflammatory indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications;

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- We have identified a material weakness in our internal control over financial reporting. If we are unable to implement and maintain the effectiveness of our internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price.
- We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships;
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek;
- We are dependent on the services of our senior management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer;
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business;
- The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide commercial supply of our products, if approved, could be delayed or halted;
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely impacted;
- 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 deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates;
- The operations of our suppliers, many of which are located outside of the United States, including our current sole contract manufacturing organization ("CMO") for drug substance and drug product are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects;
- 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 public offering price, if at all; and
- The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed.

Corporate and Other Information

TRex Bio, Inc. was incorporated on May 24, 2018, as a Delaware corporation. Our business was originally conducted through TRex Bio Limited, a company incorporated under the laws of England and Wales on January 30, 2018 (initially named Cingularity Therapeutics Limited). In November 2021, we completed a corporate reorganization pursuant to which TRex Holdings Inc., a newly formed Delaware corporation, acquired all of the outstanding shares of TRex Bio Limited through a share exchange, and subsequently acquired all of TRex Bio Limited's assets and liabilities pursuant to a business transfer agreement, in order to consolidate our business and legal entity structure into the United States. On December 31, 2024, TRex Holdings Inc. merged with and into TRex Bio, Inc., its wholly-owned Delaware subsidiary, with TRex Bio, Inc. continuing as the surviving corporation; in connection with the merger, all outstanding shares of capital stock and options of TRex Holdings Inc. were converted on a one-for-one basis into corresponding shares of capital stock and options of TRex Bio, Inc. Our principal executive offices are located at 269 East Grand Avenue, Suite 300, South San Francisco, CA 94080, and our telephone number is (650) 567-5582. Our corporate website address is trex.bio. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only. You should not rely on any such information in deciding whether to purchase our common stock.

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This prospectus contains references to our trademarks and trade names, including, without limitation, "TRexBio" and our logo, which are protected under applicable intellectual property laws and are our property. This prospectus also contains trademarks, trade names, and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ®, ™ or SM symbols, but such references are not intended to indicate in any way that we or the applicable owner will not assert, to the fullest extent under applicable law, our or its 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' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other entities.

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

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.235 billion in total annual gross revenues (based on our most recently completed fiscal year), we have more than $700.0 million in market value of our common stock held by non-affiliates as of the last business day of the second fiscal quarter of such year (and we have been a public company for at least 12 months and have filed one Annual Report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

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. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. 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.

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. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

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 (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) 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. We may continue to be a smaller reporting company until the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

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The Offering

Common stock offered by us	8,333,334 shares.
Underwriters' option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 1,250,000 additional shares of our common stock.
Common stock to be outstanding immediately after this offering	27,445,682 shares (or 28,695,682 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that our net proceeds from this offering will be approximately $103.5 million (or approximately $119.8 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $14.00 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 (i) to advance the clinical development of TRB-061, including to fund Phase 2 trials for patients with AD and AA through topline data, (ii) to advance the clinical development of TRB-071, including initiating and completing a Phase 1 trial in healthy volunteers, and (iii) to use the remainder for working capital and other general corporate purposes. See the section titled "Use of Proceeds."
Indication of Interest	Lilly has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount, when combined with shares of common stock beneficially owned by Lilly prior to the initial public offering, that does not exceed 19.9% of the number of shares of common stock issued and outstanding after this offering. Because this indication of interest is not a binding agreement or commitment to purchase, Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Lilly. The number of shares of common stock available for sale to the public will be reduced to the extent that Lilly purchases shares of common stock in the offering.
Risk factors	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Directed share program	At our request, the underwriters have reserved up to 3% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers, employees and certain other individuals identified by management. The sales will be made at our direction by J.P. Morgan Securities LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of our common stock offered by this prospectus. Except for any shares acquired by our directors and officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. See the section titled "Underwriting" for additional information.
Nasdaq trading symbol	"TRXB"

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The number of shares of our common stock to be outstanding immediately after this offering is based on 19,112,348 shares of our common stock outstanding as of June 30, 2026, after giving effect to the Preferred Stock Conversion (as defined below), and excludes:

- 2,980,123 shares of our common stock issuable upon the exercise of outstanding stock options under our 2024 Equity Incentive Plan, as amended (the "2024 Plan"), as of June 30, 2026, with a weighted-average exercise price of $1.22 per share;
- 768,560 shares of common stock reserved for future issuance under the 2024 Plan as of June 30, 2026, which shares ceased to be available for issuance at the time our 2026 Equity Incentive Plan (the "2026 Plan") became effective in connection with this offering;
- 2,757,753 shares of our common stock reserved for future issuance under the 2026 Plan (which includes up to 151,188 shares of common stock underlying stock option awards granted to certain of our directors and other employees under the 2026 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share), as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder; and
- 275,775 shares of our common stock reserved for issuance under our 2026 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

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

- a 1-for-3.8649 reverse stock split of our common stock effected on October 2, 2026;
- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of June 30, 2026 into an aggregate of 17,742,217 shares of our common stock in connection with the completion of this offering (the "Preferred Stock Conversion");
- the filing and effectiveness of our fourth amended and restated certificate of incorporation (the "Restated Charter") and the adoption of our second amended and restated bylaws (the "Restated Bylaws"), in connection with the completion of this offering;
- no vesting or exercise of the outstanding stock options described above subsequent to June 30, 2026;
- no purchases of the shares of our common stock by existing stockholders or their affiliates pursuant to the directed share program; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

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SUMMARY FINANCIAL DATA

You should read the following summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus and our financial statements and the related notes included elsewhere in this prospectus. The statements of operations data for the years ended December 31, 2024 and 2025 have been derived from our audited financial statements included elsewhere in this prospectus. The summary interim statements of operations data for the six months ended June 30, 2025 and 2026, and the summary interim balance sheet data as of June 30, 2026, have been derived from our unaudited interim financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any future period, and our results for any interim period are not necessarily indicative of results that may be expected for any full year. The summary financial data in this section are not intended to replace our financial statements and the related notes included elsewhere in this prospectus and are qualified in their entirety by our financial statements and the related notes.

	For the Year Ended December 31,		For the Six Months Ended June 30,	
	2024	2025	2025	2026
Collaboration revenue	$ 39,108	$ —	$ —	$ —
Operating expenses:				
Research and development	34,989	29,809	14,966	26,030
General and administrative	6,500	8,036	4,258	4,988
Total operating expenses	41,489	37,845	19,224	31,018
Loss from operations	(2,381)	(37,845)	(19,224)	(31,018)
Interest income	2,007	3,154	1,568	1,755
Other expense, net	(70)	(69)	(66)	(3)
Total other income, net	1,937	3,085	1,502	1,752
Loss before provision for income taxes	(444)	(34,760)	(17,722)	(29,266)
Provision for income taxes	2,700	46	—	42
Net loss	(3,144)	(34,806)	(17,722)	(29,308)
Series A preferred stock dividends	(5,745)	—	—	—
Net loss attributable to common stockholders	$ (8,889)	$ (34,806)	$ (17,722)	$ (29,308)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (8.92)	$ (33.20)	$ (17.33)	$ (24.08)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted[1]	996,143	1,048,231	1,022,728	1,217,219
Comprehensive loss:				
Net loss	(3,144)	(34,806)	(17,722)	(29,308)
Unrealized gain on marketable securities	8	9	(11)	(165)
Comprehensive loss	$ (3,136)	$ (34,797)	$ (17,733)	$ (29,473)
Pro forma net loss per share, basic and diluted (unaudited)[1]		$ (1.85)		$ (1.55)
Pro forma weighted-average shares used to compute net loss per share, basic and diluted (unaudited)[1]		18,790,449		18,959,437

(1) See Note 2 to our financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our historical basic and diluted net loss per share attributable to common shareholders and the weighted-average number of shares of common stock used in the computation of these per share amounts.

	As of June 30, 2026		
(in thousands)	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 90,854	$ 90,854	$ 194,855
Working capital[3]	85,603	85,603	191,032
Total assets	96,612	96,612	198,684
Total liabilities	8,984	8,984	7,556
Redeemable convertible preferred stock	208,838	—	—
Accumulated deficit	(123,567)	(123,567)	(123,567)
Total stockholders' (deficit) equity	(121,210)	87,628	191,128

(1) The pro forma balance sheet data gives effect to (i) the Preferred Stock Conversion and the related reclassification of the carrying value of the redeemable convertible preferred stock to permanent equity immediately prior to and in connection

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with the completion of this offering and (ii) the filing and effectiveness of our Restated Charter in connection with the completion of this offering.

(2) The pro forma as adjusted balance sheet data gives effect to the (i) pro forma adjustments described in footnote (1) above, and (ii) issuance and sale of 8,333,334 shares of our common stock in this offering at an initial public offering price of $14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets, less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the 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 audited financial statements and the related notes. The risks and uncertainties set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition, results of operations, liquidity and stock price. If any of the following events occur, our business, financial condition, and operating results could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are an early-stage biotech company with a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred net losses in every year except one since our inception. We expect to continue to incur net losses in the future.

We are a clinical-stage biotechnology company with a limited operating history. Since our inception in 2018, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, conducting business planning, organizing and staffing our company, raising capital, conducting preclinical studies and, more recently, clinical trials and providing general and administrative support for these operations. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment on development or commercialization. To date, we have not yet demonstrated our ability to successfully obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each year since our inception except for the year ended December 31, 2023 during which we received a one-time upfront payment of $55.0 million from Eli Lilly and Company, and recognized total collaboration revenue of $41.9 million across our collaboration agreements. For the years ended December 31, 2024 and 2025, we had net losses of $3.1 million and $34.8 million, respectively. For the six months ended June 30, 2026, we had a net loss of $29.3 million. As of June 30, 2026, we had an accumulated deficit of $123.6 million. We expect to continue to incur significant losses for the foreseeable future and expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our wholly-owned clinical-stage product candidates, TRB-061 and TRB-071, along with any other product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our most advanced wholly-owned product candidates, TRB-061 and TRB-071;
- increase the amount of research and development activities to identify and develop product candidates to advance into clinical trial development;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and intend to commercialize on our own or jointly with third parties;
- procure the manufacturing of preclinical, clinical and commercial supply of our current or any other product candidates;
- incur additional costs associated with operating as a public company following the closing of this offering;
- establish agreements with contract research organizations ("CROs"), and contract manufacturing organizations ("CMOs"); and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies or trials, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we and any current or potential future collaborators must develop and 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, manufacturing our product candidates, either on our own or with our CMOs, obtaining regulatory approval for product candidates, marketing and selling any products for which we may obtain regulatory approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we 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. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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 may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future results of operations will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Even if this offering is successful, we will need substantial additional funding in order to maintain our operations and advance the development and commercialization of our product candidates. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, reduce or eliminate certain of our product development or research operations.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since inception. To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our Phase 1 trial of TRB-061 and continue to research, develop and initiate clinical trials of TRB-071 and our other product candidates. In addition, if we successfully develop and obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or any future commercialization efforts.

As of June 30, 2026, we had cash, cash equivalents, and marketable securities of approximately $90.9 million. Based on our current operating plan, we expect that our existing cash, cash equivalents, and marketable securities, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2029. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. We expect to attempt to raise additional cash in advance of exhausting our available capital resources.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, and we may not ever generate significant revenue or profits. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, and other expenses that we did not incur as a private company. If we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Because of the numerous risks and uncertainties, length of time and scope of activities associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements, both near and long-term, will depend on, and could increase significantly as a result of, many factors, including, but not limited to:

- the scope, timing, progress results and costs of our ongoing TRB-061 and TRB-071 clinical and preclinical studies and other research and development activities associated with the development of our other and future product candidates;
- the costs, timing and outcome of regulatory review of product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;

- the costs of establishing and maintaining arrangements with third party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the costs and timing of manufacturing for TRB-061, TRB-071, and other product candidates, including commercial manufacturing at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the cost of being a public company, including implementing operational, financial and management systems to remediate an existing material weakness;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- 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;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, current or future product candidates, if any; and
- the costs associated with operating as a public company following the completion of this offering, including legal, accounting, or other expenses in operating our business.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms or at all. Until we can generate sufficient product or other revenue to finance our cash requirements, which we may never achieve, we expect to finance our future cash requirements through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from geopolitical and economic instability, including as a result of trade policy, inflation and the wars between Russia and Ukraine and in the Middle East or other factors could also adversely impact our ability to access capital as and when needed. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

Raising additional capital may cause dilution to our stockholders and may restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect the rights of our stockholders. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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Further, we may not be able to access a portion of our existing cash due to market conditions. 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 and financial condition.

Risks Related to Product Candidate Development and Commercialization

Preclinical and clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our product candidates.

Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We face substantial risk of failure with our product candidates, and we may fail to receive regulatory approval for any of our product candidates. To obtain the requisite regulatory approvals to commercialize any product candidate, we must demonstrate to the satisfaction of applicable regulatory authorities, through extensive preclinical studies and lengthy, complex and expensive clinical trials, that a product candidate is safe, pure and potent (or effective) for its intended uses. Clinical testing often takes many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not predict results of later-stage clinical trials, and results in one indication may not predict results for the same product candidate in another target indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials raise challenges for extrapolating the results of earlier clinical trials to later clinical trials.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. The results of our clinical trials for any product candidates may not achieve statistical significance or demonstrate a favorable risk-benefit profile. Further, negative clinical trial results for a product candidate with respect to one target indication may impact the potential or perceived potential of other target indications. Moreover, preclinical and 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.

Before commencing clinical trials of a product candidate in a jurisdiction, we must submit an investigational new drug application ("IND") or foreign equivalent to the United States Food and Drug Administration ("FDA") or comparable foreign regulatory authority. We may not be able to submit INDs to the FDA or similar regulatory submissions to foreign regulatory authorities for our product candidates on the timelines we expect. Additionally, we may experience manufacturing delays or other delays with IND-enabling studies, or the FDA or other comparable regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we have had only limited interactions with the FDA, and we cannot be sure that submission of an IND or similar regulatory submissions will result in the FDA or other comparable regulatory authority allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by institutional review boards ("IRBs") or independent ethics committees, or by the FDA or other comparable regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if the FDA or other comparable regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or other similar regulatory submission, we cannot guarantee that they will not change their requirements or expectations in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to submit INDs or similar regulatory submissions on the timelines we expect or to obtain regulatory authorization or allowance for our clinical trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. A high failure rate characterizes product candidates proceeding through clinical trials, and failure may occur at all stages of the clinical trial process. Most product candidates that commence clinical trials are never approved as products, and our current or future clinical trials ultimately may fail to support the approval of our current or any other product candidates.

We expect to continue to rely, in part, on collaborators, CROs and clinical trial sites to conduct our clinical trials, including participant enrollment, and we have limited influence over their performance. We or our collaborators may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay, prevent or terminate our clinical trials, or delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- the FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies or impose additional requirements before permitting us to initiate a clinical trial;
- the FDA or comparable foreign regulatory authorities, IRBs or ethics committees may disagree with our study design, may require that we modify or amend our clinical trial protocols, or may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site; we may experience delays in

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reaching, or fail 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 investigators or clinical trial sites may deviate from trial protocols or Good Clinical Practice requirements ("GCPs") or drop out of a trial, and we may need to add new investigators or sites;
- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining IRB or ethics committee approval at each clinical trial site;
- the number of participants required for clinical trials may be larger than expected, enrollment in clinical trials may be slower than expected or participants may drop out or fail to return for post-treatment follow-up at a higher rate than expected;
- we may be required to evaluate clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- we may observe unexpectedly high placebo response rates;
- the cost of clinical trials and preclinical studies may be greater than we anticipate, or we may have insufficient funds to conduct such trial or study or to pay the substantial user fees required by the FDA upon the submission of a Biologics License Application ("BLA");
- our third-party contractors, including CROs and contract manufacturers, may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- we may be unable to obtain or be delayed in obtaining sufficient product supply of a product candidate for use in preclinical studies or clinical trials from third-party suppliers;
- our product candidates may have undesirable side effects or other unexpected characteristics that are viewed to outweigh their potential benefits;
- reports from clinical testing of other similar therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, 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 preclinical studies or we may decide to abandon product candidate development.

If we are required to conduct additional preclinical studies or 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 studies, trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by the data safety monitoring board, if any, for such clinical trial or by the FDA or other comparable regulatory authorities. Such authorities may suspend, place on clinical hold, or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other comparable regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur at any time, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to the FDA or comparable foreign regulatory authorities, or to IRBs and ethics committees for reexamination, which may impact the costs, timing, ability to proceed, or successful completion of a clinical trial.

To date we have conducted clinical trials only in Australia and New Zealand, and we have not conducted any clinical trials in the U.S. Conducting clinical trials in foreign countries, as we currently do and may do in the future, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks, including war, relevant to such foreign countries. It is also possible that the FDA or other regulatory authorities may not accept the clinical data generated in research conducted in a foreign country.

If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and regulatory approval process and jeopardize our ability to commence product sales and generate revenues.

We are substantially dependent on the success of our two most advanced wholly-owned product candidates, TRB-061 and TRB-071, and our clinical trials of such product candidates may not be successful.

Our future success is substantially dependent on our ability to timely obtain regulatory approval for, and then successfully commercialize, our two most advanced wholly-owned product candidates, TRB-061 and TRB-071. We are investing a majority of our efforts and financial resources into the research and development of these programs. We have initiated a Phase 1 clinical trial for TRB-061. The success of this program is dependent on observing adequate safety and tolerability results, in addition to early signs of clinical efficacy in AD patients. We have initiated a Good Laboratory Practice ("GLP") toxicology study for TRB-071. Our ability to advance this program into the clinic is dependent on observing adequate safety and tolerability results in our GLP studies. If we do not observe adequate safety, tolerability, or efficacy results in these studies such results would significantly and adversely affect the clinical and commercial potential of our programs.

Our programs will require additional clinical development, including further clinical, preclinical and manufacturing activities, receipt of regulatory approvals, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these programs, or any other programs, before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

The success of our programs will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we may never be able to generate revenue through the sale of these programs, even if approved. If we are not successful in commercializing TRB-061, TRB-071 or our other programs, or are significantly delayed in doing so, our business will be materially harmed.

Delays or difficulties in the enrollment and dosing of patients in our clinical trials may cause delays or prevent receipt of necessary regulatory approvals.

The timing of our clinical trials depends on our ability to recruit patients to participate in our studies as well as the dosing of such patients and completion of required follow-up periods. Participant enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the number and location of clinical sites, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, patient referral practices of physicians, challenges in obtaining and maintaining participant consents, enrolled participants dropping out, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us.

In addition, our clinical trials currently, and may in the future, compete with other clinical trials for product candidates that address the same indications as those we are pursuing for our product candidates, and this competition reduces the number and types of participants available to us, because some participants who might have opted to enroll in our trials instead opt to enroll in a trial conducted by a competitor or elect to use a marketed therapy. We also could encounter delays if doctors face ethical challenges associated with enrolling participants in a clinical trial rather than prescribing an existing treatment with an established safety and efficacy profile.

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If we or our collaborators are unable to enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate, continue or complete clinical trials for our product candidates. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment may result in increased costs, delay completion or adversely impact the outcome of the trial.

Additionally, our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including: difficulty in establishing or managing relationships with CROs and physicians; different standards for the conduct of clinical trials; different standard-of-care for patients with a particular disease; difficulty in locating qualified local consultants, physicians and partners; and potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

We have experienced participant discontinuations from our trials. Participants, including in any control groups, frequently withdraw from a clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience adverse side effects or other issues. Withdrawal of participants from our clinical trials may compromise the quality of our data.

Difficulties enrolling a sufficient number of patients to conduct our clinical trials as planned could require us to delay, limit or terminate clinical trials for our product candidates, or expand to additional jurisdictions, which could impose additional challenges on our company. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines. Failure to successfully conduct our clinical trials as planned would have an adverse effect on our business, financial condition, results of operations and prospects.

Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following regulatory approval, if any.

If our product candidates are associated with serious or significant adverse side effects in clinical trials or have adverse safety findings in non-clinical studies, we may decide or be required to halt or delay their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe, or more acceptable from a benefit-risk perspective. The FDA or other comparable foreign regulatory authority or an institutional review board or ethics committee may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the indication, if approved.

Adverse events observed in preclinical studies or clinical trials could adversely affect our future clinical trial plans. For example, there were adverse findings observed in our preclinical studies for TRB-061, including one female cynomolgus monkey being dosed intravenously at 3 mg/kg/dose in a non-GLP dose-ranging toxicology study for TRB-061 who was found dead on day 29 of that study, and a male cynomolgus monkey being dosed subcutaneously at 3 mg/kg/dose in the currently ongoing 6 month GLP chronic toxicology study for TRB-061 who required early euthanasia on day 22. Our investigation of the findings in the 6 month TRB-061 study is ongoing, and the cause of death has not been determined. However, we believe that the death in the non-GLP study of TRB-061 was likely related to generation of anti-drug antibodies ("ADA") and ADA-mediated immune complex formation. Such adverse findings in preclinical studies could result in the regulatory authorities imposing, or us proactively proposing, an exposure cap in our planned clinical trials, if otherwise allowed to proceed. Any of our current or other product candidates may be subject to new, partial or full clinical holds in the future.

We, the FDA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Many potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development and approval. Even if side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance. Adverse events or negative patient experiences may also result in negative publicity, including through social media, online forums or peer networks, which could damage our reputation and harm clinical trial enrollment and market acceptance of our product candidates, if approved.

Even if we successfully develop a product candidate and it receives regulatory approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to healthcare practitioners, restricted distribution methods, patient registries, extensive patient monitoring and other risk minimization tools that are highly controlled, restrictive, and more costly than what is typical for the

industry. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered when a significantly larger number of patients have been exposed to the product candidate. If our product candidates receive regulatory approval and we or others identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to change the way such products are distributed or administered, conduct additional clinical trials or change the labeling of the products with the potential restriction of their clinical use;
- regulatory authorities may require a REMS to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may be required to suspend marketing of a product, or we may decide to remove such products from the marketplace;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be subject to personal injury claims, actions, lawsuits and proceedings that may arise from exposure to or taking our products;
- a product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us or our collaboration partners from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

We face potential competition from different sources that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize, if approved, will compete with existing therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition, the existence of therapeutic alternatives and the availability of coverage and reimbursement from government and other third-party payors.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our current product candidates, initially under development for treatment of various autoimmune and inflammatory indications would, if approved, face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing (i) TRB-061 for the treatment of moderate-to-severe AD and AA and (ii) TRB-071 for IBD. There are a number of products and product candidates in clinical development by other companies which may become available in the future, which treat AD, AA, and IBD. See the section titled "Business—Clinical Development—Current Treatment Landscape" for additional information.

To compete successfully, we need to disrupt currently marketed drugs, meaning we must demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered or less expensive than the current standard of care or future competing products. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of development and commercialization. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. If we are not able to effectively compete for any of the foregoing reasons, our business will be materially harmed.

Changes in product candidate manufacturing, 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, 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.

Interim, top-line 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. Data from our clinical trials reported as of a measurement date may not be predictive of the effect, if any, of our product candidates at any later measurement date.

From time to time, we may publish interim, top-line or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, top-line 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. As a result, preliminary, top-line and interim data should be viewed with caution until the final data are available. Moreover, in connection with any data that is presented, caution should be exercised in drawing any conclusions from a comparison of data that does not come from head-to-head analysis. Additionally, data from a clinical trial as of any measurement date are only reflective of observations in such clinical trial at such date and should not be unduly used to predict any effect at a later measurement date.

Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data could result in volatility in the price of our common stock. Further, others, including regulatory agencies, 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 delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate and harm our business prospects. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary and interim 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, operating results, prospects or financial condition.

We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships.

Our current or future collaborations or licensing arrangements may not be successful. Additionally, we may partner with third parties with respect to the clinical development and commercialization, if approved, of certain of our programs in certain regions outside the United States, and we may not be successful in identifying, negotiating and executing partnerships. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- agreements with collaborators may not provide exclusive rights to use their 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 product candidates in the future;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our other product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable other product candidates;
- 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; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and any such approval may be for a narrower indication than we seek.

Any product candidates we or our collaborators develop are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, record keeping, reporting, labeling, storage, pricing, advertising, promotion and distribution of drugs. Failure to obtain regulatory approval for a product candidate we may develop will prevent us from commercializing the product candidate in a given jurisdiction. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that the product candidates we and our collaborators are developing will not obtain the regulatory approvals necessary for us or our collaborators to begin commercialization. Moreover, approval by the FDA does not ensure approval by any regulatory authority outside the U.S. and vice versa.

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The time required to obtain FDA and other regulatory approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us are not always applied in a predictable or uniform manner and can change over time. Any analysis we perform of data from non-clinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

If we or our collaborators complete clinical development and submit a BLA or other marketing application to the FDA or comparable foreign regulatory authority, such authorities may request additional clinical or other data or information in connection with the regulatory review of such marketing applications, including by issuing a complete response letter that may require that we or our collaborators submit additional clinical or other data or impose other conditions that must be met in order to secure approval of our or our collaborators' marketing applications, such as further inspections or reviews of manufacturing facilities. Even if such data and information are submitted, or any such inspection is completed, the FDA or foreign regulatory authority may ultimately decide that the BLA or other marketing application does not satisfy the criteria for approval.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contraindications with respect to conditions of use, or they may grant approval subject to the performance of costly post marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of any product candidates we may develop, or they may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations, and prospects.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or our interpretation of the resulting data;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective and have a positive risk-benefit profile for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may not approve our CMOs' manufacturing process or facilities;
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;

- the FDA or comparable foreign regulatory authorities may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from the U.S. or applicable foreign jurisdiction; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Regulatory approval for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Additionally, TRB-061, TRB-071 and our other product candidates may be regulated as a combination product that consists of both a therapeutic biologic and medical device for delivery such as a prefilled syringe or autoinjector. 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, adverse event 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 such as ours, 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.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings, including IND and BLA submissions. From time to time, we may publicly announce the expected timing of such milestones. The achievement of these milestones is, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates.

We may develop our current or other product candidates in combination with other therapies, which would expose us to additional risks.

We may develop our current or potential other product candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or other product candidates were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or other product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved therapies that do not ultimately obtain regulatory approval. In addition, developing combination regimens may require that we adequately demonstrate the efficacy of each therapy within the combination regimen, which may prove difficult and otherwise require us to generate more data than we would in connection with a monotherapy program.

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our product candidates on commercially reasonable terms or at all. Any failure to obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If the FDA or comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or, if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or other product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or other product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or other product candidates are unable to produce sufficient quantities for

clinical trials or for commercialization of our current or other product candidates, or, if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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.

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our clinical stage product candidate, TRB-061, for the treatment of moderate-to-severe atopic dermatitis and other 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. Additionally, negative clinical trial results with respect to one indication of a product candidate may impact the potential or perception of other indications of the product candidate. Our resource allocation decisions may result in our failure 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.

We are currently conducting, and may in the future conduct, clinical trials for current or other product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting clinical trials outside the United States, including in Australia and New Zealand, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States by the FDA, or data from clinical trials conducted outside a foreign jurisdiction by the applicable foreign regulatory authority, may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for approval in the United States, regardless of whether the applicable clinical trial was conducted pursuant to an IND, the FDA will generally not approve the application unless the data are applicable to the United States population and United States medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to GCP and the FDA is able to validate the data through an onsite inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the trial was not otherwise subject to an IND, the FDA will not accept the data as support for a submission unless the study was 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 applicable foreign authority will accept data from trials conducted outside of the United States or the applicable jurisdiction.

Even where the FDA or comparable foreign regulatory authority accepts such data, such regulatory authorities could require us to modify our planned clinical trials to receive allowance or authorization to initiate or continue such trials in the United States or the applicable foreign jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept data from trials conducted outside of the United States or the applicable jurisdiction, such non-acceptance would result in the need for additional trials that could be costly and time-consuming and could result in the product candidate not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements including with respect to data privacy and security, which may impose heightened requirements and data transfer restrictions;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- varying standards of care;
- any pandemic, epidemic or public health emergencies;
- diminished protection of intellectual property in some countries; and
- political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

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

We plan to seek regulatory approval of our current or other product candidates outside of the United States including in the European Union ("EU") and United Kingdom ("UK"). In order to market any product outside of the United States we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable jurisdictions. Regulatory approval processes vary among countries but generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval and can require additional product candidate testing and additional administrative review periods. In many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such 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 other product candidates in such foreign markets. Any such impairment would limit the commercial potential of the product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities, government health benefit programs, private health insurance and other third-party payors establish broad coverage, adequate reimbursement levels and favorable pricing of such product.

The availability of coverage and the adequacy of reimbursement by governmental healthcare authorities or programs such as Medicare and Medicaid, private health insurance and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for any approved products will affect our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. and there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. The coverage determination process is often time consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage will be obtained. Third-party payors may not provide or may limit coverage or may control utilization (e.g., by requiring that patients try other therapies first or that prescribers obtain specific approval of coverage on a patient by patient basis).

Third-party payors may deny or establish payment for any marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. We may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. More generally, we may need to offer price concessions to third-party payors to obtain favorable coverage or to purchasers to achieve sales.

Limited or no coverage or reimbursement or the offer of pricing concessions could have a negative impact on our ability to successfully commercialize any of our product candidates, if approved, and obtain a satisfactory financial return on our product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products like our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be lower than in the United States and may be insufficient to generate meaningful revenue and profits.

We may seek accelerated approval for some of our product candidates but may not be able to obtain it as the sufficiency of our clinical trial results for accelerated approval are subject to the FDA's discretion.

We may explore strategies for our product candidates that involve use of the FDA's accelerated approval pathway. Obtaining accelerated approval requires demonstration of meaningful benefit over available therapies for a serious condition. The determination of what constitutes available therapy is wholly up to the FDA and is subject to change. No assurance can be given that other therapeutics will not receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved products. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving

accelerated approval. If any of our drugs were ever to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

We may seek fast track designation, breakthrough therapy designation and/or priority review designation from the FDA or similar designations from comparable foreign regulatory authorities for one or more of our product candidates. Even if one or more of our product candidates receive these designations, we may be unable to obtain or maintain the benefits associated with such designation.

The FDA has established various designations to facilitate more rapid and efficient development and approval of certain types of drugs intended to treat serious conditions that fill an unmet medical need. Such designations include fast track designation, breakthrough therapy designation, and priority review designation. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for a designation, the FDA could decide not to grant it. If any of our programs or product candidates receive any of these designations by the FDA or similar designations by comparable foreign regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional procedures. A grant of these designations does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program.

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

Social media is increasingly being used to communicate about clinical development activities, and we intend to utilize appropriate social media in connection with our commercialization efforts of our product candidates, if approved. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing, promotion of an unapproved new drug, false or misleading advertising, or other prohibited activities and heightened scrutiny by the FDA, the Federal Trade Commission ("FTC"), the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged side effect or AE. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable AE reporting obligations or that 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 product candidates. There is also a risk of inappropriate disclosure of sensitive, personal or confidential information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding us, our management, or any of our current or other product candidates. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, suffer reputational harm or incur other harm to our business.

Risks Related to Our Business and Operations

Our business depends entirely on the success of our product candidates, and we may fail to successfully develop, receive regulatory approval for, or successfully commercialize any or all of our product candidates.

We do not have any products approved for commercial sale. We have invested substantially all of our efforts and financial resources in the development of our product candidates, each of which is still in clinical development or preclinical studies, and we expect that we will continue to invest heavily in these product candidates and any other product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to acquire, develop, obtain regulatory approval for and successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts and further investment before we can generate any revenue from product sales. We may not 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 AEs or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote any product candidate before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. 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.

We have never submitted a BLA for our product candidates to the FDA, or a similar marketing application to a comparable foreign regulatory authority, and our current or any other product candidates may not be successful in clinical trials or receive regulatory approval.

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

- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing and maintain an acceptable safety profile for the products following approval;
- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- obtain and maintain healthcare coverage and adequate reimbursement;
- achieve market acceptance of our products by patients, the medical community and third-party payors;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our product candidates through our own marketing and sales activities or any co-promotion or other arrangements that we may otherwise establish;
- manufacture product candidates through CMOs in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establish sales and marketing capabilities, whether alone or through a collaboration, to support commercialization of our product candidates;
- 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 protection and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations and guidance including interactions with healthcare professionals, patient advocacy groups and communication of healthcare economic information to payors and formularies;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and capable of timely product delivery; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Any significant delays in obtaining approval for or inability to successfully commercialize our product candidates would adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our senior management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon the members of our senior management and clinical development teams. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates, if approved. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and 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. If we are not able to attract, integrate, retain and motivate personnel necessary to accomplish our business objectives, we may experience constraints that significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

As of August 31, 2026, we had 60 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. 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 third parties to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. 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, and we may not be able to implement improvements in an efficient or timely manner or may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain regulatory approval, or provide commercial supply of our products, if approved, could be delayed or halted.

Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our CMOs must comply with legal requirements, current Good Manufacturing Practices requirements ("cGMPs") and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our CMOs may have limited experience in the manufacturing of cGMP batches of our products.

Manufacturing biopharmaceuticals is highly susceptible to drug product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. The impact of drug product loss is compounded by the long lead times needed to procure additional drug product due to plant capacity limitations or other restrictions at our CMOs. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product liability claims, or other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely affect our business. Problems in third-party manufacturing process or facilities could restrict our ability to ensure sufficient clinical material for our clinical trials or delay or prevent us from obtaining regulatory approval.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task and involves additional risks, including cost overruns, process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of sufficient quantity of raw materials. Even if we obtain regulatory approval for any of our product candidates, manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our third-party manufacturers are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be a lengthy and expensive process. If our manufacturers are unable to produce sufficient quantities of drug substance and/or drug product for clinical trials or for commercialization we will need to identify and negotiate with other CMOs an agreement for clinical and/or commercial supply, and it is not certain we will be able to come to agreement timely or on terms acceptable to us, which would likely jeopardize our ability to provide any product candidates to study subjects in clinical trials and products to patients, if approved.

Any delay or interruption in clinical trial supplies will likely delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, proximity to global regions we intend to target or other reasons. Such changes may not achieve their intended objectives, and any of these changes could cause our current or other product candidates to perform differently or affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process require us to perform *ex vivo* comparability studies and to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a clinical trial to the product used in later clinical phases or later portions of the clinical trial. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We currently have no marketing, sales or distribution capabilities, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities, nor have we commercialized a product, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue. If any of our product candidates ultimately receives regulatory approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time-consuming, or to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Furthermore, we are currently developing product candidates for multiple indications in different medical specialties, which will require us to build different sales and marketing capabilities that are tailored to a given product or medical specialty. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Revenue from our product candidates, if approved, will be limited if the product does not achieve broad market acceptance.

As a company, we have never commercialized a product candidate for any indication. Even if a product candidate is approved by the appropriate regulatory authorities for marketing and sale, it 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, efficacy, tolerability and ease of administration of our product candidates;
- the prevalence and severity of side effects and AEs associated with our product candidates, and how the safety and tolerability profile of our product candidates compares to those of existing or emerging therapies;
- the clinical indications for which the product candidates may be approved and the approved claims that we may make for such products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings that may be more restrictive than competitive products;

- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- changes in the standard of care for the targeted indications for product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third-party payors including government authorities and government healthcare programs, including Medicare and Medicaid, and private health insurance;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy 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 reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product candidates 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 be receptive to such product candidates and may be slow to adopt them as an accepted treatment. If our current or other 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.

Misconduct or other improper actions, including noncompliance with regulatory standards and requirements, by our employees, independent contractors, consultants, commercial partners and vendors exposes us to potential noncompliance with regulatory standards and requirements.

Fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, vendors and any other third parties we may engage in connection with any research, development, regulatory manufacturing, distribution or marketing activities exposes us to liability. Misconduct by these parties could result from intentional, reckless and/or negligent conduct or unauthorized activities that violate various laws, including failure to comply with FDA or other regulations, provide true, complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, as will our costs associated with compliance. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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 commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials or creation of fraudulent data in preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as delay or prevent our ability to obtain or maintain regulatory approval for our product candidates.

Additionally, a person could allege fraud or other misconduct even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling known or unknown risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Any such actions instituted against us could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal or administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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The estimates of commercial opportunities for product candidates and forecasts of market growth included in this prospectus may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

We intend to initially focus our product candidate development on treatments for various autoimmune and inflammatory indications. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts included in this prospectus are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect in general or as to their applicability to our company. Further, new studies or trials may change the estimated incidence or prevalence of these diseases.

Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our commercial opportunity may also be limited by future competitor treatments that enter the market with such patients. If any of our estimates prove to be inaccurate, the commercial opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business. 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 despite obtaining such significant market share.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our ability to realize the full commercial potential of our product candidates will be harmed. Failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights in some foreign countries;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- 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 revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Strategic transactions could impact our liquidity, increase our expenses and present significant distractions to our management.

We may enter into strategic transactions, which could include acquisitions of companies, asset purchases and in-licensing and out-licensing of intellectual property. We have entered into a research and collaboration agreement with Lilly pursuant to which Lilly is advancing TRB-051 in a clinical study for autoimmune and inflammatory diseases. The expected synergies in development programs, pipelines and other areas of focus between us and our licensors and collaborators may not be realized on a timely basis or at all, and there may be risks associated with these transactions that we did not previously anticipate, such as unanticipated liabilities.

We also may enter into a variety of other business arrangements, including strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our business, financial condition, liquidity and results of operations.

Future acquisitions may require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business or assets may be disruptive, complex, risky and costly and we may never realize the full benefits of the acquisition.

Recent and future changes to tax laws could adversely affect our company.

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 adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, the Inflation Reduction Act of 2022 (the "IRA"), and the One Big Beautiful Bill Act, introduced many significant changes to the United States 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 United States federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock.

Additionally, the U.S. government may enact other significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and further limitations on the deductibility of business interest.

We are unable to predict what changes to the tax laws of the United States and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. New, changed, modified, or newly interpreted or applied tax laws could increase our compliance, operating, and other costs. Further, these events could decrease the capital we have available to operate our business. Any of these or similar developments or changes to tax laws or rulings (which changes may apply retroactively) could adversely affect our effective tax rate and our results of operations and financial condition.

If our internal information technology systems, or those used by our CROs, CDMOs, clinical sites or other third parties, are or were compromised, become unavailable or suffer security incidents, loss or leakage of data or other disruptions, we could suffer material adverse consequences, including operational or service interruption, harm to our reputation, litigation, fines, penalties, compromise of sensitive information related to our business and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, confidential information). We also rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business (collectively, "IT systems"). We own and manage some of these IT systems but also rely on third parties for a range of IT systems and related products and services, including cloud computing services.

Our IT systems and those of our CROs, CDMOs, clinical sites and other contractors and consultants, and the confidential information within these systems, 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, cracking, application security attacks, social engineering (including through phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), credential harvesting, ransomware attacks, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods and other similar threats.

Such 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), AI-driven bots, sophisticated nation states and nation-state-supported actors. 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 confidential information, loss of income, significant extra expenses to restore IT systems or confidential information, 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, or our insurance carrier objects to payment).

Some actors, including nation-state actors, also engage in cyber-attacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely are vulnerable to a heightened risk of these attacks, including cyber-attacks, that could materially disrupt our systems and operations, supply chain, critical infrastructure, and ability to conduct our development activities, including clinical trials. Nation-state weapons may also impact us even if we are not targeted. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive information about us from public sources or other means that reveals competitively sensitive details about our organization and could be used against us.

Additionally, remote work increases risks to our IT systems and confidential information, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. We may be vulnerable to attacks as a result of vulnerabilities introduced through our supply chain, including vendors we engage to provide us with security and other technologies, or to the critical infrastructure that supports communications, transportation, and payments.

Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities present in acquired or integrated entities' systems and technologies, including security issues that are not identified during due diligence. Additionally, it may be difficult to integrate companies into our IT systems and security program.

We may not be able to detect and remediate all vulnerabilities and the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. AI-driven cyber-attackers may be able to create, find, or exploit vulnerabilities faster than our systems can respond, even if our defenses are also using AI-driven systems. Therefore, vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and technologies to operate critical business systems to process confidential information in a variety of contexts, including cloud-based infrastructure, encryption and authentication technology, employee email and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services or otherwise to operate our business. Our ability to perform diligence on or monitor third parties' information security practices is limited, and third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, insurance may not be available, or we may be unable to recover such award. If the IT systems of our CROs, CDMOs, clinical sites and other 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. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and 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 IT systems (including our services) or the third-party IT systems that support us.

A security incident or other interruption could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our confidential information or our IT systems, or those of the third parties upon whom we rely, any of which could disrupt our ability (and that of third parties upon whom we rely) to advance clinical development or commercial activities for any products, if approved. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts, significantly increase our costs to recover or reproduce the data or limit our ability to effectively execute a product recall, if required. In addition, we could incur liability if any disruption or security incident results in the loss of or damage to our confidential information or applications. Applicable data privacy and security obligations also may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. A disruption or security incident could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, damage to our reputation or a loss of confidence in us and our ability to conduct clinical trials, and/or significant incident response, system restoration or remediation and future

compliance costs, which could delay the clinical development of our product candidates. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or other product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new therapies. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval to market any product candidate, product liability claims could result in FDA or other investigation of the safety and effectiveness of our other product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, 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 or inability to enroll 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 and products that we may develop, and a decline in our stock price. We may require higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates, and our insurance 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 claims that could adversely affect our business, financial condition, results of operations and prospects.

Public opinion and scrutiny of autoimmune and inflammatory disease treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to autoimmune and inflammatory disease treatments in general could result in greater government regulation and stricter labeling requirements of products to treat autoimmune and inflammatory diseases, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. AEs in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants or impact our ability to enroll participants or lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

If earthquakes, fires, other natural disasters, terrorism and similar events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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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 may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and record keeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information, to require post-market studies or clinical trials to evaluate safety risks related to the use of a product, or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, including biologics. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMPs. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We will not have complete control over compliance with applicable rules and regulations by such manufacturers.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although physicians are generally permitted, based on their medical judgment, to prescribe products for indications other than those approved by the applicable regulatory agency, manufacturers are prohibited from promoting their products for such off-label uses. If we promote our products in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action, including issuance of a warning or untitled letter, injunction, seizure, and significant fines and criminal penalties. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters.

The failure by us or our collaborators to comply with applicable regulatory requirements in the United States or foreign jurisdictions in which we seek to market our product candidates may result in, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. The occurrence of any such event or penalty may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response, and could generate negative publicity.

Moreover, the FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies, including as a result of funding shortages or staffing limitations, could hinder their ability to hire, retain or deploy key leadership and other personnel or otherwise prevent product candidates from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and applicable foreign authorities to review and approve new product candidates 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.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed or laid off critical employees and ceased critical activities. Additionally, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with administrative agencies, including the FDA, which have led to substantial personnel changes, and it remains unclear the degree to which these efforts or the resulting changes in FDA personnel may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 set.

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act, as amended, the Health Care and Education Reconciliation Act (the "Affordable Care Act"), which, among other things, expanded health care coverage through Medicaid expansion and included a number of changes to the coverage and reimbursement of drug products under government healthcare programs.

Other health care reform initiatives, including legislative, administrative and executive actions, have taken place in the United States since the Affordable Care Act was enacted. A number of changes have focused on drug pricing and payment. For example, changes to Medicaid effective in 2024 eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers. More broadly, the IRA includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the Affordable Care Act Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs taking effect in 2026). The IRA has had and will likely continue to have significant impact on the pharmaceutical industry.

In April 2025, President Trump issued an Executive Order with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another executive order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the executive orders and related executive initiatives, a number of pharmaceutical manufacturers announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government that offers pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the One Big Beautiful Bill Act of 2025 imposed significant reductions in Medicaid funding, additional work requirements for certain Medicaid beneficiaries and more frequent eligibility redeterminations. These changes are expected to place increased pressure on state Medicaid budgets and could reduce enrollment, utilization and reimbursement levels for prescription drugs, including our products, which could adversely affect our business.

Other more general federal government actions may also affect prices or payments for prescription drugs. For example, federal legislation passed in early 2026 is intended to reform the pharmacy benefit manager industry by restricting compensation and requiring greater transparency and is anticipated to have an impact on drug pricing and market access. As another example, President Trump issued an executive order in April 2026 to establish a tariff framework for certain patented pharmaceuticals and associated pharmaceutical ingredients, with some tariffs taking effect as early as July 31, 2026. As yet another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 that remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries and bulk purchasing. These types of initiatives may result in additional reductions in healthcare funding, and may otherwise affect the prices we may obtain for our product candidates, if approved. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, hospitals and health systems 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 product pricing, which could negatively affect our business, results of operations, financial condition, and prospects.

Health care reform initiatives at the federal or state level could affect demand for, or pricing of, our current or other product candidates if approved for sale. Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Our business operations, including our interactions with healthcare professionals and other healthcare providers, third-party payors, patients and other third-parties in the healthcare industry are or may in the future be subject to a wide range of federal and state healthcare laws and regulations that may constrain our business and/or financial arrangements, including how we research, market, sell and distribute our product candidates, if approved. Restrictions under applicable federal and state healthcare laws and regulations, some of which will apply only if and when we receive regulatory approval for a product candidate, include the following:

- federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing, ordering or recommending of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal false claims, false statements and civil monetary penalties laws which prohibit, among other activities, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement material to an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements to obtain money or property from a health benefit program. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to calculate, certify, and report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires certain pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians (as defined by statute), certain non-physician healthcare 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 to the federal government for re-disclosure to the public;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers;
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to file reports relating to pricing and marketing information, and state and local laws may require registration of pharmaceutical sales representatives; and other state laws that require licensure for, or otherwise regulate, the manufacture and distribution of, pharmaceutical products.

Efforts to ensure that our business arrangements with third-parties comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including FDA and the Center for Medicare & Medicaid Services, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

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We are and in the future may be subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). We also depend on a number of third-party vendors in relation to the operation of our business, including our CROs, CDMOs and other service providers, a number of which process sensitive data on our behalf.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements, regulations, industry standards, privacy policies, contractual requirements, and other obligations governing the collection, use, disclosure, retention, and security of sensitive data, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business.

For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health 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 we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. Additionally, the California Consumer Privacy Act ("CCPA") applies to personal information of California consumers, business representatives, and employees, and among other things requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. At least 19 other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self- regulatory standards that may place additional burdens on us.

In addition, the U.S. Department of Justice "Data Security Program" regulations issued pursuant to Executive Order 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," restrict, and in some cases prohibit, data transfers involving countries of concern or covered persons, including the People's Republic of China (including Hong Kong and Macau), Russia, Iran, North Korea, Cuba and Venezuela that involve certain U.S. government-related data and bulk human'omic, geolocation, biometric, health, financial, and other sensitive personal data. The Data Security Program applies even to data that has been de-identified, anonymized or encrypted. Entities organized under the laws of the United States as well as U.S. persons are restricted in their ability to provide access to such data to such countries as well as "covered persons" that have certain nexuses to such countries, and they are also required to prohibit foreign parties from making an "onward transfer" of such data to countries of concern and covered persons. These restrictions may inhibit or preclude our ability to fully realize the value of such data, to use such data effectively or efficiently, or to engage in some data transactions that would otherwise be available to entities not subject to the Data Security Program. Compliance with the Data Security Program may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Non-compliance with the Data Security Program could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

There are also various laws and regulations in other jurisdictions outside the United States relating to data privacy and security, with which we may need to comply. For example, the EU GDPR and the UK's equivalent ("UK GDPR" and collectively, "GDPR"), impose strict requirements for processing personal data. Notably, the EU GDPR and UK GDPR impose large penalties for noncompliance, including the potential for fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or 4% of the annual global revenue of the noncompliant entity, whichever is greater. The EU GDPR and UK GDPR also provide for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Additionally, EU member states and other jurisdictions may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of special categories of personal data, including personal data related to health, biometric data used for unique

identification purposes and genetic information, which could limit our ability to collect, use and share data from the EU and other jurisdictions, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to countries whose privacy laws it believes are inadequate. Case law from the Court of Justice of the European Union ("CJEU"), however, states that reliance on the standard contractual clauses-a standard form of contract approved by the European Commission as an adequate personal information transfer mechanism-alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. In October 2022, President Biden signed an Executive Order that introduced new mechanisms and safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework (and corresponding UK data protection framework, collectively the "DPF"), as released on December 13, 2022. The European Commission adoption of its Adequacy Decision means the DPF is effective as an EU GDPR transfer mechanism to U.S. entities self-certified under the DPF. While we have certified as a participant in the DPF, we cannot guarantee that the validity of the DPF will not undergo further legal challenge as occurred with previous transfer mechanisms like the EU/US Privacy Shield.

Other jurisdictions may adopt similarly stringent interpretations of their 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 UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses and the recently approved DPF, 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. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too 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 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 UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of sensitive data, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs or CDMOs, or another third party, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The implementation of the CCPA, GDPR and other similar laws have increased our responsibility and liability in relation to sensitive data that we process and we may in the future be required to put in place additional mechanisms to ensure compliance with these and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any actual or perceived failure by us or our third-party service providers to comply with any federal, state or foreign laws, rules, regulations, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of sensitive data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process sensitive data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our CROs, CDMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants' and employees' sensitive data for which we are responsible may breach contractual obligations imposed by us, or they may experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. Our contractual measures and our own privacy and security-related safeguards may not protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and by our customers. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

Our contracts may not contain limitations of liability, and even where they do, the limitations of liability in our contracts may not be sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Further, the successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

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International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate and currently have no plans to establish any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States. We also rely on specialized laboratory equipment, supplies and materials, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs could result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs could increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating entirely domestically or in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, results of operations and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this prospectus.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely and intend to continue to rely on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current and other product candidates. Because of this reliance, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than if we conduct them ourselves. Third parties are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties have contractual relationships with other entities, some of which may be our competitors, which may divert time and resources from our programs.

Our reliance on third parties reduces our control over our development 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. For example, we remain responsible for ensuring that certain of our preclinical studies are 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 GCP 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 GCP 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. 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 privacy and security laws.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If our third party contractors do not successfully carry out their contractual duties, meet 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, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, 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.

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 contractors involves cost, takes time and diverts management's attention. In addition, there is a natural transition period when a new third party commences work. Delays 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. We may be required to report some of these relationships to the FDA, and the FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affects 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 currently rely and expect to rely in the future on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if the third-party manufacturers encounter difficulties in production.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing and must currently rely on CMOs to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have sole source relationships for our supply of TRB-061 and TRB-071. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole suppliers, it could have a negative effect on the clinical development of our product

candidates and other operations while we work to qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our programs, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of programs or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our programs or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our programs at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our programs by the FDA, result in higher costs or adversely impact commercialization of our product candidates.

We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.

We are currently party to license and collaboration agreements, and we expect to enter into similar strategic transactions in the future. Our current or any future collaborators may act in a manner that is adverse to our best interests and our interests may conflict with theirs, including concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. Any disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights related to our product candidates, or data from third parties, we could lose such rights that are important to our business.

Our licensors may have relied upon, and any future licensors may rely upon, third-party companies, 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-license. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize our current or other product candidates that are or may be the subject of such licensed rights could be adversely affected. Further development and commercialization of our product candidates and development of any other product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our current or other product candidates.

In spite of our efforts, our licensors or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing 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 and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, 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 increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect 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 licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

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.

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

- geopolitical tensions, 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 and safety standards, information and data transfer, 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 comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trade secret protection, in some countries;
- disruptions in operations due to global, regional, or local epidemics, pandemics and other 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 and inhibit our suppliers' ability to procure certain materials, any of which could delay our clinical trials or otherwise harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or any other product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely impacted.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing and licensing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued. Issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, and the patents issued may be infringed, designed around, invalidated by third parties, or may not effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. 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. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. 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, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to obtain patents and to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued which protect our product candidates, effectively prevent others from commercializing our product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and we may not be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind 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 cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were 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. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

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The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. 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. For example, our or our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review proceedings, oppositions, derivations, reexaminations, interferences, *inter partes* review proceedings or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. In some cases, such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, 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. The degree of future protection for our proprietary rights 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. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We may not obtain or maintain necessary rights to our product candidates through acquisitions and in-licenses.

The growth of our business depends in part on our ability to acquire, in-license, or use third-party proprietary rights, and we may not be able to do so on commercially reasonable terms or at all. Licenses 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 established companies may have a competitive advantage over us due to their size, capital resources or 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 also 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 adversely affect our business, financial condition, results of operations, and prospects.

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 patents and patent applications relating to our product candidates are controlled by our licensors or collaboration partners. If any of our current or future licensors or collaboration partners fails 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 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 patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Patent rights relating to inventions described and claimed in our or our licensors' pending patent applications may not issue and patents based on our or our licensors' patent applications could be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and we, our licensors, or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. We and our licensors have several pending U.S. and foreign patent applications in our portfolio. We cannot predict:

- if and when patents may issue based on our and our licensors' patent applications;
- the scope of protection of any patent issuing based on our and our licensors' patent applications;
- whether the claims of any patent issuing based on our and our licensors' patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our and our licensors' patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our and our licensors' patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our and our licensors' patent rights which will be costly whether we win or lose;
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates due to global pandemics and epidemics.

The claims in our or our licensors' pending patent applications directed to our product candidates may not be considered patentable by the USPTO or by patent offices in foreign countries, and any such patent applications may not issue as granted patents. One aspect of the determination of patentability of our and our licensors' inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or our licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or our licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, there may be prior art not considered by the patent office that is raised by a third party to challenge the validity of any patents that issue from our or our licensors' patent applications. Furthermore, even if they are unchallenged, patents in our and our licensors' portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our research programs and product candidates 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 licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or our licensors' 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 and our licensors have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many 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 and our licensors' patents or marketing of competing products in violation of our proprietary rights.

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Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or our licensors are forced to grant a license to third parties with respect to any 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. 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.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

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

The degree of 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 make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or the patents or patent applications that we license;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications 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 noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive 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 cannot predict the scope of protection of any patent issuing based on our and our licensors' patent applications, including whether the patent applications that we own, presently in-license, or, in the future, in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- 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;
- 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;

- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

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

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners may file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our or our licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or our licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our 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 patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or our licensors' patents could limit our ability to assert our or our licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, business, financial condition, results of operations or prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in- license needed technologies or other product candidates or enter into development partnerships that would help us bring our product candidates to market.

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We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or other product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our current or other product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the valid intellectual property and other proprietary rights of third parties. Identifying third-party patent rights that may be relevant to our operations 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. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting 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 which could adversely affect the market price of our common stock and harm our reputation. 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 adequately conduct such litigation or proceedings. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot be certain that our product candidates will not infringe existing or future valid patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of their merit. We may decide in the future to seek a license to such third-party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As this burden is a high one, a court of competent jurisdiction may not invalidate the claims of any such United States patent or find that our product candidates do not infringe any such claims. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non-infringing manner, which may not be commercially feasible. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a

license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* reexamination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office ("EPO"), or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates. Further, third-party patents or other intellectual property rights may be enforced against our current technology, including our research programs, product candidates, and their respective methods of use, manufacture and formulations thereof, which could result 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.

Changes in patent law in the United States and other jurisdictions 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, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology, products and enforce our intellectual property rights. We cannot assure you that subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted.

Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways, particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our or our licensors' or collaborators' existing patents and patents that we might obtain in the future.

We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Union Patent Package (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. 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 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 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 do not meet all of the formalities and requirements for opt-out under the UPC, said 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 European patents and allow for the possibility of a competitor to obtain a pan-European injunction in UPC member states. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and any other 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 may become subject to claims challenging the inventorship or ownership of our or our licensors' patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail to defend 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, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, 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 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 and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we 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. Such claims could adversely affect our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on products or 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 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 products or product candidates are obtained, 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 products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours. For example, the patents covering TRB-061 and TRB-071's composition of matter expire in September 2044 and June 2046, respectively, excluding any extension of patent term that may be available.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, 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. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension ("PTE") under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), which permit a PTE of up to five years as compensation for 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, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted any extensions for which we apply 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. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or 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 business, financial condition, results of operations and prospects could be materially harmed.

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

Regulatory authorities in some jurisdictions, including the U.S. and Europe, allow for abbreviated approval processes for generic and/or biosimilar products. In the United States, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted as part of the ACA, 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 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 using that company's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product, 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 adverse effect on the future commercial prospects for our biological products.

We believe that any of the 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. For example, in recent years, the FDA has sought to reduce the data required for biosimilar product sponsors to demonstrate biosimilarity to, or interchangeability with, a biologic reference product.

The approval of a biosimilar of our 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 product candidates, our 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 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 product candidates it could adversely affect our business, financial condition, results of operations and prospects.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other confidential proprietary information could be disclosed or competitors could otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. 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 trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate 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 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.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. 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 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

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We may be subject to claims asserting that our employees, consultants, advisors or other third parties have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants, advisors or other third parties have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. 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. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, former employees, consultants, advisors or other third parties may assert an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims 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 therapeutics, without payment to us, or could limit the duration of the patent protection covering our product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or other product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

Rights to improvements to our product candidates may be held by third parties.

In the course of testing our current or other product candidates, we have entered and may enter into agreements with third parties to conduct clinical testing, which do and may provide that improvements to our product candidates may be owned solely by a third party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby potentially giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our current or other product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against other parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our intellectual property licensed from third parties may be subject to retained rights.

Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

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Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. Co-developed intellectual property may be subject to government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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 public offering price, if at all.

Prior to this offering, no market for shares of our common stock existed. Our common stock has been approved for listing on Nasdaq under the symbol "TRXB". After the consummation of this offering, an active or liquid trading market for our common stock may never develop or be sustained following the completion 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. Moreover, the initial public offering price for our common stock was determined through negotiations with the underwriters, and will vary from the market price of our common stock following the completion of 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 or at a price that you consider reasonable. Furthermore, an inactive market may reduce the fair market value of your shares, 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.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- volatility in our operating results or the failure of our operating results to meet the expectations of investors or securities analysts;
- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical and clinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- our failure to commercialize our product candidates;
- the success of the development of companion diagnostics, if required, for use with our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;

- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales or perceived potential sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- any changes to our relationship with manufacturers, suppliers, collaborators or other strategic partners;
- manufacturing or supply shortages;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- press reports, whether or not true, about our business;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- changes in the structure of healthcare payment systems;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the inability to obtain additional funding;
- market conditions in the pharmaceutical and biotechnology sectors;
- general global economic, industry, political and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control; and
- the other factors described in this "Risk Factors" section and elsewhere in this prospectus, including those which are outside of our control.

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 the completion of this offering. The market price of our common stock may decline below the initial public offering price, and you may lose some or all of your investment. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future.

You will incur immediate and substantial dilution as a result of the completion of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $7.04 per share, representing the difference between the initial public offering price of $14.00 per share, and our pro forma net tangible book value per share as of June 30, 2026 after giving effect to the completion of this offering. To the extent that shares are issued upon the exercise of options or the underwriters exercise their over-allotment option, you will incur further dilution. For a further description of the dilution you will experience immediately after the completion of this offering, see the section titled "Dilution."

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 could occur at any time. These sales upon the expiration of the lock-up agreements (described in the "Underwriting" section of this prospectus), the early release of the lock-ups, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After the completion of this offering, we will have 27,445,682 shares of common stock outstanding, or 28,695,682 shares if the underwriters exercise their over-allotment option in full, in each case

based on the shares of our common stock outstanding as of June 30, 2026. Of these shares, the 8,333,334 shares (or 9,583,334 shares if the underwriters exercise their over-allotment option in full) we are selling in this offering may be resold in the public market immediately, unless purchased by certain of our affiliates. The remaining shares are currently restricted under securities laws or as a result of lock-up or other agreements but will be able to be sold after the completion of this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time in their sole discretion and without notice, except for directors and officers, which would allow for earlier sales of shares in the public market.

In addition, Lilly has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount, when combined with shares of common stock beneficially owned by Lilly prior to the initial public offering, that does not exceed 19.9% of the number of shares of common stock issued and outstanding after this offering. The shares of common stock to be purchased by Lilly will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Lilly.

If Lilly is allocated all or a portion of the shares it has indicated an interest in purchasing in this offering or more, and purchases any such shares, such purchases could reduce the available public float for our shares of common stock if Lilly holds such shares long-term.

Moreover, after the completion of this offering, holders of an aggregate of 17,541,654 shares of our common stock will have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also plan to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders will continue to have substantial influence over us after the completion of this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.

After the completion of this offering, our directors, executive officers and greater than 5% stockholders and their affiliates, in the aggregate, will beneficially own shares representing approximately 58.5% of our outstanding common stock (assuming no exercise of the underwriters' over-allotment option, no exercise of outstanding options, and excluding any purchases that may be made in this offering). As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock in the foreseeable future. See the section titled "Dividend Policy" for additional information.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling 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 shares of common stock purchased in this offering. While certain of our existing stockholders and their affiliated entities have expressed interest in potentially participating in this offering, they may not participate in the offering to a material extent, or at all.

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We are an emerging growth company ("EGC") and a smaller reporting company, and the reduced reporting requirements applicable to EGCs 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 and we may remain an emerging growth company until December 31, 2031. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, 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. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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 stock 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. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, (as amended, the "Exchange Act"). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. 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.

Provisions in our Restated Charter, our Restated Bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our Restated Charter and Restated Bylaws, which will become effective prior to the completion of this offering, and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our Restated Charter and Restated Bylaws, which will become effective prior to the completion of this offering, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- do not permit stockholders to cumulate votes at any election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our Restated Bylaws; and
- require super-majority votes of all holders of our common stock to amend provisions of our Restated Charter and Restated Bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware ("DGCL") which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our Restated Charter, Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control 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 Restated Charter will designate specific courts as the sole and exclusive forum for certain claims or causes of action that may be brought by our stockholders, which could discourage lawsuits against us and our directors and officers.

Our Restated Charter will provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if, and only if, the Court of Chancery of the State of Delaware dismisses a Covered Claim (as defined below) for lack of subject matter jurisdiction, any other state or federal court in the State of Delaware that does have subject matter jurisdiction) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the following types of claims: (i) any derivative claim brought in the right of the Company, (ii) any claim asserting a breach of a fiduciary duty to the Company or the Company's stockholders owed by any current or former director, officer or other employee or stockholder of the Company, (iii) any claim against the Company arising pursuant to any provision of the DGCL, our Restated Charter or Restated Bylaws, (iv) any claim to interpret, apply, enforce or determine the validity of our Restated Charter or Restated Bylaws, (v) any claim against the Company governed by the internal affairs doctrine, and (vi) any other claim, not subject to exclusive federal jurisdiction and not asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"), brought in any action asserting one or more of the claims specified in clauses (a)(i) through (v) herein above (each a "Covered Claim"). This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our Restated Charter will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Restated Charter will provide that any person or entity purchasing or otherwise acquiring any interest in the shares of capital stock of the Company will be deemed to have notice of and consented to these choice-of-forum provisions and waived any argument relating to the inconvenience of the forums in connection with any Covered Claim.

The choice of forum provisions to be contained in our Restated Charter may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions to be contained in our Restated Charter are inapplicable or unenforceable if they are challenged in a proceeding or otherwise, which could cause us to incur additional costs associated with resolving such action in other jurisdictions. The choice of forum provisions may also impose additional litigation costs on stockholders who assert that the provisions are not enforceable or invalid.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the "Use of Proceeds" section of this prospectus. Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, fluctuating inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, tariffs and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict and conflict in the Middle East). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute 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. Further deterioration in economic or market conditions may occur, and challenges may persist for an unknown period of time. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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 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, 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.

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

After the completion of this offering, as a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, 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 impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often 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.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

We are not currently required to comply with the rules of the SEC implementing SOX Section 404 and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be

required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

As a private company, we do not currently have any internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business.

We have identified a material weakness in our internal control over financial reporting. If we are unable to implement and maintain the effectiveness of our internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price.

We identified a material weakness in our internal control over financial reporting. 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. The material weakness is related to the lack of sufficient internal technical accounting resources, which resulted in an overreliance on external advisors for complex accounting matters without maintaining adequate internal controls to review, validate, and document the resulting accounting positions and disclosures.

We are in the process of remediating this material weakness by hiring additional accounting and finance personnel with technical accounting and SEC reporting experience, enhancing our use of external specialists where appropriate, implementing improved review procedures and documentation requirements, and providing training to existing personnel. We cannot assure you that these measures will remediate the material weakness in a timely manner or that additional material weaknesses will not be identified in the future. The material weakness will not be considered remediated until management completes the design and implementation of the controls and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures we will take may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not remediate the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected.

Our management will not be required to evaluate the effectiveness of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act until our second annual report on Form 10-K after the effectiveness of the registration statement of which this prospectus forms a part. As part of that evaluation, we may identify additional control deficiencies that are determined to constitute one or more material weaknesses. In addition, there can be no assurance that our remediation efforts will be successful, that our internal control over financial reporting will be effective as a result of these efforts, or that any future control deficiencies identified may not be material weaknesses that would be required to be reported in future periods.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if 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 stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design 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 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 realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related person transaction disclosures. 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.

We may not be able to satisfy listing requirements of Nasdaq or obtain or maintain a listing of our common stock on Nasdaq.

If, after listing, we fail to satisfy Nasdaq's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely 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, there may not be any action we can take to restore compliance with listing requirements that would allow our common stock to become listed again on the Nasdaq or any other securities exchange, 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 Nasdaq's listing requirements.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. Some of the policies we currently maintain include general liability, crime insurance, products liability, workers' compensation, cyber, directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Changes in the market conditions and our business operations may necessitate the addition of new insurance policies or change of our existing insurance policies. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We also expect that operating as a U.S. public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

We could be subject to securities class action litigation or other litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the trading price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

From time to time we may also be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources.

We could be subject to changes in tax rates, the adoption of new tax legislation or could otherwise have exposure to additional tax liabilities, which could harm our business.

As discussed above, changes to tax laws or regulations, or to the interpretation of such laws or regulations, in the jurisdictions in which we operate could significantly increase our effective tax rate and materially affect our financial condition. In addition, other factors or events, including business combinations and investments, changes in our stock-based compensation, changes in the valuation of our deferred tax assets and liabilities, adjustments to our taxes upon finalization of any of our various tax returns or as a result of deficiencies asserted by taxing authorities against us, increases in any of our expenses that are not deductible for tax purposes, changes in our available tax credits, and changes in the apportionment of our income and our activities among tax jurisdictions, could also increase our effective tax rate. Our tax filings are subject to review or audit by the U.S. Internal Revenue Service (the "IRS"), and state, local and foreign taxing authorities. We may also be liable for taxes in connection with businesses we acquire. Our determinations in respect of our tax liabilities are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in our tax provisions, accruals and returns. An assessment of additional taxes because of an audit or other proceeding could harm our business.

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Our ability to use certain net operating loss ("NOL") carryforwards and certain other tax attributes may be limited.

As of December 31, 2025, we had federal NOL carryforwards of approximately $96.1 million. Federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely but are permitted to be used in any taxable year to offset only up to 80% of taxable income in such taxable year, if any. It is uncertain if and to what extent various states will conform to federal law.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code") if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. In general, an "ownership change" occurs if there is a cumulative change in ownership of the corporation by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. We have completed an analysis of Section 382 ownership changes in our stock through December 31, 2024 and have concluded that, as of December 31, 2024, we have experienced ownership changes that will result in limitations in our ability to use certain of our NOL carryforwards and other tax attributes. We may also experience an ownership change upon future issuances of our stock or due to secondary trading of our stock which may be outside of our control. If we were to undergo an additional ownership change in the future, further limitations could be imposed on our ability to utilize our NOL carryforwards and other tax attributes. Any of these ownership changes and their resulting limitations on our ability to use NOL carryforwards and other tax attributes could adversely impact our business, financial condition, results of operations and cash flows.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position and financial condition, business strategy and plans, expected market growth, our plans and objectives for future operations and commercialization, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, and future results of anticipated products and prospects, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that 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.

The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "could," "target," "predict," "seek," "consider," "contemplate," "plan," "potential," "project," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the commercial opportunities stemming from the development of our product candidates for multiple autoimmune and inflammatory diseases;
- our ability to develop and, if approved, ultimately commercialize our product candidates and other future programs;
- the initiation, timing, progress, results, and cost of our development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of our clinical trials, and the period during which the results of the trials will become available;
- the success, cost and timing of our clinical development of our product candidates;
- our ability to establish clinical differentiation of our product candidates;
- our ability to develop product candidates that have broad therapeutic potential;
- our ability to utilize our business development strategy and expertise to build a balanced portfolio;
- our ability to build our operational and commercial capabilities for supplying and marketing our products, if approved, in key markets;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- the trading volume of our common stock;
- our ability to obtain additional funding;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our reliance on third parties to manufacture drug substance for use in our clinical trials;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our expected uses of the net proceeds to us from this offering and our existing cash and the sufficiency of our existing cash and proceeds from this offering to fund our future operating expenses and capital expenditure requirements;
- our ability to identify collaborations and strategic partnerships to maximize the value of our portfolio;

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- the potential benefits of strategic collaboration agreements;
- our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to remediate a material weakness in our internal control of financial reporting;
- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- our expectations regarding the time during which we will be an emerging growth company and smaller reporting company under the JOBS Act;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;
- our financial performance;
- developments and projections relating to our competitors or our industry; and
- other risks and uncertainties, including those included in the section titled “Risk Factors.”

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate, future events and financial trends that we believe may affect our business, financial condition, results of operations and prospects. These forward-looking statements are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements included in this prospectus are made only as of the date of this prospectus. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

In addition, statements that “we believe” and similar expressions 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.

You should read this prospectus with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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MARKET AND INDUSTRY DATA

The market data and certain other statistical information used throughout this prospectus, including potential market opportunities, are based on our management's estimates and research, independent industry publications, government publications, industry reports and other published sources. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates and information. 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. 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. You are cautioned not to give undue weight to any such estimates and information.

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USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $103.5 million, or approximately $119.8 million if the underwriters exercise their option to purchase additional shares in full, based on an initial public offering price of $14.00 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, as follows:

- approximately $90.0 million to advance the clinical development of TRB-061, including to fund Phase 2 trials for patients with AD and AA through topline data;
- approximately $10.0 million to advance the clinical development of TRB-071, including initiating and completing Phase 1 trial in healthy volunteers; and
- the remainder for working capital and other general corporate purposes.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2029.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. We cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business, and we may find it necessary or advisable to use the net proceeds for other purposes.

Pending the uses described above, we plan to invest the net proceeds from this offering in a variety of capital preservation investments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit, or direct or guaranteed obligations of the United States government.

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DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects, and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

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CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2026:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the Preferred Stock Conversion and the related reclassification of the carrying value of the redeemable convertible preferred stock to permanent equity immediately prior to and in connection with the completion of this offering and (ii) the filing and effectiveness of our Restated Charter in connection with the completion of this offering; and
- on a pro forma as adjusted basis giving effect to: (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 8,333,334 shares of our common stock in this offering at the initial public offering price of $14.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with the financial statements and related notes as appearing at the end of this prospectus and the information set forth under the sections titled "Summary Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of June 30, 2026		
(in thousands, except share and per share amounts)	**Actual**	**Pro Forma**	**Pro Forma As Adjusted**
Cash, cash equivalents and marketable securities	$ 90,854	$ 90,854	$ 194,855
Series A-1 redeemable convertible preferred stock, par value $0.0001 per share; 5,000,000 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	6,530	—	—
Series A-2 redeemable convertible preferred stock, par value $0.0001 per share; 7,700,000 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	25,181	—	—
Series A-3 redeemable convertible preferred stock, par value $0.0001 per share; 12,482,976 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	43,730	—	—
Series B redeemable convertible preferred stock, par value $0.0001 per share; 43,388,910 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	133,397	—	—
Stockholders' (deficit) equity:			
Preferred stock, par value $0.0001 per share; no shares authorized, issued or outstanding, actual; 25,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, par value $0.0001 per share; 89,000,000 shares authorized, 1,370,131 shares issued and outstanding, actual; 225,000,000 shares authorized, pro forma and pro forma as adjusted; 19,112,348 shares issued and outstanding, pro forma; 27,445,682 shares issued and outstanding, pro forma as adjusted	—	2	3
Additional paid-in capital	2,505	211,341	314,840
Accumulated other comprehensive income	(148)	(148)	(148)
Accumulated deficit	(123,567)	(123,567)	(123,567)
Total stockholders' (deficit) equity	(121,210)	87,628	191,128
Total capitalization	$ 87,628	$ 87,628	$ 191,128

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization as of June 30, 2026 would be $211.1 million, $331.1 million, $207.4 million and $207.4 million, respectively.

The information in the table above excludes:

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- 2,980,123 shares of our common stock issuable upon the exercise of outstanding stock options under the 2024 Plan, as of June 30, 2026, with a weighted-average exercise price of $1.22 per share;
- 768,560 shares of common stock reserved for future issuance under the 2024 Plan as of June 30, 2026, which shares ceased to be available for issuance at the time our 2026 Plan became effective in connection with this offering;
- 2,757,753 shares of our common stock reserved for future issuance under the 2026 Plan, which became effective in connection with this offering, (which includes up to 151,188 shares of common stock underlying stock option awards granted to certain of our directors and other employees under the 2026 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share), as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder; and
- 275,775 shares of our common stock reserved for issuance under the ESPP, which became effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately 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 after this offering.

Our historical net tangible book value (deficit) as of June 30, 2026 was $(123.1) million, or $(89.87) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our redeemable convertible preferred stock, which is not included within stockholders' deficit. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 1,370,131 shares of common stock outstanding as of June 30, 2026.

Our pro forma net tangible book value as of June 30, 2026 was $85.7 million, or $4.48 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our liabilities, after giving effect to (i) the Preferred Stock Conversion and the related reclassification of the carrying value of the redeemable convertible preferred stock to permanent equity immediately prior to and in connection with the completion of this offering and (ii) the filing and effectiveness of our Restated Charter in connection with the completion of this offering.

After giving further effect to our issuance and sale of 8,333,334 shares of common stock in this offering at the initial public offering price of $14.00 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 $191.1 million, or $6.96 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $2.48 per share to existing stockholders and an immediate dilution of $7.04 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. 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:

Initial public offering price per share		$	14.00
Historical net tangible book value (deficit) per share as of June 30, 2026	$ (89.87)		
Increase attributable to pro forma adjustments described above	94.35		
Pro forma net tangible book value per share as of June 30, 2026	4.48		
Increase in pro forma net tangible book value per share attributable to new investors purchasing common stock in this offering	2.48		
Pro forma as adjusted net tangible book value per share after this offering			6.96
Dilution per share to new investors purchasing common stock in this offering		$	7.04

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after the offering would be approximately $7.23, representing an immediate increase in pro forma as adjusted net tangible book value per share of approximately $0.27 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of approximately $6.77 to new investors purchasing common stock in this offering, based on the initial public offering price of $14.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of June 30, 2026, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration and the weighted-average price per share (1) paid by existing stockholders and (2) to be paid by new investors purchasing common stock in this offering at the initial public offering price of $14.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

(in thousands, except share, per share amounts and percentages)	Shares Purchased		Total Consideration			Weighted Average Price Per Share
	Number	Percent		Amount	Percent	
Existing stockholders[1]	19,112,348	70 %	$	160,898	58 %	$ 8.42
New investors	8,333,334	30%		116,667	42%	14.00
Total	27,445,682	100 %	$	277,565	100 %	$ 10.11

(1) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make in this offering.

The table above assumes no exercise of the underwriters' option to purchase additional shares from us. If the underwriters exercise their option to purchase additional shares in full, the number of shares of common stock held by existing stockholders would be reduced to 66.6% of the total number of shares of common stock to be outstanding upon completion of this offering,

and the number of shares of common stock held by new investors purchasing common stock in this offering will be increased to 33.4% of the total number of shares of our common stock to be outstanding upon completion of the offering.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares and excludes:

- 2,980,123 shares of our common stock issuable upon the exercise of outstanding stock options under the 2024 Plan, as of June 30, 2026, with a weighted-average exercise price of $1.22 per share;
- 768,560 shares of common stock reserved for future issuance under the 2024 Plan as of June 30, 2026, which shares ceased to be available for issuance at the time our 2026 Plan became effective in connection with this offering;
- 2,757,753 shares of our common stock reserved for future issuance under the 2026 Plan, which became effective in connection with this offering, (which includes up to 151,188 shares of common stock underlying stock option awards granted to certain of our directors and other employees under the 2026 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share), as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder; and
- 275,775 shares of our common stock reserved for issuance under the ESPP, which became effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

To the extent that stock options are exercised, new stock options are issued under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future, there will be further dilution to investors participating in this offering. In addition, 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. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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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 the section titled "Prospectus Summary—Summary Financial Data" and our audited financial statements and unaudited interim condensed financial statements and the related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors including, but not limited to, those set forth under the section titled "Risk Factors" and elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future, and you should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on tissue Treg biology for the discovery and development of immunoregulatory medicines designed to restore immune balance and promote tissue repair to address unmet needs of patients with autoimmune and inflammatory diseases. TRexBio was built on a pivotal scientific insight: that regulatory T cells ("Tregs") in human tissue are not merely passive suppressors of inflammation, but active orchestrators of tissue immune homeostasis and repair. Leveraging our Deep Biology drug discovery and design platform, we integrate tissue-level insights into human biology and Treg function to identify and characterize novel targets and approaches for therapeutic intervention. Our tissue-first conviction and unique insights in Treg biology are the foundation of our pipeline of therapeutic candidates aimed at restoring immune balance and promoting tissue repair for more durable disease control.

Our pipeline is focused on augmenting tissue Tregs to address critical treatment gaps in autoimmune and inflammatory diseases. Our most advanced wholly-owned product candidate, TRB-061, is an investigational tumor necrosis factor receptor 2 ("TNFR2") agonist designed to expand and activate Tregs in inflamed tissues. We believe TRB-061 has broad, multi-indication potential, and are currently conducting a Phase 1a/b clinical trial of TRB-061 in healthy volunteers and patients with moderate-to-severe atopic dermatitis ("AD"). We expect to announce topline data from the Phase 1b portion of the TRB-061 trial in patients with moderate-to-severe AD in mid-2027. Our second wholly-owned product candidate, TRB-071, is an investigational TNF receptor superfamily member 8, better known as TNFRSF8 (or "CD30") agonist designed to both augment tissue Tregs and block immune system inflammatory signaling axes. Genetic studies support the involvement of CD30 and its ligand in inflammatory bowel disease ("IBD"). TRB-071 is currently in IND-enabling studies and, subject to regulatory allowance to proceed, is expected to enter a Phase 1 trial in the first half of 2027. We believe TRB-071 has the potential to address the significant unmet need in IBD by directly targeting the immune system dysfunction in the gut barrier that drives disease pathology.

We believe each of our two lead product candidates has the potential to treat a range of autoimmune and inflammatory diseases with high unmet need, including AD, alopecia areata ("AA") and IBD. Beyond our lead product candidates, we are advancing multiple preclinical-stage programs focused on differentiated aspects of Treg biology with the goal of transforming the lives of patients affected by autoimmune and inflammatory diseases. We believe our Deep Biology platform, built on a proprietary database of healthy and diseased tissue samples, is key to achieving this goal. Our platform is designed to decode Treg functionality in human tissue, mapping key drivers of immune dysregulation and uncovering novel targets and insights that inform our drug discovery and translational efforts.

Our Deep Biology platform is designed not only to advance current programs but also to generate a continuous pipeline of future therapeutic opportunities. Autoimmune and inflammatory diseases are biologically complex and heterogeneous, with distinct mechanisms driving disease initiation, progression, and response to therapy across tissues and patient populations. Through the analysis of human tissues across multiple diseases, our platform is designed to identify targets associated with tissue Treg biology, immune regulation, and tissue repair, enabling us to prioritize and position therapeutic programs where we believe the underlying biology is most likely to provide meaningful clinical benefit. In addition, insights from our platform support our therapeutic design and candidate selection, indication prioritization, and translational strategies. The advancement of TRB-061, TRB-071, and TRB-051 into development demonstrates the platform's potential to identify differentiated targets and generate novel immunoregulatory therapeutic candidates, supporting our continued efforts to expand our pipeline across a broad range of autoimmune and inflammatory diseases.

On December 31, 2024, TRex Holdings Inc. merged with and into TRex Bio, Inc., its wholly-owned Delaware subsidiary, with TRex Bio, Inc. continuing as the surviving corporation; in connection with the merger, all outstanding shares of capital stock and options of TRex Holdings Inc. were converted on a one-for-one basis into corresponding shares of capital stock and options of TRex Bio, Inc.

Since inception, our operations have focused on research and development activities with respect to our product candidates as described above, as well as raising capital, business planning, organizing and staffing our company, establishing our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations. Through June 30, 2026, we have financed our operations primarily with the proceeds from the issuance of shares of our redeemable convertible preferred stock and from payments received under our strategic license and collaboration agreements with Lilly and JJDC. From inception through June 30, 2026, we have raised aggregate gross proceeds of approximately $220.0 million through the sale and issuance of our common stock and redeemable convertible preferred stock and $91.0 million through our collaboration agreements.

To date, we have no product candidates approved for commercial sale in any country and have not generated any revenue from product sales. We have incurred significant operating losses and negative cash flows since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net losses for the years ended December 31, 2024 and 2025 were $3.1 million and $34.8 million, respectively. For the six months ended June 30, 2025 and 2026, our net losses were $17.7 million and $29.3 million, respectively. As of June 30, 2026, we had an accumulated deficit of $123.6 million. We expect to continue to incur significant and increasing losses for the foreseeable future. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue clinical development of TRB-061;
- advance our TRB-071 program and our other product candidates through preclinical trials;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- procure the manufacturing of preclinical, clinical and commercial supply of our current or any future product candidates;
- seek marketing regulatory approvals for our current or any future product candidates that successfully complete clinical trials;
- commercialize our current or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharmaceutical company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- continue to develop, maintain and defend our intellectual property portfolio, including against third-party interference, infringement and other intellectual property claims, if any;
- seek to attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- attempt to address any competing therapies and market developments;
- experience delays in our preclinical studies, clinical trials or regulatory approval for our current or any future product candidates, including with respect to failed studies, inconclusive results, safety issues or other regulatory challenges;
- establish agreements with additional CROs and CMOs; and
- incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with an exchange listing and the SEC requirements, director and officer insurance premiums and investor relations costs.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, and we cannot assure you that we will ever generate significant revenue or profits. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical studies and expenditures related to our research and development activities.

Furthermore, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant audit, legal, regulatory and tax-related expenses, as well as director and officer insurance premiums and investor relations costs that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy as a public company. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity financings, debt financings, or other capital sources, which could include collaborations with other companies, or other strategic transactions and licensing agreements. We may be unable to obtain financing on acceptable terms, or at all, and we may be unable to enter into collaborations or other arrangements. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition, including requiring us to have to delay, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves.

As there are numerous risks and uncertainties associated with development of treatments for autoimmune and inflammatory diseases, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. We will need to generate significant revenue to achieve profitability, and we may never do so. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then 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 $90.9 million in cash and cash equivalents and marketable securities. We believe that our existing cash as of June 30, 2026, together with the anticipated net proceeds from this offering will be sufficient to fund our operations and capital expenditure requirements into the second half of 2029. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. See section titled "—Liquidity and Capital Resources."

Collaboration Agreements

Eli Lilly Research Collaboration and License Agreement

In January 2023, we entered into a Research Collaboration and License Agreement (the "Lilly Collaboration Agreement") with Eli Lilly and Company ("Lilly"), wherein we granted to Lilly exclusive worldwide rights to develop and commercialize certain program molecules and products. Lilly paid us a one-time $55.0 million upfront payment during the year ended December 31, 2023. In July 2024, Lilly also paid us a $15.0 million development milestone payment. The research term for the Lilly Collaboration Agreement expired during the year ended December 31, 2024; however, our right to receive potential future milestone and royalty payments survives the expiration of the research term and remains in effect, unless earlier terminated in accordance with its terms.

After giving effect to the $15.0 million development milestone payment received in July 2024, we are eligible to receive up to an additional $577.5 million in development, commercialization and sales milestone payments under the Lilly Collaboration Agreement. We are also eligible for tiered royalties ranging from six to ten percent on annual aggregate net sales of licensed products, subject to specified adjustments under the Lilly Collaboration Agreement. These payments will be included in the transaction price when it becomes probable that a significant reversal of cumulative revenue recognized will not occur and will be recognized as revenue based on our progress toward satisfaction of the combined performance obligation. See the section titled "Business—Intellectual Property—License and Collaboration Agreements—Our Research Collaboration and License Agreement with Lilly."

Components of Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to do so in the foreseeable future. Our ability to generate product revenue, if ever, will depend on the successful development, regulatory approval and commercialization of one or more product candidates by us. If we fail to complete the development of any future product candidates in a timely manner or to obtain regulatory approval for such product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

During the periods presented, our revenue, when recognized, was derived solely from the Lilly Collaboration Agreement described above. Revenue under the Lilly Collaboration Agreement relates to research and development activities under the applicable research plan and the transfer of related license rights and know-how. The research and development services, related license rights and know-how under the Lilly Collaboration Agreement were accounted for as a single combined performance obligation. The timing and amount of collaboration revenue may vary significantly from period to period based on our progress toward satisfaction of the combined performance obligation and the achievement of development, regulatory,

commercialization and sales milestones by Lilly. We did not recognize collaboration revenue during the year ended December 31, 2025, or the six months ended June 30, 2026, and we may not recognize additional revenue under the Lilly Collaboration Agreement unless and until additional milestone or royalty consideration qualifies for recognition in a future period.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses account for the largest component of our total operating expenses. Research and development expenses consist primarily of direct and unallocated costs incurred for the research and development of our product candidates.

Research and development expenses are recorded as expense in the period in which the related activities occurred, and payments we make prior to the receipt of goods or services to be used in research and development efforts are deferred as prepaid expenses until the goods or services are received and used. We accrue expenses for contract research and development as the related services are performed by monitoring the status of specified activities and billings received from our external service providers. These expenses are accrued based on estimates and are adjusted as actual expenses become known.

A significant portion of our research and development costs have been external costs, which we track by product candidate once it has reached a certain stage of development. However, we do not track our unallocated costs on a product candidate specific basis because these costs are deployed across multiple projects and, as such, are not separately classified.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We expect that our research and development expenses will increase substantially in absolute dollars for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we begin to conduct clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, and as we incur expenses associated with hiring additional personnel to support our research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, costs related to maintenance and filing of intellectual property, legal fees related to corporate matters, professional fees paid for accounting, auditing, consulting, tax services, insurance costs, general corporate expenses, and facility-related costs not otherwise included in research and development expenses. Personnel-related costs include salaries, bonuses, benefits, and stock-based compensation expense for our personnel in executive, finance and accounting, human resources, and other administrative functions.

We expect that our general and administrative expenses will increase substantially in absolute dollars for the foreseeable future as we continue to increase our headcount to support our business growth. We have incurred, and expect to continue to incur, significant costs in connection with preparing to operate as a public company. Following the completion of this offering, we expect to incur additional significant expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and expenses related to audit, legal, regulatory services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income, Net

Other income primarily consists of interest earned on our cash and cash equivalents and marketable securities during the period.

Provision for Income Taxes

We are subject to United States federal and state corporate income taxation. As of December 31, 2025, we had federal net operating loss ("NOL") carryforwards of $96.1 million. Federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely but are permitted to be used in any taxable year to offset only up to 80% of taxable income in such taxable year, if any. As of December 31, 2025, the Company has no state net operating loss carryforwards.

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Additionally, we had federal and state research and development tax credits carryforwards of $4.4 million and $3.9 million, respectively, as of December 31, 2025. The federal research and development tax credits will begin to expire in 2041 if not utilized. The state research and development tax credits have no expiration date.

Under Section 382 and Section 383 of the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (including research and development tax credits) to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. In general, an "ownership change" occurs if there is a cumulative change in ownership of the corporation by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. The Company has completed a Section 382 analysis through December 31, 2024 and has concluded that, as of December 31, 2024, ownership changes have occurred that will result in limitations on the use of certain NOL carryforwards and other tax attributes. If we were to undergo an additional ownership change in the future, further limitations could be imposed on our ability to utilize our NOL carryforwards and other tax attributes. We establish a valuation allowance against all of our net deferred tax assets. We consider all available evidence, both positive and negative, including but not limited to our historical operating results, income or loss in recent periods, cumulative losses in recent years, forecasted earnings, future taxable income, and significant risk and uncertainty related to forecasts, and concluded the deferred tax assets are not more likely than not to be realized.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for purposes of financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. As of December 31, 2024 and 2025, we had unrecognized tax benefits of $1.9 million and $12.0 million, respectively, of which $1.1 million would affect our income tax expense if recognized, before consideration of our valuation allowance.

Results of Operations

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

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

	For the six months ended June 30,		
	2025	**2026**	**Change**
Operating expenses:			
Research and development	$ 14,966	$ 26,030	$ 11,064
General and administrative	4,258	4,988	730
Total operating expenses	19,224	31,018	11,794
Loss from operations	(19,224)	(31,018)	(11,794)
Interest income	1,568	1,755	187
Other expense, net	(66)	(3)	63
Total other income, net	1,502	1,752	250
Loss before provision for income taxes	(17,722)	(29,266)	(11,544)
Provision for income taxes	—	42	42
Net loss	(17,722)	(29,308)	(11,586)
Unrealized loss on marketable securities	(11)	(165)	(154)
Comprehensive loss	$ (17,733)	$ (29,473)	$ (11,740)

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Operating Expenses (Income)

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2025 and 2026 (in thousands):

	Six months ended June 30,		
	2025	2026	Change
Direct costs:			
TRB-061	$ 4,496	$ 8,425	$ 3,929
Other product candidates	2,946	8,625	5,679
Unallocated costs:			
Employee-related expenses, including stock-based compensation	4,558	5,477	919
Facility-related and office costs	880	915	35
Other costs	2,086	2,588	502
Total research and development expense	$ 14,966	$ 26,030	$ 11,064

Research and development expense was $15.0 million and $26.0 million for the six months ended June 30, 2025 and 2026, respectively. The increase was primarily attributable to (i) a $3.9 million increase in costs associated with TRB-061, resulting from higher clinical trial costs, (ii) a $5.7 million increase in costs associated with other product candidates, resulting from increased preclinical development and chemistry, manufacturing and controls work, (iii) a $0.9 million increase in employee-related costs resulting from increased headcount, and (iv) a $0.5 million increase in other research and development costs.

General and Administrative

General and administrative expenses were $4.3 million and $5.0 million for the six months ended June 30, 2025 and 2026, respectively. The increase was primarily due to (i) $0.4 million of higher professional fees and outside services, driven primarily by costs associated with patent prosecution and the expansion of our intellectual property portfolio, and (ii) $0.3 million of higher employee-related costs, driven primarily by increased headcount.

Other Income, Net

Interest income was $1.6 million and $1.8 million for the six months ended June 30, 2025 and 2026, respectively. The increase was due to higher average balances of our cash and cash equivalents and marketable securities.

Comparison for the Years Ended December 31, 2024 and 2025

Our results of operations for each of the periods indicated are summarized in the table below (in thousands):

	For the Year Ended December 31,		
	2024	2025	Change
Collaboration revenue	$ 39,108	$ —	$ (39,108)
Operating expenses:			
Research and development	34,989	29,809	(5,180)
General and administrative	6,500	8,036	1,536
Total operating expenses	41,489	37,845	(3,644)
Loss from operations	(2,381)	(37,845)	(35,464)
Interest income	2,007	3,154	1,147
Other expense, net	(70)	(69)	1
Total other income, net	1,937	3,085	1,148
Loss before provision for income taxes	(444)	(34,760)	(34,316)
Provision for income taxes	2,700	46	(2,654)
Net loss	(3,144)	(34,806)	(31,662)
Unrealized gain on marketable securities	8	9	1
Comprehensive loss	$ (3,136)	$ (34,797)	$ (31,661)

Revenue

Our revenue of $39.1 million for the year ended December 31, 2024 was generated under the Lilly Collaboration Agreement and relates to research and development activities under the applicable research plan and the transfer of related license rights and know-how. The $39.1 million consisted of approximately $24.1 million representing recognition of the remaining portion of the original $55.0 million upfront payment and $15.0 million of variable consideration associated with the achievement of a development milestone under the Lilly Collaboration Agreement. The upfront payment and milestone consideration were included in the transaction price for the single combined performance obligation comprising the license rights, related know-how and research and development services. The milestone did not require additional research and development services by us. Upon achievement of the milestone, the $15.0 million of variable consideration was no longer constrained and was included in the transaction price. Because the combined performance obligation was fully satisfied during the year ended December 31, 2024, the remaining upfront consideration and the full amount of the milestone consideration were recognized as revenue during 2024. We did not receive separate payments or cost reimbursements specifically for research and development services performed under the initial research plan during the year ended December 31, 2024, and no portion of the transaction price was allocated separately to those services.

No collaboration revenue was recognized during the year ended December 31, 2025 because the combined performance obligation was fully satisfied during the year ended December 31, 2024 and no additional milestone or royalty consideration qualified for recognition during the year ended December 31, 2025.

Operating Expenses (Income)

Research and Development

The following table summarizes our research and development expenses for the periods indicated by direct and unallocated costs (in thousands):

	Years Ended December 31,		
	2024	2025	Change
Direct costs:			
TRB-061	$ 15,343	$ 9,182	$ (6,161)
Other product candidates	2,014	5,447	3,433
Unallocated costs:			
Employee-related expenses, including stock-based compensation	10,387	9,297	(1,090)
Facility-related and office costs	2,443	1,734	(709)
Other costs	4,802	4,149	(653)
Total research and development expense	$ 34,989	$ 29,809	$ (5,180)

Research and development expense was $35.0 million and $29.8 million for the years ended December 31, 2024 and 2025, respectively. The decrease was primarily due to (i) a reduction of $6.2 million in external research expenses for TRB-061 primarily due to the completion of manufacturing activities, (ii) $1.1 million of lower employee-related costs as a result of decreased headcount, (iii) $0.7 million of facility-related and office costs due to a decrease in depreciation expense from the change in the useful life of lab equipment (see Note 4 of the accompanying financial statements), and (iv) $0.7 million of other expenses due to no amortization expense in 2025 associated with the intangible asset as it was fully amortized during the year ended December 31, 2024 along with increased efficiencies. This was partially offset by an increase of $3.4 million due to increased costs as we progressed our preclinical pipeline.

General and Administrative

General and administrative expenses were $6.5 million and $8.0 million for the years ended December 31, 2024 and 2025, respectively. The increase was primarily due to (i) $1.3 million of higher employee-related costs as a result of increased headcount (ii) $0.2 million of other expenses.

Other Income, Net

Interest income was $2.0 million and $3.2 million for the years ended December 31, 2024 and 2025, respectively. The increase was due to higher average balances of our cash and cash equivalents and marketable securities.

Provision for Income Taxes

Provision for income taxes of $2.7 million for the year ended December 31, 2024 was primarily related to the collaboration revenue generated under the Lilly Collaboration Agreement. Provision for income taxes as of December 31, 2025 was immaterial.

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Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2026, we had cash and cash equivalents and marketable securities of $90.9 million. We have incurred net losses and negative cash flows from operations since inception, with the exception of the year ended December 31, 2023, during which we commenced the Lilly Collaboration Agreement, received a one-time upfront payment of $55.0 million from Lilly, and recognized total collaboration revenue of $41.9 million across our collaboration agreements, resulting in net income for the year and positive cash flows from operations. As of June 30, 2026, we had an accumulated deficit of $123.6 million.

We have historically funded our operations primarily through the issuances of redeemable convertible preferred stock. We expect to continue to incur substantial losses for the foreseeable future, and our ability to achieve and sustain profitability will depend on the successful development, approval and commercialization of any product candidates we may develop, and on the achievement of sufficient revenue to support its cost structure. We may never achieve profitability and, unless and until we do, we will need to continue to raise additional capital to fund ongoing research and development activities and maintain future operations. Our management plans to monitor expenses and may raise additional capital through a combination of public and private equity. Our ability to access capital when needed is not assured and, if capital is not available to us when, and in the amounts, needed, on the terms which are favorable, we could be required to delay, scale back, or abandon some or all of our planned development product candidates and other operations, which could materially harm our business, financial condition and results of operations.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Six months ended June 30,		Year ended December 31.	
	2025	2026	2024	2025
Net cash used in operating activities	$ (22,130)	$ (27,023)	$ (25,582)	$ (41,358)
Net cash used in investing activities	(33,281)	(28,555)	(17,304)	(32,989)
Net cash provided by financing activities	41,899	49,429	41,851	42,070
Net decrease in cash, cash equivalents, and restricted cash	$ (13,512)	$ (6,149)	$ (1,035)	$ (32,277)

Net Cash Used in Operating Activities

Net cash used in operating activities was $22.1 million and $27.0 million for the six months ended June 30, 2025 and 2026, respectively. The net cash used in operating activities for the six months ended June 30, 2025 was due to our net loss of $17.7 million and $4.7 million of net change in operating assets and liabilities primarily driven by $4.0 million of decrease in accrued liabilities. The net cash used in operating activities for the six months ended June 30, 2026 was due to our net loss of $29.3 million, partially offset by $2.2 million of cash provided by changes in operating assets and liabilities, primarily due to a $1.3 million decrease in prepaid expenses and other current assets and a $1.4 million increase in accrued liabilities.

Net cash used in operating activities was $25.6 million and $41.4 million for the years ended December 31, 2024 and 2025, respectively. The net cash used in operating activities for the year ended December 31, 2024 was due to our net loss of $3.1 million, $24.6 million of net change in operating assets and liabilities primarily driven by $24.1 million of decrease to deferred revenue, and $0.6 million of amortization of premiums and discounts on marketable securities, partially offset by $2.7 million of non-cash charges for depreciation, stock-based compensation, and operating lease expense. The net cash used in operating activities for the year ended December 31, 2025 was due to our net loss of $34.8 million, $6.8 million of net change in operating assets and liabilities, and net amortization of premiums and discounts on marketable securities of $1.8 million, partially offset by $2.0 million of charges for depreciation, stock-based compensation, and operating lease expense.

Net Cash Used in Investing Activities

Net cash used in investing activities was $33.3 million and $28.6 million for the six months ended June 30, 2025 and 2026, respectively. The net cash used in investing activities for the six months ended June 30, 2025 was attributable to purchases of marketable securities of $51.3 million, partially offset by the maturity of $18.0 million of marketable securities. The net cash used in investing activities for the six months ended June 30, 2026 was attributable to purchases of marketable securities of $81.5 million, partially offset by the maturity of $53.0 million of marketable securities.

Net cash used in investing activities was $17.3 million and $33.0 million for the years ended December 31, 2024 and 2025, respectively. The net cash used in investing activities for the year ended December 31, 2024 was attributable to purchases of marketable securities of $41.2 million and $0.1 million purchases of property and equipment, partially offset by the maturity of $24.0 million of marketable securities. The net cash used in investing activities for the year ended December 31, 2025 was attributable to purchases of marketable securities of $130.9 million and $0.1 million of property and equipment, partially offset by the maturity of $98.0 million of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $41.9 million and $49.4 million for the six months ended June 30, 2025 and 2026, respectively. Net cash provided by financing activities for the six months ended June 30, 2025 was attributable to net proceeds from the issuance of redeemable convertible preferred stock of $41.8 million and issuance of common stock of $0.1 million. Net cash provided by financing activities for the six months ended June 30, 2026 was attributable to net proceeds from the issuance of redeemable convertible preferred stock of $49.8 million and issuance of common stock of $0.1 million, partially offset by $0.5 million of payments for costs related to a planned initial public offering.

Net cash provided by financing activities was $41.9 million and $42.1 million for the years ended December 31, 2024 and 2025, respectively. Net cash provided by financing activities for the year ended December 31, 2024 was attributable to net proceeds from the issuance of redeemable convertible preferred stock of $41.8 million and issuance of common stock of $0.1 million. Net cash provided by financing activities for the year ended December 31, 2025 was attributable to proceeds from the issuance of redeemable convertible preferred stock of $41.8 million and issuance of common stock of $0.3 million.

Future Funding Requirements

Our primary use of cash is to fund our operations, primarily research and development expenditures. Cash used for operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress results and costs of our ongoing TRB-061 and TRB-071 clinical and preclinical studies and other research and development activities associated with the development of our other and future product candidates;
- the costs, timing and outcome of regulatory review of product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;
- the costs of establishing and maintaining arrangements with third party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the costs and timing of manufacturing for TRB-061, TRB-071, and other product candidates, including commercial manufacturing at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the cost of being a public company, including implementing operational, financial and management systems to remediate an existing material weakness;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;

- 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;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, current or future product candidates, if any; and
- the costs associated with operating as a public company following the completion of this offering, including legal, accounting, or other expenses in operating our business.

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and general corporate activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholders' rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have historically financed our operations primarily through the issuances of redeemable convertible preferred stock. Since our inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business and scientific planning, conducting discovery, research and development activities, establishing, maintaining, and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and component materials, engaging in collaboration activities, and providing general and administrative support for these operations.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations and capital expenditure requirements for at least twelve months from the date of this prospectus.

Contractual Obligations and Other Commitments

In April 2026, we entered into a new operating lease agreement with a related party for approximately 33,780 square feet. The new lease has an initial term of 27 months and provides for total fixed lease payments of approximately $3.3 million over the initial lease term. As of June 30, 2026, the new lease had not commenced, and we had not recognized a right-of-use asset or lease liability. The new lease subsequently commenced in August 2026. See "Certain Relationships and Related Person Transactions—Alexandria Real Estate Lease" and Note 10 to our unaudited condensed financial statements for additional information regarding the related-party nature of the lease agreement.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products used in our operations. These contracts generally provide for termination after a notice period, and, therefore, generally do not represent material noncancelable contractual commitments.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules and regulations or any holdings in variable interest entities.

Critical Accounting Estimates, Significant Judgments and Use of Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other

sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We generated revenue for the year ended December 31, 2024 under the Lilly Collaboration Agreement, which relates to research and development activities under the applicable research plan and the transfer of related license rights and know-how. We consider revenue to be earned when all of the following criteria are met: (i) we have a contract with a customer that creates enforceable rights and obligations; (ii) promised products or services are identified; (iii) the transaction price, or the amount we expect to receive, including an estimate of uncertain amounts subject to a constraint in an amount that would result in a significant reversal upon resolution of the uncertainty, is determinable; (iv) and we have transferred control of the promised items to the customer. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the contract. The transaction price for the contract is measured as the amount of consideration we expect to receive in exchange for the goods and services expected to be transferred. When a contract includes variable consideration, we estimate the amount to include in the transaction price and apply a constraint so that variable consideration is included only to the extent that it is probable that a significant reversal of cumulative revenue recognized will not occur when the related uncertainty is resolved. A contract's transaction price is allocated to each distinct performance obligation on a relative standalone selling price basis and recognized as revenue when, or as, control of the distinct good or service is transferred.

Stock-Based Compensation

Stock-based compensation is measured based on the estimated grant date fair value of the award and is recognized as expense on a straight-line basis over the requisite service period (usually the vesting period). Forfeitures are accounted for in the period in which they occur.

In determining the fair value of the options granted, we use the Black-Scholes option pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Fair Value of Common Stock — See the subsection titled "Fair Value of Common Stock" below.

Expected Term — The expected term represents the period that our stock options granted are expected to be outstanding and is determined using the simplified method as we do not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Expected Volatility — Since we are not a public company and have no trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period, where available, equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage of development and financial leverage.

Risk-free Interest Rate — The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the options.

Expected Dividend — We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We recorded stock-based compensation of $0.2 million and $0.5 million for the years ended December 31, 2024 and 2025, respectively, and $0.2 million and $0.3 million for the six months ended June 30, 2025 and 2026, respectively.

The intrinsic value of all outstanding incentive awards as of June 30, 2026 was $38.1 million based on the initial public offering price of $14.00 per share, of which $13.8 million was related to vested stock options and $24.3 million was related to unvested stock options and restricted stock.

Fair Value of Common Stock

Historically, for all periods prior to this offering, the grant-date fair market value of our common stock underlying stock options have been determined by our board of directors with assistance from unrelated third-party valuation specialists. Because there has been no public market for our common stock, our board of directors has exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value, which include important developments in our operations, the prices at which we sold shares of our redeemable convertible preferred stock, the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of common stock, actual operating results, financial performance, external market conditions in the life sciences industry, general U.S. market conditions, equity market conditions of comparable public companies, and the lack of marketability of our common stock. Given the absence of a public trading market for our common stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including: our stage

of development and material risks related to our business; the progress of our research and development product candidates; sales of our preferred stock; the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock; the lack of marketability of our securities; our financial condition and operating results, including our levels of available capital resources; the likelihood of achieving a liquidity event such as an initial public offering in light of prevailing market conditions; equity market conditions affecting comparable public companies; the trends, developments and conditions in the life sciences and biotechnology industry sectors; and general U.S. market and economic conditions. Valuations of our common stock were prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, referred to as the "Practice Aid."

In accordance with the Practice Aid, the fair value of our common stock was determined using the Option Pricing Method ("OPM") as we determined the OPM was the most appropriate method to utilize based on our stage of development and other relevant factors. The OPM uses the preferred stockholders' liquidation preferences, participation rights, dividend policy, and conversion rights to determine how proceeds from a liquidity event shall be distributed among the various ownership classes at a future date.

After the equity value was determined and allocated to the various classes of equity securities, a discount for lack of marketability ("DLOM") was applied to arrive at the fair value of common stock on a non-marketable basis.

A DLOM is applied based on the theory that as an owner of a private company stock, the holder has limited information and opportunities to sell the stock. A market participant that would purchase this stock would recognize this risk and thereby require a higher rate of return, which would reduce the overall fair market value.

The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development activities, costs related to research activities, preclinical studies, production of preclinical materials, non-human studies, contract manufacturing of clinical materials, clinical trial costs, consulting fees, costs related to laboratory operations, fees paid to other entities that conduct certain research and development activities on our behalf, and allocated overhead costs including facility-related expenses and IT-related costs. Payments made prior to the receipt of goods and services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered.

We have entered into various agreements with outsourced contract manufacturing and development vendors. We estimate accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. We periodically confirm the accuracy of our estimates with internal management personnel and external service providers, and we make adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Recent Accounting Pronouncements

See Note 2 to our audited financial statements included elsewhere in this prospectus for more information.

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Internal Control Over Financial Reporting

We have identified a material weakness in our internal control over financial reporting for the year ended December 31, 2025, which material weakness remained unremediated as of June 30, 2026. See "Risk Factors—We have identified a material weakness in our internal control over financial reporting. If we are unable to implement and maintain the effectiveness of our internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price."

Emerging Growth Company Status and Smaller Reporting Company Status

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include: (i) being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and (v) an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. 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 voting and 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 voting and common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on tissue Treg biology for the discovery and development of immunoregulatory medicines designed to restore immune balance and promote tissue repair to address unmet needs of patients with autoimmune and inflammatory diseases. TRexBio was built on a pivotal scientific insight: that regulatory T cells ("Tregs") in human tissue are not merely passive suppressors of inflammation, but active orchestrators of tissue immune homeostasis and repair. Leveraging our Deep Biology drug discovery and design platform, we integrate tissue-level insights into human biology and Treg function to identify and characterize novel targets and approaches for therapeutic intervention. Our tissue-first conviction and unique insights in Treg biology are the foundation of our pipeline of therapeutic candidates aimed at restoring immune balance and promoting tissue repair for more durable disease control.

Our pipeline is focused on augmenting tissue Tregs to address critical treatment gaps in autoimmune and inflammatory diseases. Our most advanced wholly-owned product candidate, TRB-061, is an investigational tumor necrosis factor receptor 2 ("TNFR2") agonist designed to expand and activate Tregs in inflamed tissues. We believe TRB-061 has broad, multi-indication potential, and are currently conducting a Phase 1a/b clinical trial of TRB-061 in healthy volunteers and patients with moderate-to-severe atopic dermatitis ("AD"). We expect to announce topline data from the Phase 1b portion of the TRB-061 trial in patients with moderate-to-severe AD in mid-2027. Our second wholly-owned product candidate, TRB-071, is an investigational TNF receptor superfamily member 8, better known as TNFRSF8 (or "CD30") agonist designed to both augment tissue Tregs and block immune system inflammatory signaling axes. Genetic studies support the involvement of CD30 and its ligand in inflammatory bowel disease ("IBD"). TRB-071 is currently in IND-enabling studies and, subject to regulatory allowance to proceed, is expected to enter a Phase 1 trial in the first half of 2027. We believe TRB-071 has the potential to address the significant unmet need in IBD by directly targeting the immune system dysfunction in the gut barrier that drives disease pathology.

We believe each of our two lead product candidates has the potential to treat a range of autoimmune and inflammatory diseases with high unmet need, including AD, alopecia areata ("AA") and IBD. Beyond our lead product candidates, we are advancing multiple preclinical-stage programs focused on differentiated aspects of Treg biology with the goal of transforming the lives of patients affected by autoimmune and inflammatory diseases. We believe our Deep Biology platform, built on a proprietary database of healthy and diseased tissue samples, is key to achieving this goal. Our platform is designed to decode Treg functionality in human tissue, mapping key drivers of immune dysregulation and uncovering novel targets and insights that inform our drug discovery and translational efforts.

Our approach is to fundamentally rethink the approaches historically utilized in autoimmune disease drug development. Current therapies in this space rely on broad immunosuppression or focus on inhibiting one or more of the pathways that drive inflammation and often leave patients with chronic residual disease or disease progression. Many patients do not achieve lasting, durable remission, and, given these limitations, a significant number of patients remain untreated or fail to continue treatment with current therapeutic options. By moving away from systemic immunosuppression to immunoregulation, we believe Treg augmentation has the potential to represent a transformative shift in treating and maintaining durable remission of immune-mediated diseases.

Tregs are master regulators of immune tolerance and mediators of tissue regeneration. The quantitative insufficiency, functional impairment, and phenotypic instability of Tregs in inflamed tissues are increasingly recognized as critical contributors to the pathogenesis of autoimmune and chronic inflammatory diseases. By studying Tregs in human tissues at high resolution, we better understand how those regulatory pathways affect other tissue immune and stromal cells, and how the failure of Treg-mediated tissue homeostasis drives chronic, self-perpetuating inflammatory cycles. Our approach is designed to address disease at its source—in the tissue—by developing medicines focused on tissue immune homeostasis that we believe have the potential to provide a durable clinical benefit.

Our most advanced wholly-owned product candidate, TRB-061, is a fragment crystallizable-fusion, or Fc-fusion, protein designed to agonize TNFR2, selectively, without activation of proinflammatory cells. TNFR2 is a member of the TNF receptor superfamily, a family of cytokine receptors that regulate immune responses and inflammation, and is enriched on tissue Tregs, including in the skin and gut. Our platform identified TNFR2 as a key node in tissue Treg regulatory pathways. Evidence from our preclinical and Phase 1a clinical trial in healthy participants has shown activation and expansion of a highly active subpopulation of Tregs in the tissue following administration of TRB-061, which function to promote restoration of immune balance, forkhead box P3 ("FOXP3") epigenetic stabilization, and a tissue-reparative phenotype that we believe can address barrier dysfunction. TRB-061 is currently in Phase 1b clinical development in patients with moderate-to-severe AD, and we expect to announce topline data in mid-2027. In addition, we are exploring expanding development of TRB-061 into other autoimmune and inflammatory diseases, including AA, based on data from our platform and published evidence supporting TNFR2 agonism or Treg augmentation as a therapeutic strategy in these conditions.

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We are also developing TRB-071, an investigational monoclonal antibody designed to leverage the biology of CD30 and its associated ligand ("CD30L") by agonizing CD30 to drive Treg activation, expansion and enhanced immune-regulatory capacity, while modulating the inflammatory pathway of CD30L. CD30 is a member of the TNF superfamily highly expressed on tissue Tregs. Human genetic studies have associated variants in both CD30 and CD30L with IBD susceptibility. In *in vivo* colitis models we saw reduced inflammation following treatment with TRB-071, and in our preclinical non-human primate studies, following administration of TRB-071 we observed Treg activation and expansion. We believe this dual mechanism, activating Tregs to restore immune balance while simultaneously modulating inflammatory signaling, has the potential to address underlying immune dysregulation in immune-mediated diseases such as IBD. We are currently conducting a three-month Good Laboratory Practice ("GLP") toxicology study of TRB-071 in cynomolgus monkeys and, subject to regulatory allowance to proceed, expect to initiate a Phase 1 clinical trial in the first half of 2027.

A central principle of our approach is the ability to connect human disease biology to Treg mechanism of action. Leveraging our proprietary Deep Biology platform, we analyze gene expression, pathway activity and cellular states in disease-relevant human tissues to identify where Treg function is disrupted, whether through impaired activation, instability, altered trafficking, or loss of tissue-reparative programs. These insights inform our target selection process and our design of translational strategies to align with the underlying disease biology. By linking target biology, Treg functional programs, and disease-specific immune dysregulation, we aim to establish a coherent framework that enables rational clinical development and early demonstration of biological activity in patients. Our platform is built on three integrated pillars: (1) Deep tissue biology and computational mapping to pinpoint disease-relevant biology with speed and precision; (2) our Treg Atlas, which recreates human tissue-specific Treg states *in vitro*; and (3) our Functional Assay Cascade, that interrogates multiple dimensions of Treg biology. Together, we believe these capabilities give us unique access to immune-mediated disease pathology, targets, and insights into how to approach the validation and development of therapeutic candidates in relevant target indications.

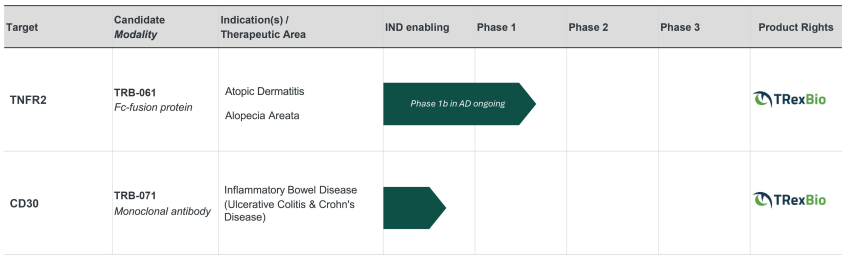
In addition to our own pipeline of product candidates, we believe the translational power and proprietary ability to discover novel ways to augment Treg biology through our Deep Biology platform have been validated through strategic target-discovery collaborations with global pharmaceutical leaders. We have an ongoing collaboration with Eli Lilly and Company ("Lilly"), which is advancing a clinical product candidate first identified and developed utilizing our platform.

We have assembled an experienced management team and board of directors with decades of experience in the foundational areas of immunology, Treg biology, and drug development. M. Johnston Erwin, Jr., our Chief Executive Officer, spent over 35 years at Lilly in leadership roles across regulatory, clinical, and corporate development. We are also guided by our board of directors, and scientific advisors who are key opinion leaders in Treg biology, dermatology, and gastroenterology.

We believe our deep understanding of Treg function and dysfunction, coupled with our experienced leadership team, uniquely positions us to harness the biology of these cells for a potential paradigm shift in the treatment of autoimmune and inflammatory diseases.

Our Pipeline

We are leveraging our Deep Biology platform to discover and develop product candidates for the treatment of a wide range of immune-mediated diseases. Our therapeutic product candidates are summarized in the table below:



We have an ongoing collaboration with Lilly for TRB-051, a modulator of immune effector cells, first identified and advanced under a multi-year discovery collaboration leveraging our platform. In June 2024, we announced that Lilly had initiated a Phase 1 first-in-human study for TRB-051. In June 2026, we announced that Lilly intends to move TRB-051 into a Phase 2a clinical trial in lupus with cutaneous involvement in the second half of 2026.

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TRB-061: A TNFR2 agonist

Our most advanced wholly-owned clinical-stage product candidate, TRB-061, is a novel, selective TNFR2 agonist Fc-fusion protein designed to activate and expand Tregs in inflamed tissues and restore immune balance without stimulating unwanted immune cells. We are developing TRB-061 for a variety of autoimmune and inflammatory diseases, with an initial focus on patients with AD. We initiated a Phase 1a clinical trial in healthy volunteers in June 2025. Based on the safety and biomarker data supporting proof-of-mechanism from the Phase 1a portion of this trial, the Phase 1b portion of this clinical trial in patients with moderate-to-severe AD began in April 2026, and we expect to announce topline data in mid-2027. In addition to evaluating safety and pharmacokinetics ("PK"), the Phase 1b part of this study includes pharmacodynamic ("PD") biomarkers from skin and includes exploratory clinical efficacy endpoints.

AD is a chronic, relapsing, intensely itchy inflammatory skin disease that can cause severe disruption to daily life and affects approximately 16 million American adults and an estimated 225 million individuals globally. Available treatments for AD are often limited by contraindications, side effects, and lack of efficacy, and are commonly associated with disease rebound when patients stop treatment. No approved therapies have been shown to induce durable remission independent of ongoing treatment, highlighting an unmet medical need for safer, more effective treatment options that address the underlying pathophysiology of AD.

TRB-071: A CD30 agonist

TRB-071 is an investigational agonist monoclonal antibody targeting CD30, a TNF receptor superfamily selectively enriched on a subset of tissue Tregs. TRB-071 is designed to induce expansion and increase immune-regulatory activity in Tregs and additionally block the inflammatory action of CD30L. Blocking CD30L has been shown to inhibit disease in third-party colitis models. Human genetic studies have associated variants in both CD30 and CD30L with IBD susceptibility. Together with our findings on tissue Treg biology, these data suggest that the CD30/CD30L axes contribute to both immune regulation and inflammatory responses. In our preclinical studies in non-human primates, we observed Treg activation and expansion following administration of TRB-071, and in *in vivo* colitis models we observed reduced inflammation after administration of TRB-071. We believe this dual mechanism of activating Tregs to restore immune balance while simultaneously modulating inflammatory signaling, has the potential to address underlying immune dysregulation in immune-mediated diseases such as IBD. IND-enabling activities for TRB-071 are ongoing, and, subject to regulatory allowance to proceed, we expect to initiate a Phase 1 clinical trial in the first half of 2027.

IBD, including Crohn's disease ("CD") and ulcerative colitis ("UC"), currently affects approximately 3 million Americans and is expected to affect more than 10 million patients worldwide by 2032, with its highest prevalence found in North America and Europe. Approved systemic treatments for IBD often carry safety concerns, including infections, cardiovascular events, malignancies, gastrointestinal perforations, and progressive multifocal leukoencephalopathy, among others, suggesting a meaningful gap in adequate patient care and therapeutic benefit. Development of additional therapies with novel mechanisms of action is imperative as patients often progress through existing advanced therapies. Considering the significant unmet medical need and treatment burden, we have identified IBD as an initial priority disease area for exploration.

Collaboration and Early Research and Discovery Pipeline

We are also advancing multiple preclinical-stage programs addressing differentiated aspects of tissue Treg biology informed by our proprietary Deep Biology platform. We believe the scientific depth and translational value of our platform have been independently validated by multi-year, de novo target-discovery and selection collaborations with global pharmaceutical companies. We have an ongoing collaboration with Lilly for a therapeutic candidate that we call TRB-051. TRB-051 is a modulator of immune effector cells, first identified and advanced under a multi-year discovery collaboration leveraging our platform. In June 2024, we announced that Lilly had initiated a Phase 1 first-in-human study for TRB-051. In June 2026, we announced that Lilly intends to move TRB-051 into a Phase 2a clinical trial in lupus with cutaneous involvement in the second half of 2026.

Our Team

Our Founding Story

TRexBio was founded in 2018, based on (i) foundational work establishing that Tregs acquire tissue-adapted programs and play specialized roles in different organ functions and integrity and (ii) pioneering research demonstrating that human Tregs localized to hair follicles in skin directly regulated follicular stem cell biology and communicated not only with immune cells, but also with tissue stromal cells to control both inflammation and tissue repair. These observations crystallized the founding thesis of TRexBio: Treg deficiency and dysfunction are not merely a downstream consequence of autoimmune and inflammatory disease, but fundamental drivers of it. To meaningfully address autoimmune and inflammatory diseases, we believe therapeutics must be built from a deep understanding of how Tregs function in inflamed human tissues, not only in peripheral blood or based on animal models. We have been decoding this biology ever since.

The scientific foundation underlying our approach has received what we believe is the highest possible external validation: the 2025 Nobel Prize in Physiology or Medicine was awarded to Shimon Sakaguchi, Mary E. Brunkow, and Fred Ramsdell "for their discoveries concerning peripheral immune tolerance"—specifically for discovering Tregs and establishing FOXP3 as their master transcription factor. The Nobel Committee noted that these discoveries "launched the field of peripheral tolerance, spurring the development of medical treatments for cancer and autoimmune diseases." As a company founded precisely to translate this Nobel Prize-winning biology into medicines that address autoimmune disease, we believe this recognition represents an extraordinary moment for the field and for our strategy at TRexBio.

Our Leadership Team

Our leadership team has significant experience discovering, developing and commercializing therapies. Our leadership team consists of:

- ***M. Johnston Erwin, Jr.***, our Chief Executive Officer, has over 40 years of experience in leadership roles across regulatory, clinical, and corporate development. Prior to TRexBio, he led Lilly New Ventures, Lilly's internal venture capital team, growing invested capital more than five times with seven consecutive cash-on-cash positive years. Before this, Mr. Erwin led the Lilly clinical team responsible for global regulatory submissions for blockbuster products Evista® and Forteo®, which gained approval in more than 80 countries.
- ***Laura Berner, JD, MBA***, our Chief Operating Officer, has 25 years of experience across business strategy, corporate development, and legal affairs in public and private biopharmaceutical companies. Prior to TRexBio, she most recently served as Head of Business Development & Investor Relations at Myovant Sciences, which was acquired by Sumitovant Biopharma. Earlier in her career, Ms. Berner led significant partnering and merger and acquisitions transactions for the pharmaceutical divisions at Roche and Genentech and was a corporate and life sciences transactions attorney in private practice.
- ***Brandon Hants***, ***MBA,*** our Chief Financial Officer, has over 25 years of experience working in finance, accounting, and other corporate functions within the biotech industry. Prior to TRexBio, Mr. Hants served as Chief Financial Officer at Applied Molecular Transport, held Chief Financial Officer and Vice President of Finance & Operations roles at Singulex, Inc., and held roles of increasing responsibility at Novartis Vaccines & Diagnostics and Genentech.
- ***Ariella Kelman, MD***, our Chief Medical Officer, has more than 20 years of experience in immunology clinical development, most recently serving as Chief Medical Officer at Biora Therapeutics, and before that, leading clinical development at Human Immunology Biosciences. Prior to TRexBio, Dr. Kelman spent 15 years at Genentech and Roche, and ten years as an attending physician and clinical faculty at Stanford University School of Medicine.
- ***Ali Zarrin, PhD***, our Chief Scientific Officer, is an accomplished immunologist with more than 25 years of experience across drug discovery and translational immunology. Dr. Zarrin has led the development of our proprietary Deep Biology platform. Prior to TRexBio, he held leadership roles in Early Research and Development at Genentech with a focus on autoimmune and inflammatory diseases. He is an inventor on numerous patents and has authored close to 50 scientific publications in leading journals.

Our Investors

TRexBio has been built with the support of a syndicate of leading healthcare investors who share our conviction in the transformative potential of tissue Treg focused immunology. We have raised approximately $220 million in aggregate equity financing to date. Our investor syndicate includes SV Health, Pfizer Ventures, Janus Henderson, Alexandria Ventures, Delos Capital, and Polaris Partners. Notably, we established pharmaceutical collaborations with each of Lilly and Janssen Pharmaceutica NV ("Janssen"), an affiliate of Johnson & Johnson Innovation—JJDC, Inc ("JJDC"). Lilly and JJDC are also each equity holders in TRexBio, reflecting their belief in both the scientific productivity of our Deep Biology platform and the long-term strategic value of our approach to Treg-biology-informed drug discovery. Notwithstanding the foregoing, these collaborations and equity investments should not be viewed as guarantees of future success, continued investment, or the achievement of any particular milestones or commercial outcomes. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and have received their shares in prior offerings at prices lower than the price offered to the public in this offering. See "Certain Relationships and Related Person Transactions" for more information.

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Our Strategy

Our goal is to become the leading company in Treg biology for restoration of immune balance and tissue repair by developing medicines that achieve durable, disease-modifying benefit by addressing autoimmune and inflammatory disease where they occur. Our deep understanding of human tissue immune biology and our expertise in how Tregs function in health and disease in specific tissue compartments are both our scientific foundation and our competitive advantage. The key tenets of our business strategy to achieve our goal of becoming the preeminent leader in Treg biology and drug development are as follows:

- ***Establish clinical proof-of-concept that targeting Treg-mediated immunoregulation in the tissue can improve disease outcomes.*** TRB-061, our TNFR2 agonist product candidate, is being investigated initially for the treatment of AD. Our ongoing Phase 1b study is designed to evaluate early efficacy signals supporting TNFR2 agonism's augmentation of immunoregulatory pathways to potentially restore tissue immune homeostasis and promote barrier repair. PD endpoints that include Treg quantification, and immunoregulatory and barrier biomarker assessments in blood and skin are designed to evaluate whether our tissue-targeted approach can produce durable immune rebalancing. Our Phase 1b program also incorporates an extended treatment-free follow-up to directly test how the intended clinical benefit of TRB-061 is maintained after treatment.
- ***Maximize the potential of TRB-061 in a broad range of chronic autoimmune and inflammatory diseases.*** While we are initially developing TRB-061 in AD, we have mapped TNFR2 pathway-mediated Treg dysfunction across a range of autoimmune and inflammatory diseases and have identified potential future expansion indications for TRB-061, including AA. We plan to advance further clinical development of TRB-061 across additional indications on a capital-efficient timeline, creating multiple independent value inflection points for the company.
- ***Advance our preclinical pipeline of product candidates, including TRB-071, for additional autoimmune and inflammatory diseases into clinical trials.*** In addition to TRB-061, we are advancing TRB-071, a wholly-owned product candidate, which targets CD30, a member of the TNF superfamily, whose expression is limited to immune cells. TRB-071 is designed to activate and expand immunoregulatory Tregs, while modulating associated inflammatory pathways. Genetic studies support the involvement of CD30/CD30L signaling axes in IBD. TRB-071 is currently in IND-enabling studies and, subject to regulatory allowance to proceed, is on track to enter Phase 1 in the first half of 2027. We believe TRB-071 has the potential to address the significant unmet need in IBD.
- ***Grow and sustain the world's leading tissue Treg biology organization, built on the foundation of our Deep Biology platform.*** Our Deep Biology platform is our proprietary discovery engine that continues to grow in scale and productivity. We believe our platform has the potential to generate additional novel product candidates with higher intrinsic translational probability through our tissue-first discovery philosophy built on human biology. In addition, we hope to continue to attract and retain exceptional scientists and drug developers with multidisciplinary expertise spanning human tissue immunology, functional genomics, computational biology, protein engineering, and multi-indication clinical development to enhance these efforts.
- ***Selectively evaluate strategic collaborations to maximize the reach and value of our technology platform in a capital efficient manner.*** Treg biology and dysfunction are implicated in a wide variety of autoimmune and inflammatory diseases, many with significant unmet medical need. We may opportunistically enter into strategic collaborations around certain diseases or product candidates, leveraging the capital, development and therapeutic expertise and commercial scale of our collaborators to maximize the value of our platform and capabilities for shareholders. Strategic collaborations may also enhance our understanding of disease pathology and accelerate our ability to discover and develop new, wholly-owned product candidates while bolstering the commercial potential of our current programs. We have previously entered into a strategic collaboration with Janssen and are currently collaborating with Lilly to discover and develop novel targets for undisclosed autoimmune disorders.

Our Approach

The Case for Tregs: Immune Balance

The past two decades of immunology drug development have yielded important advances, including TNF inhibitors, IL-4/IL-13 antagonists, IL-23 pathway blockers, and Janus kinase ("JAK") inhibitors, have meaningfully improved outcomes across autoimmune and inflammatory diseases such as psoriasis, IBD, and AD. Yet, almost every approved treatment for these conditions requires chronic treatment to maintain disease control—when the drug is discontinued, the disease returns. The reason is mechanistic: existing therapies suppress individual downstream effectors rather than restoring the upstream regulatory architecture that prevents uncontrolled immune activation in the first place.

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We believe the most promising path forward lies in re-engaging the immune system's own homeostatic control mechanism: the tissue Treg compartment. Tregs are a subset of T cells that exert immunoregulatory activity through multiple mechanisms. In addition to having anti-inflammatory effects, a subpopulation of Tregs found in tissues has been shown to induce regenerative responses in non-lymphoid cells, leading to repair of tissues and damaged organs. Tregs have been shown to be important, master regulators of inflammation and pathophysiology in a broad variety of diseases affecting barrier surfaces, such as AD and IBD, as well as other indications such as rheumatoid arthritis ("RA") and systemic lupus erythematosus ("SLE"), among others. This suggests that restoration of Treg function and immune balance, the proposed mechanism of our lead product candidates TRB-061 and TRB-071, has the potential to address a broad variety of autoimmune and inflammatory diseases.

Aberrant Treg function, characterized by reduced number and impaired activity of Tregs, is implicated in the pathophysiology of various autoimmune and inflammatory diseases, including those of the skin and gut. The strongest genetic evidence identifying the role of Tregs in the control of inflammation in skin and gut was established through investigations into the etiology of Immune dysregulation, Polyendocrinopathy, Enteropathy, and X-linked ("IPEX") syndrome. IPEX is a rare genetic condition in which mutations in FOXP3 lead to Treg dysfunction. IPEX is associated with systemic autoimmunity, most frequently affecting the skin, intestine, and pancreas. Clinical manifestations of IPEX syndrome are dominated by significant bowel inflammation and colitis. The most common skin manifestation in patients with IPEX syndrome is severe AD.

Tregs have a variety of surface receptors that govern their proliferation, function, and quality. Cell surface receptors can be targeted with therapeutics to expand Tregs, augment Treg function, and serve as biomarkers to assess changes in immunoregulatory function. Treg modulating therapies have shown promise for treating multiple autoimmune and inflammatory diseases and represent an immune tolerance paradigm that the field is now actively advancing. By restoring the Treg compartment—expanding Tregs, stabilizing their FOXP3 lineage commitment through epigenetic mechanisms, enhancing their functional regulatory repertoire and re-activating their tissue-reparative capacity—we believe it is possible to achieve genuine immune regulation, with the potential for durable benefit that outlasts active treatments directed at inhibiting specific pro-inflammatory pathways systemically.

The Case for Treg: Tissue-Reparative Dimension

A dimension of Treg biology with particular relevance to our target indications is the tissue-reparative function of tissue Tregs. Beyond their immunoregulatory function, Tregs in tissues express a suite of effector molecules that actively promote epithelial integrity, wound healing, and barrier restoration.

In AD, the epidermal barrier defect is not merely a consequence of immune activation but an active perpetuator of the inflammatory cycle. Mechanical injury from scratching and environmental insults further amplify this loop by releasing damage-associated signals such as extracellular adenosine triphosphate ("ATP") which fuels inflammation and itch.

Direct tissue damage and impaired epithelial restitution are core pathological manifestations of IBD and are part of a self-perpetuating loop with chronic immune overreaction leading to impaired gut barrier function, resulting in dysregulated healing that further amplifies the inflammatory response. Prolonged repetition of this cycle can cause irreversible tissue damage.

Tissue Tregs are naturally positioned to counteract these common pathogenic processes. Through pathways such as CD39-mediated ATP hydrolysis, Treg augmentation can dampen the inflammation triggering signal while simultaneously promoting tissue repair and restoration of barrier integrity. We believe therapies that reduce inflammation without directly restoring barrier function leave these pathogenic cycles fundamentally unresolved. By activating tissue Tregs, our approach is designed to both resolve inflammation and re-engage the body's own tissue repair programs.

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Harnessing the Power of Tregs for the Treatment of Autoimmune and Inflammatory Diseases

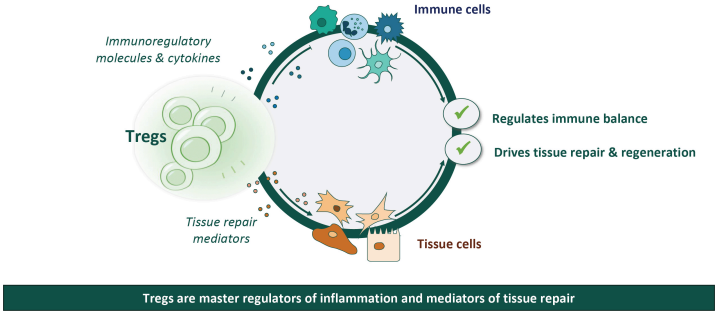


Figure 1.

Beyond shared repair programs, tissue Tregs adopt niche-specific functions that support local homeostasis and regeneration. In multiple organs, including the central nervous system and skin, Tregs engage in direct crosstalk with parenchymal and stromal cells to promote repair and restore tissue integrity. These findings highlight that Treg biology is locally adapted to the tissue microenvironment, reinforcing the importance of targeting tissue-specific Treg programs in disease.

Connecting Treg Mechanism of Action to Human Disease Biology: The TRexBio Deep Biology Platform

Our Deep Biology drug discovery and design platform is designed to decode Treg functionality in human tissue, mapping the key drivers of immune dysregulation to uncover novel targets and insights that inform our drug discovery and translational efforts. The platform combines multidisciplinary expertise across immunobiology, functional genomics, and computational and translational biology to uncover the 'deep biology' in human tissues and translate those insights directly into novel therapeutic candidates.

Our platform is built on the conviction that correcting disease processes at the tissue level leads to better clinical outcomes—and that achieving this requires starting with an understanding of human tissue in health and disease. Historically, drug discovery efforts in immunology have largely relied on peripheral blood and mouse models, which can offer only limited translatable insights into the disease processes occurring in human tissue. At TRexBio, high-quality, fresh, human tissue from healthy and diseased donors is the starting point for our discovery work. We focus on skin, gut, and lung barrier tissues, where many Tregs reside, maintaining homeostasis in response to environmental challenges.

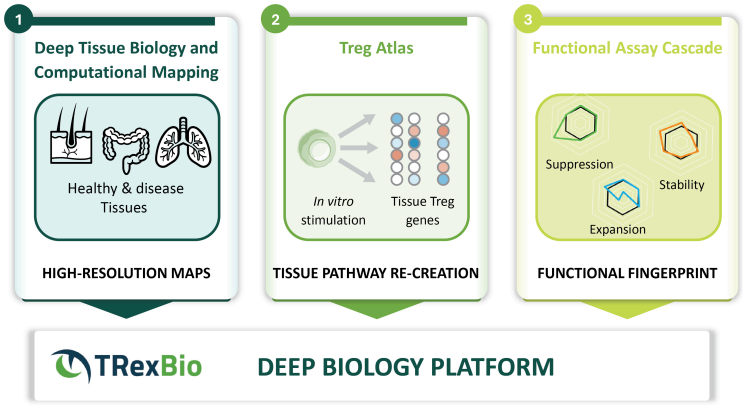


Figure 2.

The platform is organized around three integrated pillars:

Pillar 1: Deep Tissue Biology and Computational Mapping

We use advanced *in silico* tools to identify key genes and pathways in tissue immune regulation, leveraging our proprietary human tissue bank and a growing atlas of human Treg gene expression to pinpoint disease-relevant biology with speed and precision. We conduct bulk and single-cell ribonucleic acid sequencing ("RNAseq") across healthy and diseased tissue states to establish both the depth and breadth of the tissue Treg transcriptome to generate a high-resolution map of tissue regulatory pathways in health and disease. We have also incorporated additional technologies such as immunofluorescence, immunohistochemistry, imaging mass cytometry multiplex imaging, assays for transposase-accessible chromatin using sequencing, and cellular indexing of transcriptomes and epitopes by sequencing to complement our existing dataset. Modern computational tools are applied to evaluate the full catalog of gene expression and identify key tissue regulation pathways, allowing us to generate strong translational hypotheses with precision and to uncover targets in human tissues that were challenging to reach by traditional discovery methods.

Pillar 2: Treg Atlas

Our proprietary Treg Atlas captures approximately 1,000 genes enriched in tissue Tregs and recreates human tissue-specific Treg states *in vitro*. The Treg Atlas was built using rationally designed stimulations selected based on our internally generated data on genes and pathways present in tissue Tregs. Through this approach, we can reprogram blood-derived Tregs to be what we call "tissue-like Tregs" to capture approximately 70% of tissue Treg-enriched genes, providing a reliable and scalable *in vitro* model for downstream target validation anchored in human tissue biology rather than peripheral blood biology. The Treg Atlas is the critical bridge between our deep tissue biology and computational mapping outputs and functional validation, enabling us to recreate human tissue-specific regulatory pathways at scale without requiring fresh patient tissue for every experiment.

Pillar 3: Functional Assay Cascade

Our Functional Assay Cascade is a suite of high-throughput assays optimized for human primary Tregs and designed to interrogate multiple dimensions of Treg biology rapidly and in parallel across donors and inflammatory contexts. By testing targets across multiple donors and disease-relevant conditions, we generate translational data that inform target selection and validation, candidate selection, and clinical positioning. Key dimensions of the Functional Assay Cascade include interrogating Treg expansion and selectivity, suppressive function, FOXP3 epigenetic stability, tissue-repair phenotype induction, and inflammatory environment resistance—each directly linked to biological pathways identified through our deep tissue biology and computational mapping and validated through the Treg Atlas.

Together, the three pillars of our platform are designed to produce translatable insights for the initiation, validation, design, and advancement of novel drug discovery product candidates which we believe gives us the ability to identify and understand targets in ways unreachable by traditional methods, enabling rapid functional validation of therapeutic hypotheses, and generating a growing pipeline of investigational, selective, tissue-targeted Treg modulators built on a deep human tissue biology foundation.

Importantly, our Deep Biology platform extends beyond target discovery and continues to inform multiple aspects of drug development, including therapeutic candidate design, target indication selection, biomarker identification and optimization, translational PD strategies, patient stratification, and clinical study design. By linking target biology to disease-relevant immune pathways and functional Treg programs, we believe the platform enables a more integrated and data-driven approach to advancing therapeutics from discovery through clinical development. Our platform has informed the discovery design and translational strategy for all of our product candidates.

Translating Treg Augmentation to Patient Benefit: Clinical Evidence and the Limitations of Current Approaches

Several therapeutic strategies are being developed to utilize Tregs in the treatment of autoimmune and inflammatory diseases. The field has historically been organized around two principal approaches: interleukin-2 ("IL-2") pathway therapies and Treg cell therapies.

IL-2 Pathway Therapies: Proof of Concept, but with Limitations

IL-2 is a signaling cytokine protein that helps regulate the immune system. In low-doses, IL-2 has been used to stimulate Tregs selectively, establishing the foundational rationale for Treg expansion as a therapeutic strategy. By engaging the high-affinity IL-2 receptor complex located on Tregs, these agents expand Tregs preferentially and have generated early proof-of-mechanism signals across a range of autoimmune conditions. However, controlled clinical trials have consistently revealed a narrow therapeutic window, as higher doses can stimulate systemic inflammation and on-target activation of unintended cell populations, including natural killer ("NK") cells, effector T cells, and eosinophils. IL-2's short half-life and comparable potency at Treg and non-Treg receptors have compounded these challenges. Critically, an emerging scientific view is that Treg biology in diseased tissues differs fundamentally from circulating or lymphoid Tregs. Tissue Tregs operate through distinct transcriptional programs and serve non-immunological functions that IL-2-driven expansion alone cannot engage.

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Next-generation engineered IL-2 receptor-targeted agents have attempted to address these limitations. The most notable recent example is Nektar Therapeutics' rezpegaldesleukin, a pegylated IL-2 that met its primary endpoint in a Phase 2b AD study and also showed clinical improvement in a Phase 2b AA study. We believe these results provide meaningful external validation that pharmacological Treg restoration can drive clinical benefit in immune-mediated disease and establish a strong foundation for advancing next-generation therapies with opportunities for improved safety, efficacy, and convenience.

Treg Cell Therapies: Scientific Promise, Practical Constraints

Autologous and allogenic cell-based Treg therapies are under active development as an important modality for treating autoimmune and inflammatory diseases. Small cohort studies have demonstrated that *ex vivo*-expanded Tregs exhibit superior functional activity and stability relative to freshly isolated cells, particularly in patients with established autoimmunity. This body of evidence adds to the mechanistic case for Treg modulation as a treatment strategy.

However, cell therapy carries inherent limitations that are likely to constrain its applicability in large autoimmune patient populations. Manufacturing has been complex, costly, and time-consuming, with a critical time lag between treatment decision and administration. Patients have required immune ablation prior to infusion, along with hospitalization or specialized outpatient monitoring. Treatment costs can be prohibitive, effectively limiting access to those with the most severe disease. Perhaps the most detrimental limitations for chronic conditions, the durability of response and the feasibility of re-treatment, remain poorly characterized, both of which are central to the benefit-risk calculus in diseases requiring long-term management. For these reasons, while cell therapy contributes to the growing scientific support for Treg-based medicine, we believe its feasibility profile is poorly suited to the broad immunology patient populations.

The Unmet Need in Autoimmune and Inflammatory Diseases

Autoimmune and inflammatory diseases affect an estimated 4.5% of the worldwide population across 80 distinct conditions, with prevalence rising. Despite advances in anti-inflammatory therapies, many patients fail to achieve durable disease control or restoration of tissue health. Treg dysfunction or numerical insufficiency is a shared pathological feature across this spectrum and, in addition to AD and AA, has been shown in immune-mediated diseases as varied as asthma, chronic obstructive pulmonary disease ("COPD"), vitiligo, hidradenitis suppurativa, IBD, multiple sclerosis ("MS"), RA, SLE, type 1 diabetes ("T1D"), among others.

Multi-Indication Expansion Potential

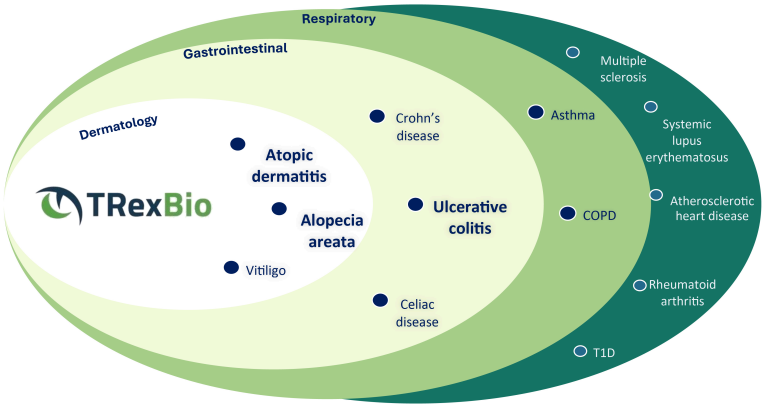


Figure 3.

By addressing a root cause of immune dysregulation rather than its consequences, we believe Treg augmentation has the potential to redefine what therapeutic success looks like in the treatment of multiple immune-mediated diseases.

Atopic Dermatitis

Disease Background, Burden and Unmet Need

AD is a chronic, relapsing, intensely itchy inflammatory skin disease that can cause severe disruption to daily life. Often referred to as eczema, this pervasive, chronic condition represents one of the most prevalent dermatological pathologies, affecting approximately 16 million American adults and an estimated 225 million individuals globally. Approximately 40% to 50% of affected individuals have moderate-to-severe disease, characterized by widespread skin involvement, severe itch, sleep disruption, and significant impairment of quality of life.

The burden of moderate-to-severe AD is profound, as its impact is associated with disruptions in work and sleep, and an increase in psychiatric comorbidities, including depression and anxiety. AD is the leading non-fatal health burden attributable to skin diseases and inflicts a substantial psychosocial burden on patients and their relatives. It is associated with a lower quality of life ("QOL") than many other common chronic illnesses, such as heart disease, diabetes, and high blood pressure. Moderate and severe AD patients were specifically associated with dramatically lower QOL than all other chronic disorders examined in a 2018 study, suggesting that AD is as burdensome as or even more burdensome than many other medical disorders. In a 2023 review of comorbidities of AD, multiple studies indicated that depressive symptoms may be directly related to AD severity and, therefore, potentially modifiable with AD treatment. In addition, the inflammatory state of severe AD is associated with increased cardiovascular risk and an atopic march to asthma and allergic rhinitis, underscoring AD as a chronic, systemic immune-mediated disease rather than just a skin condition.

Limitations of Current Treatment Landscape

Available treatments for AD are often limited by contraindications, side effects, and lack of efficacy, and are commonly associated with disease rebound when patients stop treatment. Current therapies for moderate-to-severe AD include traditional immunosuppressant drugs, such as methotrexate and cyclosporine, JAK inhibitors, such as upadacitinib (Rinvoq®), and biologic drugs that target the immune system, like dupilumab (Dupixent®). Traditional systemic immunosuppressant drugs carry risk of serious infections, organ toxicity, and other potential long-term side effects. JAK inhibitors carry boxed warnings for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis. Biologic drugs like dupilumab may cause adverse effects, including joint aches, allergic reactions, and ocular complications in up to 50% of patients. Real-world studies have demonstrated that close to 50% of AD patients who initiated dupilumab had discontinued treatment within two years.

AD pathophysiology is driven by three interacting elements that form a self-reinforcing cycle: epidermal barrier dysfunction (genetic predisposition including filaggrin mutations), immune dysregulation (Type Helper 2 ("Th2") skewing with IL-4, IL-13, IL-31, and thymic stromal lymphopoietin), and microbial dysbiosis (*S. aureus* colonization and superantigen production that directly impairs Treg function). Current approved therapies interrupt specific downstream nodes of this cycle but do not address the foundational Treg regulatory defect that permits the cycle to initiate and perpetuate—nor do they contribute to barrier restoration through the tissue-reparative program of activated Tregs. No currently approved therapies induce remission, highlighting an unmet medical need for safer, more effective treatment options that address the underlying pathophysiology of AD.

Other Diseases with Potential for Treg Modulation

Alopecia Areata

AA is an autoimmune hair loss condition that approximately 7 million Americans and 160 million patients globally have, have had, or will have, characterized by immune-mediated collapse of hair follicle immune privilege and cytotoxic CD8+ T cell attack on hair follicles during their active growth, resulting in sudden, patchy hair loss. Currently, there are approximately 700,000 Americans living with some form of AA, and 80% of these patients show signs of AA before turning 40. We have identified AA as a priority indication based on evidence of Treg depletion in AA lesional skin. In addition, published studies support that Tregs mediate hair follicle cycle and hair regrowth by activating hair follicle stem cells. Clinical studies with an IL-2 agonist have shown meaningful clinical activity in patients with AA, providing clinical proof of concept that AA is amenable to Treg based restoration of tolerance. By restoring both the immunoregulatory and tissue-reparative functions of follicular Tregs, we believe Treg augmentation has the potential to address the dual pathological drivers of follicular damage—immune privilege collapse and the tropic deficit that underlies structural deterioration.

Limitations of Current Treatment Landscape

Currently the only FDA-approved systemic medications for severe AA are JAK inhibitors. These treatments are limited by their efficacy and side effect profile. Patients treated with JAK inhibitors require strict monitoring given their risk of serious infections and laboratory abnormalities. Furthermore, these medicines carry boxed warnings for major cardiovascular events, blood clots and malignancies.

Inflammatory Bowel Disease

IBD, comprising CD and UC, affects approximately 3 million Americans and is expected to affect more than 10 million patients globally by 2032, with its highest prevalence found in North America and Europe. Despite multiple approved therapies, placebo-adjusted remission rates across all agents have not exceeded approximately 20% to 30%, a persistent therapeutic ceiling reflecting cytokine redundancy and upstream immune dysregulation. We have identified IBD as a priority indication based on evidence that Tregs have been shown to be important regulators of inflammation and pathophysiology in IBD. For example, children with rare, genetic disorders caused by IPEX syndrome, which disrupts Treg development and function, also suffer from IBD.

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Limitations of Current Treatment Landscape

Currently approved biologics for IBD include anti-TNFs, anti-integrins and anti-IL12/23s. These therapies have limited efficacy, with less than half of patients achieving clinical remission with induction, and many experiencing secondary loss of response or only partial systemic improvement. They also carry safety risks including the risks of serious infections and gastrointestinal perforation. Small molecule oral agents approved for IBD, including JAK inhibitors and sphingosine-1-phosphate ("S1P") receptor modulators, show a similar efficacy ceiling. JAK inhibitors are associated with dose-limiting toxicities including serious infections, laboratory abnormalities, and carry boxed warnings for major cardiovascular events, blood clots, and malignancies. S1P receptor modulators carry cardiovascular and infection risk.

Our Solution: TNFR2 Agonism with TRB-061

TRB-061 is an investigational novel Fc-fusion protein designed to agonize TNFR2, a surface receptor highly expressed and enriched on tissue Tregs, with relatively lower expression on other cells. Published studies support that TNFR2 signaling plays a central role in immune regulation, tissue homeostasis and repair. TNFR2 functions as a trimer, and effective signaling requires clustering of these receptor trimers. TRB-061 is designed to mimic the natural ligand, thereby enabling TNFR2 clustering that results in potent activation, and to have pharmacologic properties that support convenient subcutaneous administration.

TRB-061 Molecular Architecture

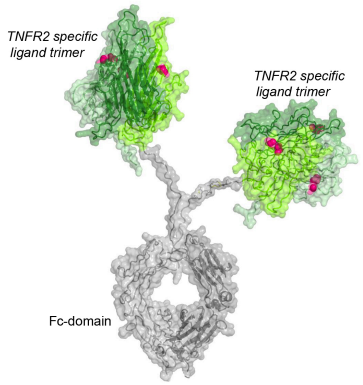


Figure 4. TRB-061 is a Fc-fusion protein containing proprietary trimeric TNFR2 agonist domains designed to mimic the natural ligand and promote efficient TNFR2 activation.

In clinical and preclinical studies, following administration of TRB-061 we observed selective expansion of a highly regulatory and tissue-licensed subset of Tregs. In the Phase 1a clinical trial biomarker program, data in participants treated with TRB-061 showed expanded expression markers indicating enhanced Treg lineage stability, persistence, and tissue homing, and we also saw downstream immunoregulatory effects including increased production of the regulatory cytokine IL-10.

Tissue licensed Treg agonism via TNFR2 may promote tissue repair, particularly relevant in barrier diseases such as AD, where tissue injury and the associated immune response can perpetuate inflammation and itch. We believe TRB-061 has the potential to help resolve this pathogenic cycle while restoring immune homeostasis through induction of Treg and related regulatory programs. Tregs are believed to be the primary mediators of this biology, and TNFR2 signaling has also been shown to promote immunoregulatory and tissue-reparative functions in additional immune, epithelial, and neuronal cell populations. Because it is designed to modulate tissue-licensed Tregs, we believe TRB-061 could have broad applicability in the treatment of multiple autoimmune and inflammatory diseases. In AD and other inflammatory diseases, the orthogonal, immunoregulatory mechanism of action of TRB-061 may enable flexible positioning in the treatment landscape: we believe there is an opportunity for TRB-061 to be a first line treatment. We also believe TRB-061 has the potential to be used as a second line treatment, and we believe it may also be used in combination or sequentially with other therapeutics that operate via an independent pathway.

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TRB-061 Mechanistic Biomarkers

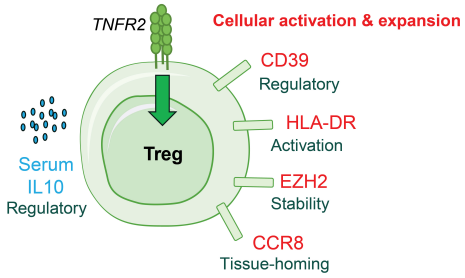


Figure 5. TRB-061-mediated TNFR2 agonism is designed to drive Treg activation, functional enhancement, tissue-homing/retention and expansion. PD activity is monitored through biomarkers of Treg abundance and functional expansion (CD39% of Tregs), activation and regulatory function (CD39, HLA-DR), stability (EZH2), tissue homing (CCR8 expression), and soluble biomarkers of Treg activity (serum IL-10).

TRB-061 Key Clinical Biomarkers and Overview of Functional Properties

Biomarker (Function)	Functional Overview	Mechanistic Significance to Treg Biology
CD39 (Regulatory)	• Drives tissue immune regulation • Metabolic enzyme converting inflammatory extracellular ATP to regulatory adenosine	• Critical to restoring tissue immune balance • Down-regulation marks Treg dysfunction
HLA-DR (Activation)	• Marker of active and highly regulatory Tregs	• Associated with enhanced contact-dependent regulation of T cells and antigen-presenting cells
EZH2 (Stability)	• Epigenetic regulator of Treg stability	• Stabilizes FOXP3 expression and Treg identity • Loss leads to Treg dysfunction and autoimmunity
CCR8 (Tissue-homing)	• Chemokine receptor directing Treg migration to and retention within tissues	• Tissue-enriched marker with limited representation in circulation
IL-10 (Regulatory)	• Anti-inflammatory cytokine supporting tissue homeostasis and promoting epithelial repair	• Reduced levels associated with disease severity in multiple autoimmune indications • Selective defect in mouse Tregs impact skin, gut and lung tissue immunity

Table 1. TRB-061's key clinical biomarkers and overview of functional properties.

TNFR2 Agonism: A Potential Paradigm Shift in the Treatment of Autoimmune and Inflammatory Diseases

We believe agonizing TNFR2 to augment tissue-licensed Tregs is a promising approach for treating autoimmune and inflammatory diseases. To our knowledge, TRB-061 is the first TNFR2 agonist to enter clinical development for the treatment of autoimmune or inflammatory diseases. We designed TRB-061 to selectively agonize TNFR2 to increase the number of Tregs, improve their function, enhance their stability in inflammatory environments, and induce a tissue repair phenotype.

Tregs have been shown to be important regulators of inflammation and pathophysiology in diseases affecting barrier surfaces, such as AD. Aberrant Treg function, characterized by reduced numbers and impaired activity, is implicated in the pathophysiology of various immune and inflammatory diseases, including those of the skin. Substantial genetic, scientific, and clinical rationale links aberrant Treg function to AD, suggesting that treatments that expand Treg numbers and boost their effector function will benefit patients with AD.

The compelling link between Treg deficiency and AD is established most directly by human genetics: the disruption of Treg cell development and function by FOXP3 loss-of-function mutations in IPEX syndrome produces severe multi-organ autoimmunity and systemic inflammation, including eczematous skin inflammation indistinguishable from AD, providing direct genetic evidence that Treg deficiency causes AD-like disease. Tregs in AD lesions have appeared insufficient to fully control inflammatory responses, suggesting defects in Treg function, stability, localization, or tissue adaptation. Together, we believe these findings support the therapeutic rationale for approaches designed to enhance Treg function to restore immune balance in AD.

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We believe TNFR2 agonism via TRB-061 could produce a highly selective immunoregulatory pathway, avoiding unwanted systemic inflammation associated with IL-2 treatments, with tissue-licensed properties designed to promote immune homeostasis.

TNFR2 pathway and Treg axes in atopic dermatitis

TNFR2 is enriched on tissue Tregs where it plays an important role in Treg activation, expansion and function. As seen in Figure 6, when we evaluated TNFR2 expression across immune cell populations in healthy and diseased tissue samples, we found TNFR2 enriched on Tregs relative to non-T cells, conventional CD4+ T cells, and CD8+ T cells across blood, colon, and skin tissues. Notably, TNFR2 expression was further enriched on tissue Tregs from the skin and colon compared with circulating blood Tregs, regardless of disease state, supporting a role for TNFR2 in tissue Treg biology and maintenance of local immune homeostasis. In addition, despite preserved, and in some cases elevated, TNFR2 expression in AD Tregs, we observed reduced TNFR2 agonism pathway activity compared with healthy skin Tregs. These findings suggest that impaired TNFR2 signaling may contribute to dysfunctional Treg biology in AD and provide a mechanistic rationale for therapeutic TNFR2 agonism.

TNFR2 was preferentially enriched on tissue Tregs across healthy and inflamed tissues.

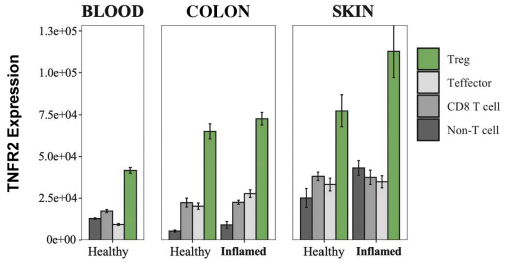


Figure 6. TNFR2 expression across immune cell populations in healthy and diseased tissue samples.

Preclinical support for selective Treg augmentation with TRB-061

To assess cellular selectivity, we evaluated TRB-061 in primary human blood containing both Treg and non-Treg immune cell populations. Following administration of TRB-061 or a TRB-061 tool molecule, Tregs were activated selectively, with limited effects on conventional T cells and other immune cell populations as in Figure 7A. Further, after treatment with TRB-061 in primary human Tregs derived from healthy skin and gut tissues, we observed expansion of tissue Tregs and increased the ratio of Tregs to conventional T cells, as illustrated for skin in Figure 7B.

Selective activation of blood Tregs and expanded skin Tregs

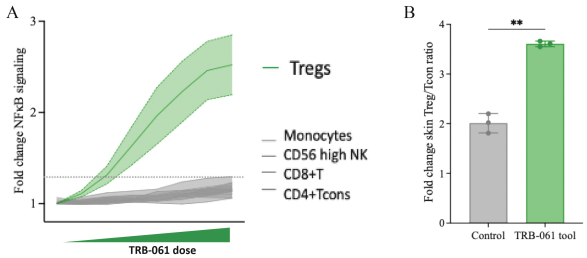


Figure 7. (A) Human peripheral blood immune cells were stimulated with increasing concentrations of TRB-061 and evaluated for activation of the non-canonical NFkB signaling pathway. (B) Human healthy skin tissue Tregs stimulated with TRB-061 tool agonist were evaluated for Treg expansion in comparison to T effector (CD4+Tcon) cells by flow cytometry. Asterisks denote statistical significance relative to the indicated comparator: *p<0.05, **p<0.01; ***p<0.001; and ****p<0.0001. "P" refers to "p-value," the conventional method for determining the statistical significance of a result, which represents the probability that random chance caused the result (e.g., a p-value = 0.01 means that there is a 1% probability that the difference between the control group and the treatment group is purely due to random chance). Generally, p-values less than 0.05 are considered statistically significant.

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To further test selectivity and the potential for off target immune stimulation, TRB-061 was evaluated in primary human peripheral blood immune cells to assess cytokine release potential. As seen in Figure 8, following administration of TRB-061, there was no measurable inflammatory cytokine production (IFN-γ, IL-6) as compared to the positive control.

No induction of interferon-gamma, a pro-inflammatory cytokine, in human blood cells

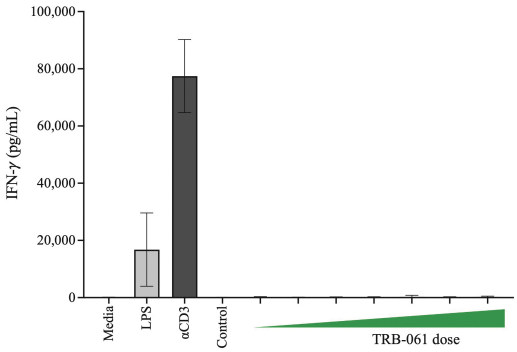


Figure 8. Human peripheral blood immune cell IFN-γ cytokine release assay following incubation with various positive control test articles or TRB-061 (n=10 donors) with increasing dose concentration. Data is shown as the mean ± standard deviation.

Preclinical and pharmacodynamic activity of TRB-061

We evaluated TRB-061 in both healthy and inflammatory disease mouse models in vivo. In humanized TNFR2 knock-in mice, following administration of TRB-061 we saw a two to five-fold expansion of Tregs in blood and across multiple tissues, including colon and skin. At later time points, Treg frequencies declined in the circulation while remaining elevated in peripheral tissues, consistent with tissue accumulation and retention of expanded Tregs.

In preclinical MC903, a skin dermatitis model, following administration of a mouse surrogate TRB-061 TNFR2 agonist, which we call "mTRB-061", we saw expansion of tissue Tregs as shown in Figure 9A, and improved skin health and histopathologic outcomes, as in Figure 9B and 9C. To further assess the impact of TNFR2 agonism in gastrointestinal inflammation, we evaluated mTRB-061 in the dextran sodium sulfate ("DSS")-induced colitis model. Following administration of TRB-061 we saw a dose-dependent increase in colonic FOXP3+ Tregs, accompanied by improvements in disease activity and histopathology. We believe these findings support the potential of TNFR2 agonism to expand tissue Tregs, suppress intestinal inflammation, and promote restoration of mucosal homeostasis.

Expansion of Tregs and improved disease in MC903-induced dermatitis

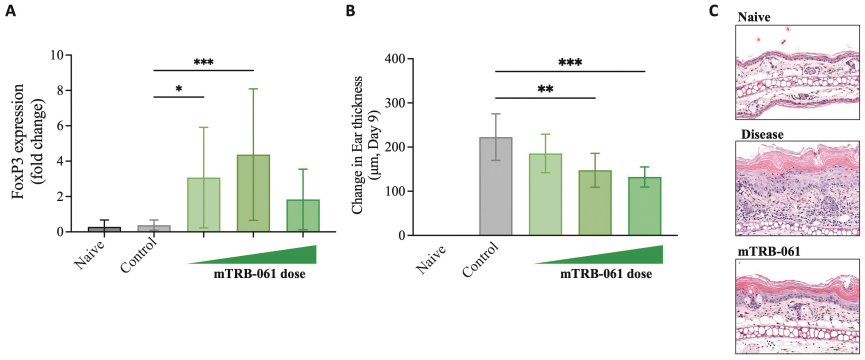


Figure 9. Treg expansion as measured by FOXP3 gene expression in mouse MC903 skin dermatitis following treatment with mTRB-061 at multiple dose levels, and associated reduction in skin inflammation and immune-pathology. Asterisks denote statistical significance relative to the indicated comparator: *p<0.05; **p<0.01; ***p<0.001; and ****p<0.0001.

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Safety and Pharmacology Results Observed in GLP toxicology study

We evaluated the *in vivo* activity of TRB-061 in several studies in cynomolgus monkeys, including a 13-week GLP toxicology study. In this study, we administered three doses of TRB-061 across three dose levels by subcutaneous injection every three weeks. Among the assessments made in this study, we evaluated the fold change in the number of Treg cells at various timepoints. As shown in Figure 10, we observed up to seven-fold selective expansion of Tregs, with the greatest activity observed within the highly immunoregulatory CD39+ Treg subset following administration of TRB-061. Peak PD activity was observed approximately seven days after dosing. In contrast, we saw no expansion of other immune cell types.

Selective expansion of CD39+ Tregs in non-human primates

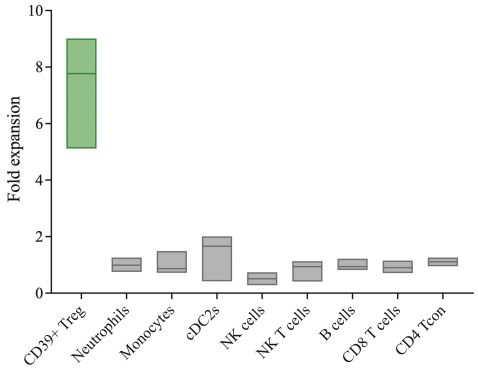


Figure 10. Cynomolgus monkeys were dosed with TRB-061 and evaluated for immune cell frequency effects pre-dose and post-dose. Blood immune cell frequencies shown as a fold change vs pre-dose mean.

All animals completed the study and appeared healthy with normal clinical parameters, and there were no concerning clinical pathology findings through the end of the study. Assessment of PK indicated dose proportional exposure and good subcutaneous bioavailability, supporting a once every four week or greater interval dosing in the clinic.

Clinical Development of TRB-061

We are conducting a randomized, double-blind, placebo-controlled three-part Phase 1a/b clinical trial in Australia and New Zealand, consisting of a single dose escalation trial in 32 healthy adult participants (Part 1), a multidose escalation trial in 32 healthy adult participants (Part 2), and a parallel group study in 51 adults with moderate-to-severe AD (Part 3). Parts 1 and 2 of the trial comprise the Phase 1a portion of the trial and have completed dosing. Part 3 of the trial comprises the Phase 1b portion of the trial and is ongoing. We expect to announce topline data in mid-2027.

TRB-061 Phase 1 Clinical Trial Design

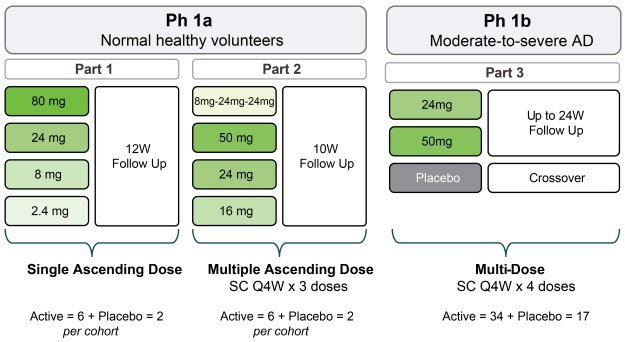


Figure 11.

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The primary objective of the Phase 1 trial is to evaluate the safety and tolerability of TRB-061. Secondary and exploratory objectives of the trial include evaluation of the drug-response (PK/PD) relationship, including the response of Treg cells as well as other types of immune cells, as an assessment of the immunoregulatory activity and selectivity of TRB-061, in order to establish proof of mechanism. The Phase 1b portion of the trial in patients with AD also includes exploratory efficacy outcomes including, but not limited to, change in Eczema Area and Severity Index ("EASI"), investigator global assessment of disease activity ("IGA") scale 0 to 1, meaning assessment of clear or almost clear skin, and EASI-75, or a change in EASI score from baseline of at least 75%.

Pharmacokinetic and pharmacodynamic profiles of TRB-061 following single and multiple doses in healthy volunteers

We observed consistent, dose dependent pharmacokinetics following subcutaneous administration of TRB-061 in both Part 1 and Part 2 of the Phase 1a trial, with a preliminary half-life of approximately twelve days, as seen in Figure 12. In addition, following each dose of TRB-061, we saw increases in the frequency of Tregs, and the expression of soluble and cellular activation and expansion biomarkers.

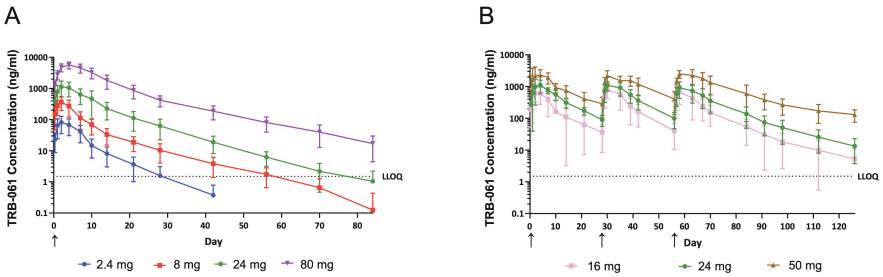


Figure 12. Serum concentrations of TRB-061 were measured by immunoassay and mean (± standard deviation) TRB-061 concentrations are shown over time following a single TRB-061 subcutaneous dose (A) or 3 doses every 4 weeks (B). Assay lower limit of quantification (LLOQ) is indicated with a dashed line, and timing of doses indicated with arrows. Data for Phase 1a, Part 2 Cohort 4 (8mg-24mg-24mg) were collected, but are not shown.

In Part 1 of the Phase 1a trial, healthy participants received TRB-061 or placebo subcutaneously using a single ascending dose trial design. Each cohort enrolled eight participants who were randomized 3:1 (six active participants and two placebo participants). Following administration of TRB-061, Treg responses were observed with peak increases approximately seven to fourteen days after dosing, remaining elevated for at least four weeks, as seen in Figure 13A.

In Part 2 of the Phase 1a trial, healthy participants received TRB-061 or placebo subcutaneously, for three doses each four weeks apart, at three dose levels, and a fourth cohort with a step-up dose design. Each cohort enrolled eight participants who were randomized 3:1 (six active participants and two placebo participants). Following each administration and at each dose of TRB-061, Treg expansion was observed as compared to placebo. Further we saw increasing PD response in Part 2 through the highest dose tested (50mg), as compared to the plateau in PD response that was observed in Part 1 between the 24mg and 80mg dose cohorts.

TRB-061 Phase 1a, Parts 1 and 2: CD39+ Treg

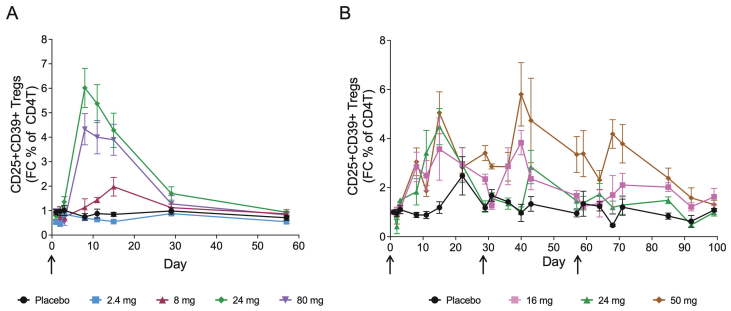


Figure 13. (A) In Phase 1a, Part 1: expansion of CD39-positive Tregs, following a single dose of TRB-061. (B) In Phase 1a, Part 2: expansion of

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CD39-positive Tregs following three doses of TRB-061 dosed every four weeks (Q4W). Data are shown as mean ± the standard error of the mean ("SEM"). Data for Phase 1a, Part 2 Cohort 4 (8mg-24mg-24mg) were collected, but are not shown.

Following single and multiple dose administration of TRB-061, total Tregs, marked by CD25, increased by up to approximately six-fold (peak mean fold change compared to baseline pre-dose), CD25 bright Tregs increased by up to 10-fold (peak mean fold change compared to baseline pre-dose) and, as shown in Figure 13B, CD25+/CD39+ Treg increased by approximately six-fold (peak mean fold change compared to baseline pre-dose). The magnitude of Treg response was dose dependent and approached a plateau in Part 1 (SAD) at the higher doses. In addition to expanded frequency of CD39+ Tregs, we also saw increased CD39 expression on a per-cell basis following both single and multiple dose administration of TRB-061. TRB-061 treated participants also showed elevated expression of key immunoregulatory functional markers corresponding with each dose, including serum IL-10, as shown in Figure 14, and other Treg cellular biomarkers such as CCR8, HLA-DR and EZH2.

TRB-061 Phase 1a: IL-10 Expression following single and multiple (Q4W) dose administration of TRB-061

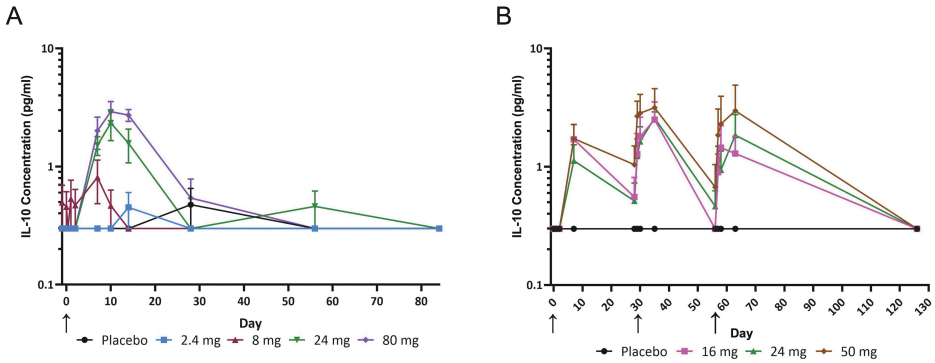


Figure 14. IL-10 concentration following a single dose TRB-061 administration. In the multidose, one outlier with high baseline IL-10 was removed in the 50mg dose cohort. Data for Phase 1a, Part 2 Cohort 4 were collected, but are not shown. Data are shown as mean ± the SEM.

Levels of conventional T cells, B cells, and NK cells were not significantly increased at any dose level. Accordingly, we believe Part 1 of the trial has explored the full therapeutic dose range of TRB-061, and we believe these data support proof of mechanism that TRB-061 has the potential to induce expansion of immunoregulatory and tissue-licensed Tregs.

Phase 1a: Safety and Tolerability Results

TRB-061 was generally well tolerated at all doses with mostly mild AEs in healthy trial participants. Prior to each dose escalation, there was a formal review by a safety review committee ("SRC"). The SRC was charged with reviewing blinded safety and tolerability study data and making further dose recommendations for the trial. Based on an unblinded review of the Phase 1a data, there were no dose-limiting toxicities or treatment-related serious adverse events ("SAEs") reported, and all treatment-emergent adverse events ("TEAEs") were reversible and mild or moderate in severity. In the Phase 1a SAD trial, the most frequently reported TEAEs (≥10% of participants) included upper respiratory tract infection, vascular access site bruising, contact dermatitis, back pain, and headache. In the Phase 1a MAD trial, the most frequently reported TEAEs (≥20% of participants) included rash, vascular access site pain, vascular access site bruising, upper respiratory tract infection, and headache. Potential follicular erythema, mild redness on the cheeks or trunk, was observed in certain participants on TRB-061. These potential events were generally mild, self-limited, and observed mainly following the first dose of TRB-061, with limited recurrence following subsequent doses. We hypothesize these cutaneous events are mechanism-based and attributable to initial perturbation of perifollicular TNFR2 expressing cells. There have been no treatment related discontinuations.

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Safety Results: Phase 1a Parts 1 and 2 (SAD/MAD) in healthy participants

Phase 1a Part 1 (SAD)					
Treatment-Emergent Adverse Events (TEAE)	**Placebo**	**TRB-061 2.4mg**	**TRB-061 8mg**	**TRB-061 24mg**	**TRB-061 80mg**
n=	8	6	6	6	6
Any TEAE, n (%)	6 (75%)	5 (83%)	5 (83%)	5 (83%)	6 (100%)
Severity: Mild	5 (62%)	4 (66%)	5 (83%)	5 (83%)	6 (100%)
Severity: Moderate	2 (25%)	1 (16%)	1 (16%)	2 (33%)	1 (16%)
Severity: Severe	0	0	0	0	0
SAEs	0	0	0	0	0
Discontinuations	0	0	0	0	0

Phase 1a Part 2 (MAD)					
Treatment-Emergent Adverse Events (TEAE)	**Placebo**	**TRB-061: 16 mg x 3**	**TRB-061: 24 mg x 3**	**TRB-061: 50 mg x 3**	**TRB-061: 8mg-24mg-24 mg**
n=	8	6	7[1]	6	6
Any TEAE, n (%)	6 (75%)	6 (100%)	7 (100%)	6 (100%)	6 (100%)
Severity: Mild	6 (75%)	6 (100%)	7 (100%)	6 (100%)	6 (100%)
Severity: Moderate	1 (12%)	1 (16%)	3 (42%)	1 (16%)	3 (50%)
Severity: Severe	0	0	0	0	0
SAEs	0	0	0	0	1 (16%)
Discontinuations	0	0	1	0	2

- SAE: pregnancy with miscarriage, not treatment related
- Reasons for discontinuation (none treatment-related): illicit drug use (n=1), pregnancy (n=1), physician decision (n=1, exacerbation of pre-existing knee-injury)
- [1] One subject replaced following discontinuation

Table 2. Phase 1a safety results. TEAE: Treatment Emergent Adverse Event; n (%): participants with any TEAE

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We believe the pharmacodynamic activity seen following administration of TRB-061 in healthy participants supports its proposed mechanism of action for the treatment of atopic dermatitis. Activation and expansion of immunoregulatory Tregs, and increased expression of biomarkers associated with tissue Treg function including CD39, is activity upstream of multiple inflammatory pathways that contribute to disease pathogenesis. We believe enhancing tissue Treg function may restore immune homeostasis, control pathogenic inflammation, and promote skin barrier repair in patients with atopic dermatitis, as illustrated in Figure 15.

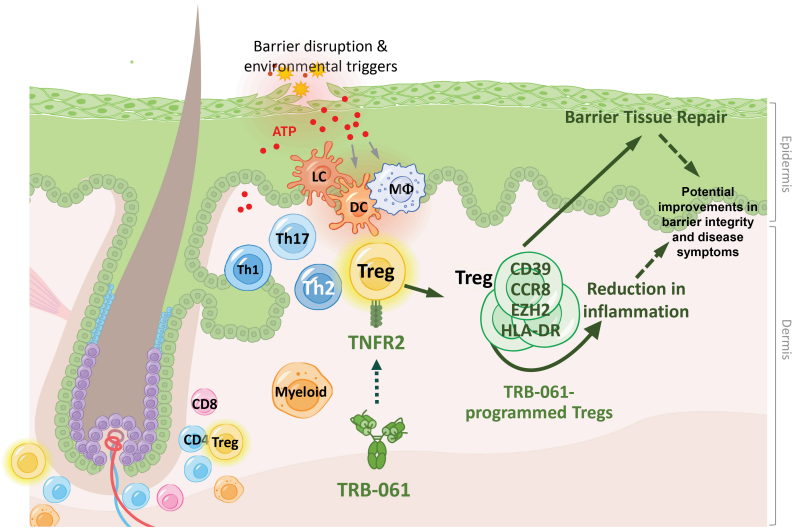


Figure 15.

Development Plan and Next Steps

We have commenced dosing in Part 3, the Phase 1b trial, in adults with moderate-to-severe AD, which is currently ongoing. Assuming supporting results and subject to regulatory submission and feedback, we expect to commence a Phase 2 clinical trial of TRB-061 in adult patients with moderate-to-severe AD at multiple sites in the United States and globally in the second half of 2027. We expect that the planned Phase 2 trial design will incorporate key learnings from other ongoing and completed pivotal AD trials. The planned target patient population will include patients who have had an inadequate response or intolerance to prior systemic therapies, including dupilumab. We anticipate that this trial will be a randomized, double-blind placebo-controlled trial to assess clinical efficacy, and extended dose regimens.

TRB-061 Additional Indications: Alopecia Areata

We are also evaluating the potential to advance TRB-061 in a host of broader autoimmune and inflammatory diseases, including AA. AA is an autoimmune disease characterized by loss of Treg function, immune tolerance and immune privilege within the hair follicle. In our platform, an analysis of scalp samples from patients with AA showed reductions in Treg frequency, TNFR2 expression and signaling, and reduced CD39 expression compared with healthy skin. In addition, a Phase 2 study with an IL-2 receptor agonist has shown meaningful improvements in patients with AA, providing proof of concept for Treg agonism for the treatment of AA. Together, we believe these findings suggest impaired TNFR2-mediated Treg function in AA and support therapeutic restoration of TNFR2 signaling to promote tissue homeostasis in the hair follicle, as shown in Figure 16. Assuming supporting results from the TRB-061 Phase 1 trial and subject to regulatory submission feedback, we expect to commence a Phase 2 clinical trial of TRB-061 in adult patients with AA at multiple sites in the United States and globally in the second half of 2027.

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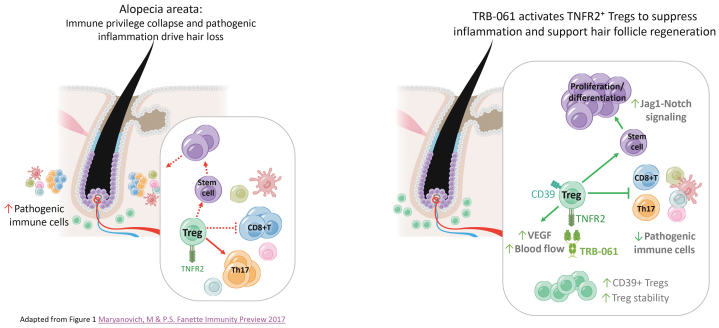


Figure 16. Proposed mechanism of action of TRB-061 in AA.

TRB-061: Additional Indications Beyond Atopic Dermatitis and Alopecia Areata

Beyond AD and AA, our Deep Biology platform has identified a broader landscape of autoimmune and inflammatory conditions characterized by tissue Treg dysfunction where TNFR2-pathway agonism may offer therapeutic benefit. In UC, our analyses have shown enrichment of TNFR2 expression on tissue Tregs and evidence of reduced TNFR2 pathway activity, supporting a role for impaired TNFR2-mediated immune regulation in disease pathogenesis. In addition, in the DSS-induced colitis model, we saw expansion of colonic Treg and reduced disease activity following administration with TRB-061. Published studies further support a role for TNFR2 signaling in intestinal homeostasis, including regulation of epithelial regeneration and restoration of mucosal integrity following injury supporting the potential applicability of TRB-061 in IBD. More broadly, Tregs play a central role in maintaining immune tolerance and preventing pathogenic immune responses across a wide range of autoimmune and inflammatory diseases. Based on the biology of Tregs and TNFR2 signaling and insights generated through our platform, we believe TRB-061 may have therapeutic potential in additional indications including asthma, COPD, vitiligo, hidradenitis suppurativa, IBD, MS, RA, SLE and T1D, among others. We believe that clinical validation, if achieved in AD, combined with the mechanistic breadth of our platform, positions us to efficiently evaluate expansion of our development efforts into these additional target indications, potentially representing a significant long-term opportunity to address unmet need across a wide range of autoimmune and inflammatory diseases.

Our Solution: CD30 Agonism with TRB-071

TRB-071 is an investigational monoclonal antibody designed to leverage the biology of the CD30/CD30L axes by agonizing TNF receptor superfamily member 8, better known as TNFRSF8 or CD30, to activate and expand immunoregulatory Tregs selectively, while modulating CD30L-associated inflammatory pathways. We are currently conducting a three-month GLP toxicology study of TRB-071 in cynomolgus monkeys and, subject to regulatory allowance to proceed, expect to initiate a Phase 1 clinical trial in the first half of 2027. CD30 is a surface protein receptor enriched on a subset of Tregs associated with enhanced regulatory function that emerged from our Deep Biology platform as a differentiated approach to selectively enhance highly regulatory tissue Tregs. We believe this receptor functions as a key regulator of tissue Treg biology and immune homeostasis.

The primary biological binding partner for the CD30 receptor is CD30L. Studies suggest that CD30L-associated signaling complexes may contribute to inflammatory responses. Human genetic studies have associated variants in both CD30 and CD30L with IBD susceptibility. Together with our findings on the role of CD30 in augmenting tissue Treg biology, these data suggest that dysfunction in the CD30/CD30L signaling axes may contribute to both immune regulation and inflammatory responses. We believe TRB-071's intended dual mechanism of activating Treg to restore immune balance, while simultaneously modulating inflammatory signaling, has the potential to address underlying immune dysregulation in immune-mediated diseases such as IBD as shown in Figure 17.

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CD30 agonism: activating tissue Tregs and blocking inflammatory pathways to restore immune homeostasis in the gut

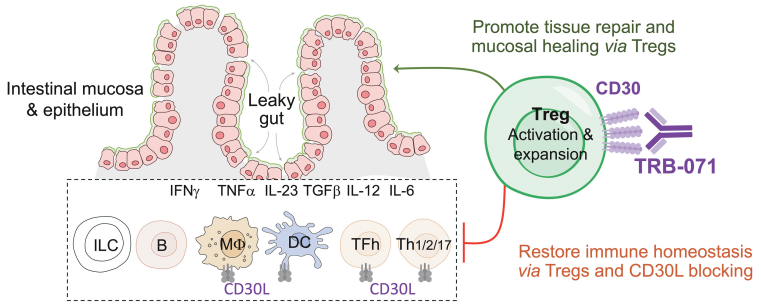


Figure 17. CD30 agonist TRB-071 is designed to activate and expand Tregs to promote tissue repair and restore immune homeostasis.

Identification of CD30 pathway from our platform

CD30 is a novel target that emerged from our Deep Biology platform as a receptor preferentially enriched on tissue Tregs across healthy and inflamed barrier tissues, especially in colon, and lung. As compared with conventional T cells and other immune cell populations, CD30 expression was consistently elevated on tissue Tregs, supporting its role as a pathway associated with maintenance of tissue immune homeostasis, as shown in Figure 18A. Further, we found CD30-positive cells enriched for a highly immunoregulatory subset of Treg, showing nearly two-fold greater blocking of T cell proliferation than CD30-negative cells, as shown in Figure 18B. Functional studies from our platform showed that activation of CD30 signaling enhanced Treg expansion and regulatory function, supporting its potential as a therapeutic target to restore immune homeostasis in autoimmune and inflammatory diseases.

CD30 was preferentially enriched on tissue Tregs and identified a highly immunoregulatory Treg subset.

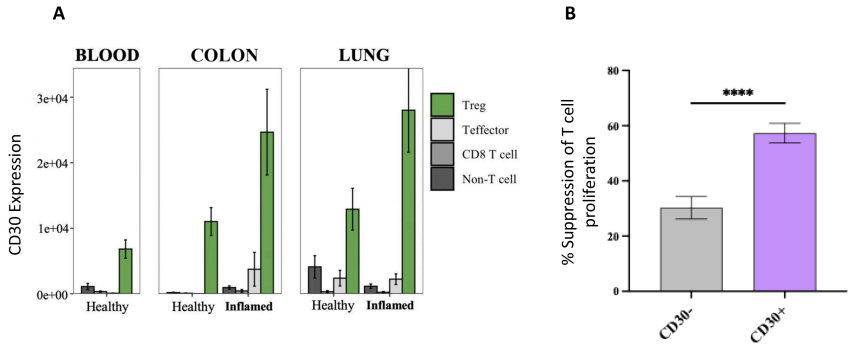


Figure 18. (A) CD30 was highly expressed on Tregs from healthy and inflamed colon and lung tissues compared with conventional CD4+ T cells, CD8+ T cells, and non-T immune cells. (B) CD30+ Tregs exhibited greater suppressive activity than CD30-negative Tregs, as measured by inhibition of effector T-cell proliferation. Asterisks denote statistical significance relative to the indicated comparator: *p<0.05; **p<0.01; ***p<0.001; and ****p<0.0001.

In human tissue-like Tregs, following treatment with TRB-071, we observed a greater than a three-fold increase in Treg expansion, as shown in Figure 19A. Furthermore, TRB-071-treated Tregs showed enhanced function resulting in a statistically significant reduction of conventional T cell proliferation, as shown in Figure 19B. Together, these findings suggest that TRB-071 activates CD30 on human Tregs, resulting in coordinated enhancement of Treg activation, expansion, and regulatory activity.

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Treg expansion and Treg-mediated suppression of effector T cell proliferation in vitro

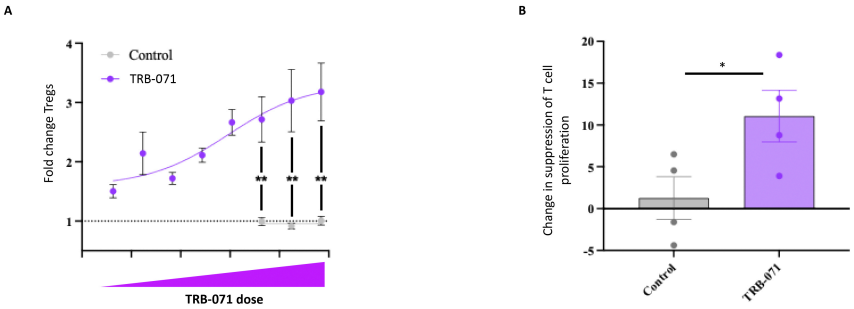


Figure 19. (A) Expansion of tissue like human Tregs with TRB-071 vs. control, (B) Treg-mediated suppression of effector T cell proliferation with TRB-071 vs. control. Asterisks denote statistical significance relative to the indicated comparator: *p<0.05; **p<0.01; ***p<0.001; and ****p<0.0001.

Preclinical and pharmacodynamic activity of TRB-071

Our preclinical studies using humanized CD30 mice or a mouse-directed anti-CD30 tool molecule that we call TRB-071-tool, have shown that CD30 agonism preferentially expands tissue Tregs within inflamed skin and colon *in vivo*, as shown in Figure 20.

CD30 agonism expanded Tregs in inflamed tissues and improved colitis pathology.

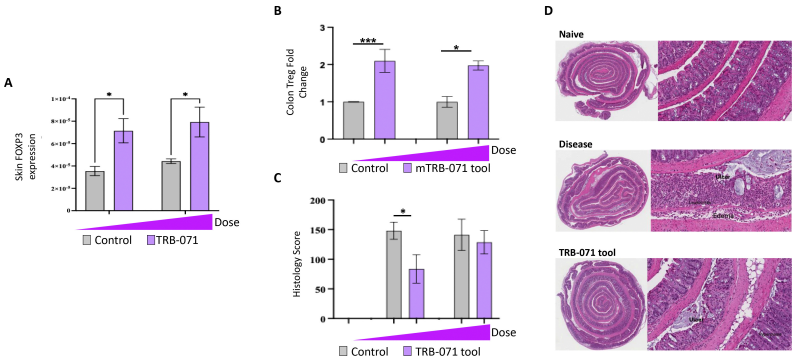


Figure 20. Following treatment with TRB-071 or a TRB-071 tool molecule: (A) Treg expansion as measured by FOXP3 gene expression in Imq-induced skin inflammation. (B) Treg expansion in DSS-inflamed colon. (C) and (D) Subsidence of DSS-driven epithelial inflammation. Triangles depict increased dose concentration. Asterisks denote statistical significance relative to the indicated comparator: *p<0.05; **p<0.01; ***p<0.001; and ****p<0.0001.

To test the activity and identify a dose range for GLP toxicology assessment, a three-month PK/PD dose range finding study was carried out in cynomolgus monkeys. Animals were administered vehicle or one of three dose levels of TRB-071. The primary PD markers included were Treg subset expansion and modulation of other immune cell types. We observed selective, dose dependent activation and expansion of immunoregulatory CD39+ Tregs by six to eight-fold with minimal effects on inflammatory immune cell populations, as shown in Figure 21. Non-Treg effects were similar across treatment and control arms.

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Expansion of Tregs in nonhuman primates with no detectable inflammatory activity in human blood cytokine release assay relative to control

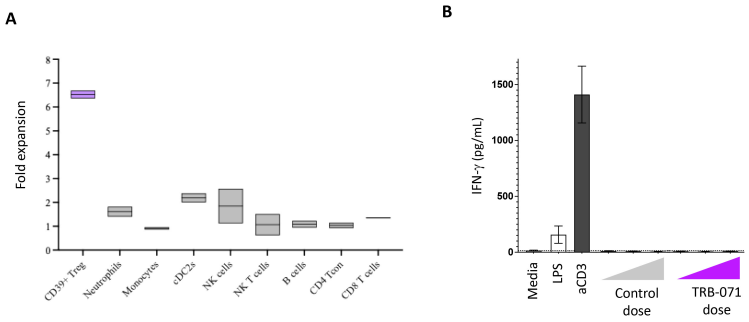


Figure 21. (A) Cynomolgus monkeys were dosed with TRB-071 and evaluated for immune cell frequency effects pre-dose and post-dose. Blood immune cell frequencies shown as a fold change vs pre-dose mean. (B) Representative cytokine (IFN-g) from human blood cytokine release assay using positive controls or increasing dose concentration of TRB-071.

Development Plan and Next Steps

TRB-071 is currently undergoing safety assessment in a 12-week cynomolgus monkey GLP toxicology study. Subject to regulatory allowance to proceed, we plan to initiate a Phase 1 trial in the first half of 2027.

Target Indication Opportunities for TRB-071

We believe target biology, tissue expression patterns, and preclinical data support clinical development of TRB-071 in patients with UC. Beyond UC, CD30 is implicated in additional gastrointestinal diseases characterized by impaired immune regulation and tissue homeostasis, including CD and Celiac disease. Our Deep Biology platform has also identified CD30-expressing immunoregulatory cell populations in lung tissues, suggesting potential applicability in chronic inflammatory and fibrotic lung diseases where we believe Treg tissue augmentation could provide therapeutic benefit. These include COPD, systemic sclerosis-associated interstitial lung disease, and idiopathic pulmonary fibrosis, among other potential indications.

Other Discovery Candidates from our Deep Biology Platform

Our Deep Biology platform is designed not only to advance current programs but also to generate a continuous pipeline of future therapeutic opportunities. Autoimmune and inflammatory diseases are biologically complex and heterogeneous, with distinct mechanisms driving disease initiation, progression, and response to therapy across tissues and patient populations. Through the analysis of human tissues across multiple diseases, our platform is designed to identify targets associated with tissue Treg biology, immune regulation, and tissue repair, enabling us to prioritize and position therapeutic programs where we believe the underlying biology is most likely to provide meaningful clinical benefit. In addition, insights from our platform support our therapeutic design and candidate selection, indication prioritization, and translational strategies. The advancement of TRB-061, TRB-071, and TRB-051 into development demonstrates the platform's potential to identify differentiated targets and generate novel immunoregulatory therapeutic candidates, supporting our continued efforts to expand our pipeline across a broad range of autoimmune and inflammatory diseases.

Competition

The biotechnology industry is intensely competitive, particularly in the race to develop new products. While we believe we have significant competitive advantages, we face competition from established multinational pharmaceutical companies, as well as from clinical-stage biotechnology companies with product candidates targeting overlapping biological pathways or indications. Our ability to compete successfully will depend on, among other things, the clinical safety and efficacy profile of our wholly-owned product candidates, our ability to differentiate the mechanisms of TRB-061, TRB-071, and future product candidates from existing and emerging therapies, the speed of our clinical development program, and our ability to obtain and maintain intellectual property protection.

The companies against which we are competing, or against which we may compete in the future, may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Due to our focus on Treg-targeted product candidates for broad autoimmune and inflammatory conditions, we are aware of several programs across AD, AA, and IBD that may be competitive to the patient populations we are currently prioritizing. Additionally, we are aware of several companies developing product candidates within the TNFR2 class for autoimmune and inflammatory conditions. We are also aware of several competitive Treg-targeted product candidates for various autoimmune and inflammatory conditions.

Intellectual Property

Our success depends in part on our ability to secure intellectual property protection for our product candidates and future products, as well as our platform technologies and any other relevant inventions and improvements that are considered commercially important to our business. Our success also depends on our ability to defend and enforce our intellectual property rights, preserve the confidentiality of our proprietary information, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties. As with other biotechnology and pharmaceutical companies, our ability to secure and maintain intellectual property protection for our product candidates, future programs, and other proprietary technologies will depend on our success in obtaining effective patent coverage and enforcing those patents if granted. However, we cannot guarantee that our pending patent applications, and any patent applications that we may in the future file, will result in the issuance of patents, or that any issued patents we may obtain will provide sufficient proprietary protection from competitors. Any issued patents that we obtain may be challenged, invalidated, or circumvented by third parties. In addition to patents, we also rely on trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology, in part, through confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and potential collaborators.

Intellectual property, including patents, trade secrets, trademarks, and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our product candidates, as well as for future programs and novel discoveries, product development technologies and know-how. Our commercial success also depends in part on our ability to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, licensing or filing applications for U.S. and foreign patents relating to our product candidates, technology, inventions, and improvements that are important to the development and implementation of our business.

Our patent portfolio is built with a goal of establishing patent protection that generally includes, for the product candidates, claims directed to compositions of matter, pharmaceutical compositions or formulations, methods of manufacturing, methods of use, and methods of treatment. We are seeking and maintaining patent protection in the United States and key foreign jurisdictions where we intend to market our product candidates, if they are approved.

Patent Rights Relating to Our TRB-061 Product Candidate

With respect to the TRB-061 product candidate, we own a patent family directed to this product candidate including composition of matter and methods of use. This patent family includes a granted United States patent and pending patent applications in numerous jurisdictions, including Argentina, the African Regional Intellectual Property Organization (ARIPO), Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, Egypt, the Eurasian Patent Organization, the European Patent Organization, Guatemala, India, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, New Zealand, Panama, Peru, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand, Ukraine, Vietnam, and the United States. The granted patent and the pending patent applications in this patent family, if issued, have a nominal expiration date of 2044, without accounting for any available patent term adjustments or extensions.

Patent Rights Relating to Our TRB-071 Product Candidate

With respect to the TRB-071 product candidate, we own a patent family directed to this product candidate including composition of matter and methods of use. This patent family includes a pending international PCT patent application and pending patent applications in Argentina, Taiwan and the United States. Patent applications in this family, or patent applications claiming priority to them, if issued, would have a nominal expiration date of 2046, without accounting for any available patent term adjustments or extensions.

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the United States Patent and Trademark Office ("USPTO") during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration of the patent. While 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, and only one patent per approved drug may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

Licenses and Collaborations

Our Research Collaboration and License Agreement with Lilly

On January 6, 2023, we entered into a Research Collaboration and License Agreement with Lilly, as amended by the First Amendment to the Research Collaboration and License Agreement dated June 24, 2026 (the "Lilly Collaboration Agreement"). The Lilly Collaboration Agreement is a research and development collaboration to advance product candidates directed to certain biological targets for the treatment of autoimmune disease. Under the Lilly Collaboration Agreement, we and Lilly agreed to collaborate to conduct research programs with respect to three target candidates, including TRB-051 (the "Licensed Programs"), using our proprietary technology platform and other resources, to develop molecules suitable for clinical testing. We granted Lilly and its affiliates an exclusive, worldwide license, with the right to sublicense through multiple tiers subject to certain restrictions, under our intellectual property related to the Licensed Program solely to develop, manufacture, commercialize, or otherwise exploit molecules and products for any and all purposes, uses, and indications, including diagnostic, prophylactic, and therapeutic uses, in humans and animals. Lilly has exercised its right under the Lilly Collaboration Agreement to terminate its rights and obligations with respect to two of the three Licensed Programs. The Lilly Collaboration Agreement remains in effect with respect to the sole remaining Licensed Program, TRB-051. Patent applications in the TRB-051 family, or patent applications claiming priority to them, if issued, would have a nominal expiration date of 2043, without accounting for any available patent term adjustments or extensions.

Pursuant to the Lilly Collaboration Agreement, Lilly paid us a one-time, non-refundable upfront payment of $55.0 million. In July 2024, we received a $15.0 million development milestone payment. We are eligible to receive additional development milestone payments of up to $70.0 million, commercial milestone payments of up to $157.5 million, and sales milestone payments of up to $350.0 million, in each case upon the achievement of certain development, commercial, and sales milestones for the sole remaining Licensed Program. We are also entitled to receive tiered royalties on net sales of Licensed Programs commercialized under the Lilly Collaboration Agreement, at rates ranging from six to ten percent of annual net sales on a product-by-product basis. Royalty payments are subject to potential partial or complete reductions in specified circumstances, including for third-party license payments, regulatory exclusivity, generic competition, and the absence of a valid patent claim. Lilly's obligation to pay royalties applies during the applicable royalty term on a country-by-country basis, which expires on the latest of (a) expiry of the last valid patent claim covering a Licensed Program in such country, (b) expiration of regulatory exclusivity for a Licensed Program in such country, or (c) the ten-year anniversary of the first commercial sale of a Licensed Program in such country. Upon expiration of the royalty term in a given country, the license granted to Lilly becomes fully paid-up, royalty-free, irrevocable, non-terminable, fully sublicensable, transferable, and perpetual with respect to a Licensed Program in such country.

The Lilly Collaboration Agreement contains commercially reasonable diligence obligations for each party with respect to their respective activities under the collaboration. Lilly is required to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize the Licensed Product in the United States and other specified major markets. During the term of the Lilly Collaboration Agreement, we are subject to exclusivity covenants providing that we shall not, and shall ensure that our affiliates do not, directly or indirectly conduct any development (including any preclinical or clinical research), manufacturing, or commercialization activities related to any compound, antibody, or product directed to the target for the Licensed Program, other than as permitted under the Lilly Collaboration Agreement. The Lilly Collaboration Agreement expires on a country-by-country and product-by-product basis at the end of the royalty term for such product in such country, unless earlier terminated. The Lilly Collaboration Agreement may be terminated (a) by either party for the other party's material breach, subject to applicable cure periods, (b) by Lilly for convenience on a Licensed Program basis or product-by-product basis upon specified prior written notice, or (c) by either party upon the other party's insolvency or bankruptcy filing.

If Lilly delivers a notice of discontinuation, the Lilly Collaboration Agreement will automatically be deemed terminated with respect to the sole remaining Licensed Program, subject to applicable post-termination rights and obligations. In certain circumstances following Lilly's discontinuation of development of the sole remaining Licensed Program, we will have an option to obtain specified reversion rights (the "Reversion Rights"). If we exercise our option to the Reversion Rights, we will obtain an exclusive, royalty-bearing, worldwide, transferable license and right of reference, with the right to sublicense through multiple tiers, to specified data, regulatory assets, patents and know-how controlled by Lilly and necessary to develop, manufacture and commercialize products developed from the sole remaining Licensed Program. Upon exercise of the Reversion Rights, we, our affiliates, or licensees will be required to pay Lilly tiered low-to-mid single digit royalties on net sales of products developed from the sole remaining Licensed Program based on annual net sales tiers. Such royalties will be payable on a product-by-product and country-by-country basis and apply during the applicable royalty term on a country-by-country basis, which expires on the latest of (a) expiry of the last valid patent claim covering a Licensed Program in such country, (b) expiration of regulatory exclusivity for a Licensed Program in such country, or (c) the ten-year anniversary of the first commercial sale of a Licensed Program in such country.

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 manufacturing organizations ("CMO") for both drug substance and finished drug product. We have engaged third-party manufacturers to supply the drug substances for our product candidates and a third-party manufacturer to develop and manufacture finished drug product for TRB-061 that we are using in our Phase 1 clinical trial. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

Our product candidates are manufactured using reliable processes from readily available starting materials. The approach is amenable to scale up and does not require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Government Regulation

Government authorities at the federal, state and local level in the United States and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of biological products such as those we are developing.

We, along with our CMOs, CROs and third-party vendors, will be required to satisfy these requirements in each of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes, regulations and other regulatory requirements, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

We are currently developing product candidates that are regulated as biological products, or biologics in the United States. In the United States, where we are initially focusing our product development, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA"), and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. Our product candidates are early-stage and have not been approved for marketing in the United States.

An applicant seeking approval to market and distribute a new biologic in the United States must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies, certain of which must be performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- manufacture of the drug substance and drug product in accordance with the FDA's current Good Manufacturing Practices ("cGMPs"), along with required analytical and stability testing;
- submission to the FDA of an investigational new drug application ("IND"), which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an independent institutional review board ("IRB") or independent ethics committee ("IEC"), representing each clinical trial site before each clinical trial may be initiated at that site;

- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice requirements ("GCPs"), necessary to establish the safety, potency and purity of the product candidate for each proposed indication;
- preparation and submission to the FDA of a Biologics License Application ("BLA"), requesting marketing approval, referred to as licensure, for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labeling;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of certain preclinical studies and clinical trial sites to assure compliance with GLPs and GCPs, as applicable, and the integrity of clinical data in support of the BLA;
- payment of user fees under the Prescription Drug User Fee Act ("PDUFA"), unless exempted;
- the FDA's review and approval of the BLA, including consideration of the views of any FDA advisory committee, if applicable; and

Failure to comply with the applicable requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process, or post-approval process, may subject an applicant to delays in the conduct of the study or regulatory review and approval, as well as administrative or judicial sanctions or other consequences. These sanctions or consequences may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, issuance of clinical holds for planned or ongoing studies, refusal to approve pending applications, suspension or revocation of existing product licenses or approvals, issuance of warning or untitled letters, adverse publicity, product recalls, marketing restrictions, product seizures, import detentions and refusals, total or partial suspension of manufacturing or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice ("DOJ"), and other governmental entities, including state agencies.

Preclinical Studies and Investigational New Drug Application

Once a therapeutic product candidate is identified for development, it must undergo preclinical studies (also known as nonclinical testing) before any testing may be conducted in humans. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animals. The conduct of certain preclinical tests and formulation of the compounds for testing must comply with applicable federal regulations and requirements, including GLPs. The results of the preclinical tests, together with manufacturing information, analytical data, protocols and plans for the proposed clinical studies, are submitted to the FDA as part of an IND. Some preclinical testing may continue after an IND is submitted.

An IND is a request for FDA allowance to administer an investigational drug product to humans. The IND must become effective before human clinical trials may begin in the U.S. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin. As a result, submission of an IND may or may not result in FDA allowance to begin a clinical trial, or to begin a clinical trial on the terms originally specified by the sponsor in the IND.

At any time during the initial 30-day IND review period or while clinical trials are ongoing under the IND, the FDA may impose a partial or complete clinical hold. Clinical holds may be imposed by the FDA when there is concern for patient safety, and may be a result of new data, findings, or developments in clinical, preclinical, and/or chemistry, manufacturing, and controls ("CMC"), or where there is non-compliance with regulatory requirements. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. Issuance of a clinical hold or partial clinical hold would delay either a proposed clinical trial or cause suspension of an ongoing trial (or portion of an ongoing trial in the case of a partial clinical hold), until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed.

Human Clinical Trials

Clinical trials involve the administration of an investigational drug product to healthy volunteers or patients with the disease or condition to be treated under the supervision of qualified investigators. Clinical trials must be conducted in accordance with GCPs, which establish ethical and data integrity standards for clinical testing, as well as the requirements for informed consent.

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Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted. While the IND is active, progress reports detailing the results of the clinical trials and preclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. 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.

For clinical trials conducted in the United States, an IND is required, and each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, and the safety of human subjects. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. An IRB must operate in compliance with FDA regulations.

The FDA, IRB or the trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the trial is not being conducted in accordance with GCPs or IRB requirements or that research subjects or patients are being exposed to an unacceptable health risk. 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 data monitoring committee. Depending on its charter, this group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA allowance to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived by the FDA. When a foreign clinical trial is not conducted under an IND, FDA may accept the results of the study in support of a BLA if the study was well-designed and conducted in accordance with GCPs, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population of healthy subjects or patients with the target disease or condition to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are generally conducted in a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, evaluate the preliminary efficacy of the product candidate for specific targeted indications and determine dosage tolerance and recommended dosage.
- Phase 3 clinical trials are generally undertaken to further evaluate efficacy, side effects and safety in an expanded patient population, typically at multiple, geographically dispersed clinical trial sites, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for regulatory approval and labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients within the approved therapeutic indication and are commonly intended to generate additional safety or effectiveness data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. Sponsors are required to publicly disseminate information about certain ongoing and completed clinical trials of FDA-regulated products on ClinicalTrials.gov, a government website administered by the National Institutes of Health.

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During the development of a new biologic, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times also may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to discuss the next phase of development.

Compliance with cGMPs

Concurrent with clinical trials, companies must finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMPs and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing controls for products like biologics whose attributes cannot be precisely defined. Material changes in manufacturing equipment, location, or process post-approval, generally require additional FDA review and approval.

Review and Approval of a BLA

The results of clinical trials and preclinical studies, together with detailed information regarding the manufacturing processes, chemistry and composition of the product candidate, the proposed labeling and other relevant information, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more specified indications. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, and potency of the investigational product to the satisfaction of the FDA. For most BLAs, the sponsor is required to pay a substantial application user fee at the time of submission and the sponsor of an approved BLA is subject to an annual program fee; the amounts of these fees are adjusted each fiscal year. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA conducts a preliminary review within the first 60 days after submission of a BLA to determine whether to accept it for filing based on the FDA's threshold determination that the BLA is sufficiently complete to permit substantive review. During that time, the FDA may request additional information before deciding whether to accept a BLA for filing. If the FDA determines that a BLA is not sufficiently complete to permit substantive review, it will issue a refuse-to-file determination and the BLA will not be substantively reviewed by the FDA. If the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has a goal of ten months from the filing date in which to complete a standard review of an original BLA and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process may be extended, including for a three-month period, if needed for FDA to respond to information deemed a "major amendment" to the application.

During its review of a BLA, the FDA may refer applications for biological products to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of any inspections of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites conducted to assure compliance with GLPs or GCPs, the FDA may approve the BLA or issue a complete response letter ("CRL"). Under the PHSA, the FDA may approve a BLA if it determines the product is safe, pure, and potent for its intended uses, and that the facility in which the product will be manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. If FDA determines the product meets these standards, it may issue an approval letter authorizing the commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a CRL, which indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL will contain the conditions that must be met in order to secure approval of a resubmitted application, and when possible, will outline recommended actions the sponsor might take to obtain approval of a resubmitted application. A CRL may require additional clinical data and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Sponsors that receive a CRL generally have one year to resubmit the application with information that represents a complete response to the deficiencies identified by the FDA. The FDA will then re-review the resubmitted application, taking into consideration the response, and determine whether the application meets the criteria for approval. Failure to respond to a CRL will serve as a withdrawal of an application. The FDA will not approve an application until issues identified in any CRLs have been addressed.

If the FDA approves a biological product, it may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical trials, to further assess the product's continued safety, purity, and potency after approval. The FDA may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a Risk Evaluation and Mitigation Strategy ("REMS"), to help ensure that the benefits of the product outweigh the potential risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and can include medication guides, communication plans for healthcare professionals and elements to assure safe use (also known as "ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, restricted distribution methods, special monitoring, the use of patient registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

After approval, certain modifications to the approved product, including changes in the indications, dosage forms, labeling, or manufacturing processes or facilities, generally require the BLA sponsor to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the generation of additional data or the conduct of additional preclinical studies and clinical trials.

Post-Approval Regulation

Upon FDA approval of a BLA, the sponsor will be required to comply with all post-approval requirements for biologics, as well as any specific post-approval requirements that the FDA has imposed as part of the approval process. Among other things, the BLA sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information, obtain FDA approval for certain manufacturing and labeling changes, and comply with requirements concerning advertising and promotional labeling, record-keeping, and drug supply chain security. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections for compliance with ongoing regulatory requirements, including cGMPs. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control, as well as pharmacovigilance activities, to maintain compliance with cGMPs and other regulatory requirements.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products, including biological products. Among other things, the FDA generally prohibits pharmaceutical companies from promoting their drugs for uses that are not approved by the FDA as reflected in the product's approved labeling, although a physician may prescribe a drug for such off-label uses in accordance with the practice of medicine. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Additionally, promotional materials for prescription drug products must be submitted to the FDA at the time of first use.

The FDA may withdraw product approval if compliance with regulatory requirements and standards is not maintained or if issues occur after the product reaches the market. Later discovery of previously unknown issues with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, including total or partial suspension of production, or complete withdrawal of the product from the market;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- warning letters or untitled letters;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure or detention, or refusal to permit the import or export of products;
- imposition of clinical holds on ongoing clinical trials;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or
- fines, injunctions or the imposition of civil or criminal penalties.

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FDA Regulation of Combination Products

Certain therapeutic products are comprised of multiple FDA-regulated components, such as drugs, biologics and medical devices, that are physically combined and produced as a single entity, packaged together in a single package, or packaged separately but intended to be labeled for use together. These products are known as combination products. We expect that TRB-061 and our other product candidates, if packaged in a prefilled syringe or autoinjector, would be subject to regulation as a combination product if consisting of a therapeutic biologic and a delivery device.

The constituent elements of such combination products would normally be subject to different FDA regulatory frameworks and regulated by different Centers at the FDA. 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.

Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application; however, FDA could require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort and information. Even when a single marketing application is required for a combination product, such as a BLA for a combination biologic and device product, both FDA's Center for Biologics Evaluation and Research and FDA's Center for Devices and Radiological Health may participate in the review. For example, if a product candidate is considered a biologic-device combination product, the sponsor will also need to comply with any post-marketing regulatory requirements applicable to both product types, including among other things, cGMPs for biological products and applicable portions of the FDA's Quality Management System Regulation, applicable to medical device products.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA has several programs intended to facilitate and expedite development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include, among others, Fast Track designation, Breakthrough Therapy designation and priority review designation. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs.

The FDA may designate a product candidate for Fast Track designation if it is intended, whether alone or in combination with one or more other drugs or biologics, for the treatment of a serious or life-threatening disease or condition, where preclinical or clinical data demonstrate the potential to address unmet medical needs for such a disease or condition. Fast Track designation applies to both the product and the specific indication for which it is being studied. For product candidates with Fast Track designation, sponsors may have more frequent interactions with the FDA, and, once a BLA 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 NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate may be designated as a Breakthrough Therapy if it is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, where preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in development. The designation includes all of the Fast Track program features. Additionally, the FDA may take certain actions to expedite the development and review of breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff managers in the review process; assigning a cross-disciplinary lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a BLA for priority review if the applicable product candidate treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. A priority review designation is intended to direct the FDA's attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original BLA from ten months to six months from the filing date.

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Fast Track designation, Breakthrough Therapy designation, and priority review do not change the standards for approval but may expedite the development or approval process. Even if a drug qualifies for one or more of these programs, the FDA may later withdraw or rescind the designation if it decides that the drug no longer meets the conditions for qualification.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides a meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. 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. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

The FDA's approval of a candidate product under the accelerated approval pathway is usually contingent on a sponsor's agreement to conduct confirmatory studies to verify and describe the product's clinical benefit, and the FDA may require such studies to be underway prior to approval. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the confirmatory studies, or dissemination of false or misleading promotional materials may allow the FDA to withdraw the product approval on an expedited basis. In addition, for products being considered for Accelerated Approval, the FDA generally requires, unless otherwise informed by the FDA, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency FDA for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Development in Pediatric Patients

Under the Pediatric Research Equity Act of 2003, as amended ("PREA"), a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective (or safe, pure and potent). A sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit a Pediatric Study Plan ("PSP") that contains an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor and the FDA must reach agreement on the PSP. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of exclusivity to the end of the term of any existing regulatory exclusivity or patent period. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of patent or exclusivity term remaining. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials or obtain approval for use in the studied pediatric indication.

Biosimilars and Exclusivity

The Affordable Care Act ("ACA"), which was signed into law in March 2010, included the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").

The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars.

Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. This 12-year exclusivity period is referred to as the reference product exclusivity period and bars approval of a biosimilar but notably does not prevent approval of a competing product pursuant to a full BLA (i.e., containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the product). The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability prior to the approval of the biosimilar. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state regulated, to regulate the use of biosimilars.

U.S. Patent Term Restoration and Extension

In the United States, a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent extension of up to five years for a single patent for an approved product to compensate for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent is typically one-half the time between the effective date of the IND and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Federal and State Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations, and standards govern the collection, use, access to, confidentiality, security, and other processing of personal information, including health-related information such as clinical trial data, and could apply now or in the future to our operations or the operations of our partners. For example, in the United States numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, comprehensive data privacy, and consumer protection laws and regulations, govern the collection, use, disclosure, protection, and other processing of personal information. Further, to the extent we collect personal information from individuals outside of the United States, through clinical trials or otherwise, we could be subject to foreign laws, which govern the privacy and security of personal information.

These statutory regimes also increase uncertainty with respect to the cross-border transfer of personal information, even with respect to service providers. For example, the U.S. Department of Justice, pursuant to Executive Order 14117, has put into effect a data security program (the "Data Security Program") that restricts, and in some cases prohibits, access by certain countries of concern such as the People's Republic of China (including Hong Kong and Macau) to certain U.S. government-related data and bulk human'omic, geolocation, biometric, health, financial, and other sensitive personal data, even if those data are de-identified, anonymized or encrypted. Entities organized under the laws of the United States as well as U.S. persons are restricted in their ability to provide access to such data to such countries as well as "covered persons" that have certain nexuses to such countries, and they are also required to prohibit foreign parties from making an "onward transfer" of such data to countries of concern and covered persons. These restrictions may result in an inability to realize the full value of such data, to use such data effectively or efficiently, or to engage in some data transactions that would otherwise be available to entities not subject to the Data Security Program. These international data restrictions may also limit our ability to develop insights and transfer data as our business would otherwise find more desirable and they may limit potential investments. Failure to comply with these restrictions could lead to civil or criminal penalties.

Because of the breadth of these laws and regulations and the narrowness of the statutory exceptions under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such data privacy and security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that we may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any applicable data privacy or security laws or regulations, we may be subject to penalties, including potentially significant civil and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, 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.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not a sponsor obtains FDA approval for a product, the sponsor must obtain the requisite approvals and authorizations from the appropriate regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, much like the IND, prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. Generally, no action can be taken to market any product in a country until an appropriate marketing application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

The processes governing approval of medicinal products in the EU and UK generally adopt a similar approach to that applied in the U.S. They entail satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. Data should be generated to demonstrate that a drug substance and a drug product can be manufactured and controlled according to the pre-specified quality standards. The data relating to quality, preclinical testing and clinical trials should be submitted to the relevant competent authorities in a marketing authorization application ("MAA") for regulatory review in order to determine whether a marketing authorization can be granted. Even after a marketing authorization is granted, each European country must approve pricing and reimbursement before the new medicine can be widely used in its national health system.

Clinical Trial Approval

Pursuant to the currently applicable Regulation (EU) No 536/2014 ("CTR") and Directive 2005/28/EC on GCP, an applicant must obtain approval from the national competent authority of, and a research ethics committee established in, each EU member state in which the clinical trial is to be conducted. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the CTR and corresponding national laws of the member states. All suspected unexpected serious adverse reactions to the investigational medicinal product that occur during the clinical trial have to be reported to the national competent authorities and research ethics committees of the member state where they occurred.

Pursuant to the CTR, a sponsor must submit a single application for a new clinical trial authorization through a centralized EU clinical trials portal called the Clinical Trials Information System ("CTIS"). One national competent authority (from the reporting EU member state selected by the applicant) takes the lead in validating and evaluating the application, as well as consulting and coordinating with the other concerned member states in which the clinical trial is to be conducted. If an application is rejected, it may be amended and resubmitted through CTIS. A concerned member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in that member state. The CTR aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the CTIS.

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The UK formally left the EU on January 31, 2020, under the terms of the Agreement on the withdrawal of the UK of Great Britain and Northern Ireland from the EU and the European Atomic Energy Community (the "EU-UK Withdrawal Agreement"). Despite this, EU law continued to apply in the UK until the expiry of the transition period on 31 December 2020. Following the UK's departure from the EU, the UK and the EU entered into a trade and cooperation agreement ("TCA"), which includes specific provisions concerning pharmaceuticals (such as the mutual recognition of cGMP inspections of manufacturing facilities for medicinal products and cGMP documents issued), but which does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At the point that the transition period expired, the Northern Ireland Protocol, which is contained in the EU-UK Withdrawal Agreement, took effect. The Northern Ireland Protocol makes certain provisions of EU law, including several concerning medicinal products, applicable in Northern Ireland. This position was subsequently revised via the Windsor Framework. Under the Windsor Framework, since January 1, 2025, all new medicinal products for the UK market have been authorized by the UK's Medicines and Healthcare products Regulatory Agency ("MHRA") (see further below).

In the UK, clinical trials of medicinal products are primarily governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended (the "UK Regulations"). The UK Regulations sought to implement the Directive 2001/20/EC while the UK was a member state of the EU. Since the CTR was not in force in the EU at the time when the UK exited the EU, it was not retained in UK law on exit day under the terms of the European Union (Withdrawal) Act 2018. Building on the foundation of the 2004 Regulations, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, enacted under the Medicines and Medical Devices Act 2021, establish a modernized framework for clinical trials in the UK and came into operation on 28 April 2026. The regime streamlines approvals, introduces binding timelines, and enhances transparency and participant protections, aligning UK requirements with international standards.

Accelerated Assessment Pathways

The EU's Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and facilitates accelerated assessment of medicinal products representing substantial innovation reviewed under the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Economic Area ("EEA") or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by, for example, introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme. Many benefits accrue to sponsors of therapeutic candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, an EMA contact and rapporteur from the Committee for Human Medicinal Products ("CHMP"), or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

The UK's Innovative Licensing and Access Pathway ("ILAP") aims to accelerate the time to market of innovative medicinal products. It is open to both commercial and non-commercial applicants, who are based in the UK or outside the UK, and who are developing medicinal products which include novel products (i.e. no other product exists in clinical practice that uses the same mechanism of action such as a first in class molecule), products containing new chemical or biological entities, products which feature new or a novel modification of existing technologies, and approved medicinal products being developed in a clinically significant new indication. It comprises of an Innovation Passport designation and a Target Development Profile, and provides applicants with access to a toolkit to support all stages of the design, development and approvals process. The major benefit of the ILAP scheme is that it provides applicants with opportunities for enhanced regulatory and stakeholder input during the development of their medicinal products.

Marketing Authorization

To obtain a marketing authorization for a medicinal product under the EU regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU member states (national, decentralized or mutual recognition procedures). A marketing authorization may be granted only to an applicant established in the EU.

Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the EU, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP"), covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP. The Paediatric Committee of the EMA ("PDCO"), may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for

children is not needed or is not appropriate, such as for diseases that only affect the elderly population. An application for marketing authorization or a variation or a line-extension which is accompanied by the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for a six months extension of their supplementary protection certificate. This pediatric reward is not automatically available and is subject to the EMA or the relevant national competent authorities confirming compliance with the agreed PIP that may require an opinion to be given by the EMA's Pediatric Committee.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, as well as the additional member states of the EEA (Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines developed by means of certain biotechnological processes (including, recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods), products designated as orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products containing a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer, HIV / AIDS, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance which was not authorized in the EU on May 20, 2004, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. An applicant for the centralized MA must demonstrate the quality, safety and efficacy of their products to the EMA for an opinion to be adopted regarding the approvability of the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Under the centralized procedure, the CHMP established within the EMA is responsible for conducting an initial assessment of a medicinal product. The maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued ordinarily within 67 days of receipt of the EMA's recommendation. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

National marketing authorizations, which are issued by the national competent authorities of the member states of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a medicinal product has already been authorized for marketing in a member state of the EEA, this national marketing authorization can be recognized in other member states through the mutual recognition procedure. If the product has not received a national marketing authorization in any member state at the time of application, it can be approved simultaneously in two or more member states through the decentralized procedure.

Pursuant to the Windsor Framework, since January 1, 2025, all medicinal products intended for commercialization in the UK market have been subject to authorization by the Medicines and Healthcare Regulatory Agency ("MHRA"). In this regard, the MHRA will grant a single UK-wide marketing authorization for all medicinal products intended for sale in the UK.

Following its departure from the EU, the UK has introduced changes to its national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, ILAP (described above) and new routes of evaluation for novel products and biotechnological products. Notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the Trade and Cooperation Agreement ("TCA"), and that EU marketing authorizations do not provide a valid basis for the commercialization of medicinal products in the UK, applicants will be able to request the MHRA to recognize marketing authorizations granted in foreign jurisdictions (including the EU) under the International Recognition Procedure.

Regulatory Data Protection in Europe

In the EU and the UK, new chemical entities (including both small molecules and biological medicinal products) and new biological substances approved on the basis of a complete independent data package consisting of quality, preclinical testing results and clinical trial data qualify for eight years of Regulatory Data Protection ("RDP") upon grant of a marketing authorization and two years of marketing protection. Data protection prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the MAA dossier of the reference medicinal product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. During the two-year period of marketing protection, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. Even if a generic or biosimilar medicinal product is approved, it

cannot be marketed until the expiration of the marketing protection. The ten-year protection period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical or a new biological entity so that the innovator gains the prescribed period of data protection, another company may market another version of the medicinal product if such company obtained marketing authorization based on an MAA with a complete and independent data package consisting of pharmaceutical and preclinical testing results and clinical trial data.

Patent Term Extensions in the EU and Other Jurisdictions

The EU also provides for patent term extension through Supplementary Protection Certificate ("SPCs") which aim to offset the loss of patent protection for pharmaceutical products arising from the lengthy testing and clinical trials required to obtain a marketing authorization. The rules and requirements for obtaining a SPC are similar to those in the U.S. An SPC may extend the term of a basic patent for up to five years after its originally scheduled expiration date in order to provide up to a maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains a marketing authorization for it to be placed on the market. As mentioned above, in certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained. Although SPCs are available throughout the EU, holders must apply the patent term extension on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the EU.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed indefinitely after five years on the basis of a reevaluation of the risk-benefit balance by the EMA, the competent authority of the authorizing member state, or the MHRA. To that end, the marketing authorization holder must provide the EMA, the relevant national competent authority, or the MHRA with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization expiry date. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission, the relevant national competent authority, or the MHRA decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any marketing authorization ceases to be valid if it is not followed by the placement of the medicinal product on the EU market (in the case of the centralized procedure), on the market of the authorizing member state (in the case of a national procedure), or the UK market (as applicable), within three years after grant of such an authorization.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product, and must adhere in strict compliance with the applicable EU laws, regulations and guidance. These include compliance with stringent pharmacovigilance rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, manufacture and control must also be conducted in strict compliance with cGMP requirements and comparable requirements of other regulatory bodies in the EU and UK. cGMP requirements apply to the methods, facilities and controls used in manufacturing, processing and packing of drugs against the quality standards appropriate to the intended use of a medicinal product and as required by the marketing authorization, clinical trial authorization or product specification.

Much like the federal healthcare program anti-kickback law in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU and the UK. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery or anti-gifts laws of EU member states and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. Applicable law in Europe further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

Pursuant to national laws, industry codes or professional codes of conduct, payments made to physicians in certain EU member states and the UK must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states, or the UK (as applicable). Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU and the UK. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, which was transposed into national law in the UK via the Human Medicines Regulations 2012, the details are governed by regulations in each European jurisdiction and can differ from one country to another.

EU Regulatory Reforms

Proposed reforms to the existing EU pharmaceutical law and regulation governing the biotechnology sector have been set out in the EU Pharma Package and the Biotech Act. The EU Pharma Package has been passed by the EU legislature and is expected to enter into force in late 2026, which will trigger a transition period until 2028. The new legislation will fully come into application and become operational in 2028. In contrast, the Biotech Act is still progressing through the legislative process and has not yet been adopted. These legislative reforms represent significant change, introducing streamlined authorization procedures, enhanced measures to improve access and affordability, stricter management of medicine shortages, strengthened post-market surveillance, and new requirements addressing environmental and ethical considerations.

The EU Pharma Package aims to modernize and harmonize medicines regulation, improve patient access to innovative therapies, and strengthen oversight of emerging technologies across the EU. Under its consolidated draft, companies launching new medicines will receive eight years of data protection and one year of market exclusivity, with a potential additional year for qualifying innovative products. The package allows EU countries to require adequate supply of protected medicines, introduces safeguards against misuse in parallel trade, and provides intellectual property exemptions for generic manufacturers to prepare for immediate market entry after patent expiry, including for procurement submissions. It also establishes a transferable exclusivity voucher to incentivize priority antibiotic development, with a "blockbuster clause" limiting its use for products with annual sales over €490 million.

The Biotech Act seeks to further harmonize regulations, accelerate market access for biotechnology products, and amend the Clinical Trials Regulation for faster trial assessments. Together, these reforms aim to create a more efficient, responsive, and unified regulatory framework for pharmaceuticals and biotechnology in the EU General Data Protection Regulation.

The processing of personal data regarding individuals in the EU, including personal health data, is regulated by Regulation (EU) 2016/679, which took effect on May 25, 2018. The General Data Protection Regulation ("GDPR") is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require us to change our business practices to ensure full compliance.

As of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, along with the UK (Data Use and Access) Act 2025, which made a number of relatively minor amendments to the UK GDPR. The UK's data protection regime is therefore independent and differs slightly from, but is still broadly aligned with, the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the U.S. and markets in other countries, patients who are prescribed treatment for their conditions generally rely on third-party payors to reimburse all or part of the associated healthcare costs. The availability of coverage and the adequacy of reimbursement by governmental healthcare authorities or programs such as Medicare and Medicaid, private health insurance and third-party payors is critical to new product acceptance.

Third party payors decide which medications they will pay for and establish reimbursement levels. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product, or will provide coverage at an adequate reimbursement rate.

Within the U.S., third-party payors are increasingly seeking to control drug costs by examining the cost-effectiveness of new products and services in addition to their safety and efficacy. To obtain or maintain coverage and reimbursement for any future product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals, and product candidates may still not be considered medically necessary or cost effective. Third-party payors may limit coverage of product by, for example, only covering specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Some third-party payors may manage utilization of a particular product by requiring patients to try other therapies first or by requiring pre-approval (known as "prior authorization") for coverage of particular prescriptions (to allow the payor to assess medical necessity) or otherwise restricting coverage of a product even if used consistent with its approved indication. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval from one or more third-party payors, less favorable coverage policies and reimbursement rates may be implemented in the future. A decision by a third-party payor not to cover a product could reduce utilization if the product is approved.

Manufacturers of marketed drugs may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. More generally, price concessions may need to be offered to third-party payors to obtain favorable coverage or to purchasers to achieve sales. Hospitals and health systems are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Arrangements with third-party payors or purchasers may include value-based arrangements under which the amount paid for products depends on the performance of the product. Net prices for drugs may be further reduced by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular medicinal product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any product candidate. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

Health care reform has been a significant trend in the U.S. health care industry and elsewhere. In particular, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services. Health care reform, specifically reform addressing pricing and payment for drugs, has been an ongoing focus and is likely to continue under the current presidential administration. A number of healthcare reforms involving drugs have been successfully implemented, including reforms related to Medicare payment for drugs and manufacturer rebate obligations under the Medicaid Drug Rebate Program.

There has been heightened governmental scrutiny in recent years over the manner in which manufacturers set prices for their marketed products, which has resulted in proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing and reform government program reimbursement methodologies for pharmaceutical and biologic products. At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

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We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

For a more detailed discussion of health care reform in the U.S., see "Risk Factors—Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set."

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain how we conduct our business, including the financial arrangements and relationships through which we research and develop, as well as sell, market and distribute any product candidates for which we obtain marketing authorization. In the U.S., restrictions under applicable federal and state healthcare laws and regulations, some of which will apply only if and when we receive marketing approval for a product candidate, include, without limitation, the following:

- Federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing, ordering or recommending of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- Federal false claims, false statements and civil monetary penalties laws which prohibit, among other activities, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement material to an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements to obtain money or property from a health benefit program. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- The Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- Federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to calculate, certify and report certain complex calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- The so-called "federal sunshine" law, which requires certain pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians (as defined by statute), 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, to the federal government for re-disclosure to the public;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;
- analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers; and

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- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to file reports relating to pricing and marketing information, and state and local laws may require registration of pharmaceutical sales representatives; and other state laws that require licensure for, or otherwise regulate, the manufacture and distribution of pharmaceutical products.

Violation of any of the laws described above or any other government regulations that apply to pharmaceutical manufacturers may result in penalties, including significant civil, criminal and administrative penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of operations.

Employees and Human Capital

As of August 31, 2026, we had approximately 60 full-time employees based at our principal offices in South San Francisco, California, of whom 26 hold PhD or MD degrees, and 47 are engaged in research and development functions. Our founding scientists bring deep expertise in human Treg biology, tissue immunology, single-cell transcriptomics, and protein engineering, and our broader team includes experienced drug developers across clinical operations, CMC, regulatory affairs, and translational medicine.

We offer competitive compensation, including base salary, annual performance bonuses, and equity-based compensation, as well as comprehensive benefits including medical, dental, and vision coverage, a 401(k) plan, and paid time off. We believe our culture of scientific rigor, collaborative discovery, and patient-centered mission is central to our ability to attract and retain the talent required to advance our pipeline. We have not experienced any work stoppages and consider our employee relations to be good.

Facilities

Our principal offices and research facilities are located in South San Francisco, California, where we lease approximately 33,780 square feet of laboratory and office space under a lease agreement expiring in 2028. We believe our current facilities are adequate to support our near-term research, development, and administrative activities, and that suitable additional space will be available on commercially reasonable terms as our needs grow.

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings or claims arising in the ordinary course of our business. We do not believe that any such proceedings currently pending, if any, would have a material adverse effect on our business, financial condition, or results of operations.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this prospectus.

Name	Age	Position(s)
Executive Officers and Employee Directors:		
M. Johnston Erwin, Jr.	65	Chief Executive Officer and Chair
Laura Berner	52	Chief Operating Officer
Brandon Hants	50	Chief Financial Officer
Ariella Kelman	52	Chief Medical Officer
Ali Zarrin	62	Chief Scientific Officer
Non-Employee Directors:		
Carol G. Gallagher	62	Director and Lead Independent Director
Alexandra Cantley*	39	Director
Travis Coy	46	Director
Julie Gilmore	55	Director
Peter Hirth	75	Director
Eric Huang*	55	Director
Joel S. Marcus	79	Director
Sanjay Mistry*	55	Director
Christopher O'Donnell*	57	Director
Eric Pham*	37	Director
Michael Ross	77	Director
Nikola Trbovic*	44	Director

* Drs. Cantley, Huang, Mistry, O'Donnell, Pham and Trbovic have each resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Executive Officers and Employee Directors

M. Johnston Erwin, Jr. has served as our Chief Executive Officer and a member of our board of directors since May 2021 and has served as chair of our board of directors since October 2026. He has over 40 years of experience in leadership roles across regulatory, clinical and corporate development. Prior to joining TRexBio, Mr. Erwin spent 36 years at Eli Lilly and Company. Between 2014 and 2021, he led Lilly New Ventures, Lilly's internal venture capital investment team, serving on the board of a number of private biopharma companies. During his tenure, Lilly New Venture's invested capital grew more than five times and was cash-on-cash positive for seven consecutive years. At his retirement, Lilly had more than 45 direct investments. Earlier in his career, Mr. Erwin led the clinical team which made global regulatory submissions for the brands of Evista and Forteo. Under his leadership, both brands were approved in more than 80 countries and each reached greater than $1 billion in worldwide sales. Mr. Erwin received his BAS from Oregon State University. We believe that Mr. Erwin is qualified to serve on our board of directors because of his operational and leadership experience in the pharmaceutical and biotechnology industries and his venture capital experience.

Laura Berner, JD, MBA has served as our Chief Operating Officer since May 2022. She joined TRexBio as Chief Business Officer in August 2020, and drives our strategic, business and corporate development matters. Ms. Berner has 25 years of experience across business strategy, corporate development and legal affairs at public and private biopharmaceutical companies. Since joining TRexBio, she has overseen our equity financings and the execution of our pharma collaborations. Prior to TRexBio she was Head of Business Development and Investor Relations at Myovant Sciences, which was acquired by Sumitovant Biopharma Ltd. Earlier in her career she led significant partnering and merger and acquisitions transactions for the pharmaceutical divisions at Roche and Genentech. She started her career as a corporate and life sciences transactions attorney in private practice. Ms. Berner obtained her BA in biology from Bryn Mawr College, her JD from Stanford Law School and her MBA from the University of Illinois Urbana-Champaign (Gies). She currently serves on the board of directors of Bolt Biotherapeutics.

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Brandon Hants, MBA, has served as our Chief Financial Officer since February 2025. Prior to joining us, Mr. Hants served as chief financial officer at Applied Molecular Transport, a clinical stage biotherapeutics company that developed a pipeline of novel oral biologic product candidates. Prior to that, he held various roles at Singulex, Inc., an immunodiagnostics company, including chief financial officer and vice president of finance and operations. Prior to Singulex, Mr. Hants held roles of increasing responsibility at Novartis Vaccines & Diagnostics and Genentech. Mr. Hants holds a BS in Cell and Developmental Biology from the University of California, Santa Barbara, and an MBA from the University of San Francisco.

Ariella Kelman, MD, has served as our Chief Medical Officer since March 2025. Previously, Dr. Kelman served as chief medical officer at Biora Therapeutics, and before that, she led clinical development at Human Immunology Biosciences. Prior to that, Dr. Kelman spent 15 years at Genentech, where she led clinical development programs for several new medicines for inflammatory and autoimmune diseases and subsequently served as global head of bioethics for Roche. Dr. Kelman was an attending physician for 10 years in the Division of Immunology and Rheumatology at Stanford University Hospital. Dr. Kelman holds a BS from UCLA, and an MD from Tel Aviv University. She completed her residency in internal medicine at Kaiser Hospitals in Los Angeles and Santa Clara and completed fellowships in rheumatology and clinical research at Stanford University Hospital.

Ali Zarrin, PhD, has served as our Chief Scientific Officer since August 2025. He joined TRexBio in August of 2019 and has led the development of our proprietary Deep Biology platform and the translational activities for our product candidates. Dr. Zarrin is an accomplished immunologist with more than 25 years of experience across immunobiology, drug discovery and translational immunology. Prior to TRexBio, Dr. Zarrin held leadership roles in Early Research and Development at Genentech, with a focus on autoimmune and inflammatory diseases. He is an inventor on multiple patents and has authored close to 50 scientific publications in leading journals. Dr. Zarrin earned his BS from the University of Minnesota, his PhD in Immunology from the University of Toronto, and conducted postdoctoral studies in the laboratory of pioneering geneticist and molecular immunologist Fred Alt at the Howard Hughes Medical Institute and Harvard Medical School.

Non-Employee Directors

Carol G. Gallagher, PharmD, has served as a member of our board of directors since July 2019 and as our lead independent director since October 2026. From January 2025 through September 2026, Dr. Gallagher served as the chair of our board of directors, and from September 2020 through January 2025, Dr. Gallagher served as executive chair of our board of directors. From October 2014 to December 2023, Dr. Gallagher served as a partner, venture partner and venture advisor at New Enterprise Associates, a venture capital firm. Prior to joining New Enterprise Associates, Dr. Gallagher served as a venture partner with Frazier Healthcare, a venture capital firm, from October 2013 to September 2014. Dr. Gallagher served as the president and chief executive officer of Calistoga Pharmaceuticals, a biopharmaceutical company, from 2008 to 2011, when the company was acquired by Gilead Sciences, Inc. From 2007 to 2008, Dr. Gallagher was the president and chief executive officer of Metastatix, Inc., a biopharmaceutical company. Prior to that time starting in 1989, she served in various roles at pharmaceutical companies, including at Eli Lilly and Company, Amgen, Inc., and Pfizer. Dr. Gallagher serves on the board of directors of Atara Biotherapeutics, Inc. and PMV Pharmaceuticals, Inc. Dr. Gallagher attended Vanderbilt University and holds a B.S. and Doctor of Pharmacy degrees from the University of Kentucky. We believe that Dr. Gallagher is qualified to serve on our board of directors due to her extensive experience in the pharmaceuticals industry, her leadership and management experience, and her service as a director of other biopharmaceutical companies.

Alexandra Cantley, PhD, has served as a member of our board of directors since February 2022. Dr. Cantley joined Polaris Partners in April 2019 and has served as a partner since June 2021. From August 2017 to April 2019, Dr. Cantley was a part of the initial research team at Inzen Therapeutics. Prior to this, she was a research fellow at Vertex Pharmaceuticals. Dr. Cantley attended New York University and holds a PhD in chemical biology from Harvard University. We believe that Dr. Cantley is qualified to serve on our board of directors due to her extensive experience in the pharmaceuticals industry and her service as a director of other biopharmaceutical companies. Dr. Cantley has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Travis Coy has served as a member of our board of directors since November 2021. Mr. Coy has served as the chief financial officer and head of corporate development at Immunocore Holdings plc since January 2025. Previously, Mr. Coy served as vice president, head of transactions and M&A, corporate business development at Eli Lilly and Company from October 2019 to December 2024. Prior to this role, Mr. Coy had a variety of finance and business development experiences at Lilly beginning in 2003, including positions as vice president, transactions – oncology and diagnostics; vice president, transactions – cardiometabolic diseases, drug delivery and devices; finance director of the oncology business unit; director of investor relations; director of corporate finance and investment banking; and other financial controllership roles. Before transitioning to finance and business development, he was a chemist in Lilly's research laboratories and a production manager for Milliken & Company. Mr. Coy has also been a member of the board of directors at Immunocore Holdings plc since September 2019. Mr. Coy holds a BS in Chemistry from Rose-Hulman Institute of Technology and an MBA from the Ross School of Business at the University of Michigan. We believe that Mr. Coy is qualified to serve on our board of directors due to his extensive experience in the pharmaceuticals industry and his leadership and management experience.

Julie Gilmore, PhD, has served as a member of our board of directors since December 2024. Dr. Gilmore has spent nearly 20 years at Eli Lilly and Company, serving as vice president and global head of Gateway Labs by Lilly and Catalyze360 Portfolio Management. She also serves on the board of IgGenix, Inc. and Mozart Therapeutics. She received a PhD in biophysics from Purdue University and attended Indiana University School of Medicine as a post doctoral fellow studying membrane biophysics. We believe that Dr. Gilmore is qualified to serve on our board of directors due to her extensive experience in the pharmaceuticals industry.

Peter Hirth, PhD, has served as a member of our board of directors since July 2019. Dr. Hirth has over 30 years of experience in biotechnology and pharmaceutical discovery and development. Prior to entering the biotechnology sector, Dr. Hirth served as vice president of Research at Boehringer Mannheim in Germany. From 1991 to 2000, he held several positions at Sugen, Inc., ultimately serving as President, where he helped build the company from inception and advance kinase inhibitors through clinical trials in oncology. Sugen was acquired by Pharmacia/Pfizer in 1999. In 2001, Dr. Hirth co-founded Plexxikon, Inc., a pharmaceutical company, and served as its chief executive officer until April 2013. Plexxikon was acquired by Daiichi Sankyo in 2011. Dr. Hirth currently serves on the board of directors of Aligos Therapeutics, IO Biotech, Inc., and several private companies. He previously served on the board of directors of Vaxcyte, Inc. from January 2017 to April 2025. Dr. Hirth holds an MSc and PhD in Molecular Genetics from Heidelberg University, Germany and completed his post-doctoral work at the University of California, San Diego. We believe that Dr. Hirth's extensive experience in the biopharmaceutical and biotechnology industries, his proven track record of building companies from inception through successful exits, and his educational background provide him with the qualifications and skills necessary to serve as a member of our board of directors.

Eric Huang, PhD, has served as a member of our board of directors since November 2024. Dr. Huang has served as a partner at Delos Capital since April 2024. From May 2012 to April 2024, Dr. Huang worked for Moderna Inc. serving as the founding Chief Science Officer of Moderna's New Ventures Labs and Autoimmune Therapeutic Area, and most recently General Manager and Chief Scientific Officer of Moderna Genomics. Dr. Huang also serves as a director on the board of Taigen Bioscience. Dr. Huang received a BS in biology from Emory University, a PhD in molecular and medical parasitology from New York University and an MBA from Boston University's Questrom School of Business. We believe that Dr. Huang is qualified to serve on our board of directors due to his extensive experience in the pharmaceuticals industry. Dr. Huang has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Joel S. Marcus, JD, CPA, has served on our board of directors since November 2024. Mr. Marcus is the Executive Chairman and Founder of Alexandria, a real estate investment trust ("REIT") that pioneered life science real estate and transformed it from a specialty niche to a mainstream asset class. Since co-founding the company in 1994, Mr. Marcus has led its remarkable growth into a leading REIT focused on the life science industry. Prior to April 2018, Mr. Marcus served as the company's Chairman, Chief Executive Officer, and President. Mr. Marcus founded Alexandria Venture Investments, the company's strategic venture capital platform, in 1996. Alexandria Venture Investments actively invests in disruptive life science companies that are advancing transformative new modalities, platforms, and innovative medicines to meaningfully improve human health. Some of its most notable early-stage investments include Alnylam Pharmaceuticals, Google, Intra-Cellular Therapies, and Moderna. Mr. Marcus also served on the board of directors of Intra-Cellular Therapies, Inc. from 2006 until its acquisition by Johnson & Johnson in 2025. Prior to co-founding Alexandria, Mr. Marcus had an extensive legal career and was one of the principal architects of the 1984 Kirin-Amgen, Inc. joint venture. He was also a practicing certified public accountant and tax manager with Arthur Young & Co. He earned his undergraduate and JD degrees from the University of California, Los Angeles. We believe that Mr. Marcus' extensive experience in the life sciences industry and as a chief executive officer and attorney qualifies him to serve on our board of directors.

Sanjay Mistry, PhD, has served on our board of directors since February 2024. In March 2013, Dr. Mistry joined Johnson & Johnson serving as the vice president of venture investments and new company creation for Johnson & Johnson Innovation – JJDC Inc. From September 2008 to March 2013, he was vice president at Quaker Partners, a healthcare venture capital firm. Dr. Mistry also serves as a member of the board of directors for Agni Bio and previously served on the board of directors for Rapport Therapeutics, Inc. Dr. Mistry received a BS from Nottingham Trent University and an MS in clinical pharmacology and a PhD in pharmacology from the University of Aberdeen. We believe that Dr. Mistry is qualified to serve on our board of directors due to his extensive experience in the pharmaceuticals industry. Dr. Mistry has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

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Christopher O'Donnell*, *PhD, has served as a member of our board of directors since January 2026. Dr. O'Donnell has served as a partner at Pfizer Ventures and vice president of business development at Pfizer Ventures since July 2020 and May 2022, respectively. Dr. O'Donnell is responsible for identifying, evaluating, making, and managing equity investments aligned with the future directions of Pfizer. Dr. O'Donnell began at Pfizer in July 1999 and has over 25 years of experience and scientific leadership there. Prior to Pfizer Ventures, Dr. O'Donnell developed and led the Applied Synthesis Technologies group within Pfizer Worldwide Research & Development organization to accelerate the delivery of Pfizer's small molecule portfolio. Prior to that, Dr. O'Donnell built and led Pfizer Antibody Drug Conjugate medicinal chemistry group and co-led the ADC Development team that delivered numerous ADCs for oncology indications. Dr. O'Donnell started his career in the Neuroscience Medicinal Chemistry group at Pfizer where he invented and helped deliver numerous clinical candidates. Dr. O'Donnell earned his BS in Chemistry from the University of Illinois-Urbana/Champaign and his PhD in Chemistry from the University of Wisconsin-Madison and joined Pfizer after his post-doctoral research studies as an American Cancer Society Fellow at the University of California—Irvine. We believe that Dr. O'Donnell is qualified to serve on our board of directors because of his extensive expertise and experience in the life sciences industry, his leadership experience in other companies in our industry and his educational background. Dr. O'Donnell has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Eric Pham, PhD, has served as a member of our board of directors since November 2024. Dr. Pham has been a managing director at Avego BioScience Capital since August 2024. From December 2023 to August 2024, Dr. Pham was vice president at Blue Owl Healthcare Opportunities. From November 2019 to December 2023, Dr. Pham worked at Cowen Healthcare Investments, most recently as a Senior Associate. Prior to Cowen, Dr. Pham was a Senior Analyst on the Investments Team at Roivant Sciences where he focused on identifying, evaluating, and acquiring promising therapeutic programs for further development. Dr. Pham currently serves on the board of directors at Ensho Therapeutics. Dr. Pham received his PhD in Molecular and Cell Biology from University of Houston and BA in Molecular and Cell Biology from University of California, Berkeley. We believe that Dr. Pham is qualified to serve on our board of directors due to his extensive experience in the pharmaceuticals industry. Dr. Pham has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

***Michael Ross, PhD*,** has served as a member of our board of directors since January 2020. Dr. Ross has been a senior partner at SV Health Investors since 2001. Prior to this, Dr. Ross served as the founding chief executive officer at MetaXen and Arris Pharmaceutical. In October 1978, Dr. Ross was the tenth employee at Genentech, where he worked for 13 years. He served as Genentech team leader for the Humulin® Roferon®, Protropin® programs and was vice president of development during the development of Activase®, Nutropin® and Pulmozyme®. He then started Genentech's antibody engineering, protein engineering and small molecule discovery effort as vice president of medicinal and biomolecular chemistry. Dr. Ross was the founding chief executive officer of Arris Pharmaceutical, MetaXen, ExSAR and CyThera (now Viacyte). Dr. Ross received his PhD in Chemistry from the California Institute of Technology and went on to do his post-doctoral work at Harvard. We believe that Dr. Ross is qualified to serve on our board of directors due to his extensive experience in the pharmaceuticals and investment industries.

Nikola Trbovic, PhD, has served as a member of our board of directors since May 2019. Dr. Trbovic joined SV Health Investors in January 2022 and has been a managing partner since January 2024. Prior to SV Health Investors, Dr. Trbovic was a partner at Pfizer Ventures from September 2014 to December 2021. Dr. Trbovic received his PhD in Biochemistry and Molecular Biophysics from Columbia University and holds a Diploma in Biochemistry from Goethe University Frankfurt. We believe that Dr. Trbovic is qualified to serve on our board of directors due to his extensive experience in the pharmaceutical and investment industries. Dr. Trbovic has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Composition of Our Board of Directors

Our business and affairs are managed under the direction of our board of directors. Our board of directors currently consists of seven directors.

Classified Board of Directors

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our Restated Charter to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Julie Gilmore, Joel S. Marcus, and Carol G. Gallagher, and their terms will expire at the annual meeting of stockholders to be held in 2027;
- the Class II directors will be Peter Hirth and Michael Ross, and their terms will expire at the annual meeting of stockholders to be held in 2028; and
- the Class III directors will be M. Johnston Erwin, Jr. and Travis Coy, and their terms will expire at the annual meeting of stockholders to be held in 2029.

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. This classification of our board of directors may have the effect of delaying or preventing changes in control of our Company.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on the information provided by each director concerning his or her background, employment and affiliations, including the information in the biographies above, our board of directors has determined that each of our non-employee directors is independent under the rules of Nasdaq. Our board of directors has determined that Mr. Erwin, by virtue of his position as our chief executive officer, is not independent under applicable rules and regulations of the SEC and Nasdaq. In making this determination, the board of directors considered the relationships that such directors have with our Company and all other facts and circumstances that the board of directors deemed relevant in determining such directors' independence, including beneficial ownership of our capital stock by each non-employee director and their affiliates, and the transactions involving them described or referenced in "Certain Relationships and Related Person Transactions."

Board Leadership Structure

Our board of directors is currently chaired by M. Johnston Erwin, Jr., our Chief Executive Officer. The board of directors has appointed Carol G. Gallagher, PharmD, as our lead independent director. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. The lead independent director is chosen by the independent members of the board of directors. We believe that this separation of responsibilities ensures the appropriate level of oversight, independence and responsibility is applied to all board decisions.

The duties of our lead independent director include the following:

- chairing meetings of the independent directors in executive session;
- facilitating communications between other members of our board and our chairman and Chief Executive Officer;
- reviewing and approving matters, such as agenda items, schedule sufficiency, and, where appropriate, information provided to other board members;
- consulting with our chairman and Chief Executive Officer on matters relating to corporate governance and board performance; and
- performing such other duties as the board may determine from time to time.

We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company. Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

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Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee operates pursuant to a written charter that satisfies the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and Nasdaq, which we have posted to our website at trex.bio. Our board of directors may establish other committees as it deems necessary or appropriate from time to time. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Audit Committee

Our audit committee operates under a written charter, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq rules.

The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance, procedures and independence of, our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of written periodic reports from such firm;
- pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- overseeing and periodically reviewing with our independent registered public accounting firm our compliance with all applicable requirements of the Public Company Accounting Oversight Board;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations and the steps taken to deal with such issues;
- reviewing disclosures about any significant deficiencies or material weaknesses in our internal control structures and procedures, including disclosures in our annual and quarterly reports;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding cybersecurity risks and processes for assessing, identifying and managing material risks from cybersecurity threats;
- discussing our risk management policies with management;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and approving any related person transactions;
- overseeing our guidelines and policies governing risk assessment and risk management;
- overseeing and periodically reviewing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

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The members of our audit committee are Travis Coy, Peter Hirth, and Joel S. Marcus. Travis Coy chairs the audit committee. Our board of directors has determined that each member of our audit committee has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has also determined that Travis Coy is an "audit committee financial expert," as defined under Item 407 of Regulation S-K. Our board of directors has determined that each member of the audit committee satisfies the independence standards of the applicable rules of Nasdaq and the SEC.

Compensation Committee

Our compensation committee operates under a written charter, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq rules.

Our compensation committee's responsibilities upon completion of this offering will include:

- reviewing and establishing our overall management compensation strategy and benefits philosophy and policies, including base salary, incentive compensation and equity-based grants;
- reviewing and approving performance goals and objectives relevant to compensation of our chief executive officer and other executive officers;
- evaluating the performance of the chief executive officer and executive officers in light of their performance goals and objectives, including during executive sessions of non-employee directors, and recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors with respect to non-employee director compensation;
- reviewing, overseeing and administering our equity incentive plans, granting awards under such plan and making recommendations to the board of directors about the adoption of any new or modifying existing equity-based, cash-based, management incentive and deferred compensation plans;
- establishing and reviewing "clawback" policies that allow the recouping of incentive compensation;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and non-employee directors;
- recommending to our board of directors any stock ownership guidelines for our executive officers and non-employee directors, periodically assessing these guidelines and recommending revisions as appropriate, and monitoring individual compliance with these guidelines;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor and determining the compensation and independence of such consultant or advisor;
- preparing, if required, the compensation committee report on executive compensation for inclusion in our annual report on Form 10-K and our proxy statement in accordance with SEC rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- reviewing and approving all employment contract and other compensation, severance and change-in-control arrangements for our executive officers;
- establishing and periodically reviewing policies and procedures with respect to perquisites as they relate to our executive officers;
- reviewing the risks associated with our compensation policies and practices;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions based on guidelines developed and recommended to the compensation committee to the full board of directors;
- reviewing our strategies, initiatives and programs with respect to our culture, talent recruitment, development, and retention, employee engagement and diversity and inclusion;
- maintaining minutes of the compensation committee and reporting its actions and any recommendations to the board of directors on a periodic basis;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee are Carol G. Gallagher, Julie Gilmore, and Joel S. Marcus. Carol G. Gallagher chairs the compensation committee. Our board of directors has determined that each member of the compensation committee satisfies the independence standards of the applicable rules of the Nasdaq and the SEC.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee operates under a written charter, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq rules.

Our nominating and corporate governance committee's responsibilities upon completion of this offering will include:

- actively seeking and identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing a policy under which our stockholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- reviewing and recommending committee slates on an annual basis;
- recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principles applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board size, composition, leadership structure and board committee structure;
- making recommendations to our board of directors of processes for annual evaluations of the performance of our board of directors and committees of our board of directors;
- overseeing the process for annual evaluations of our board of directors and committees of our board of directors;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions in the Company;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee are Carol G. Gallagher and Michael Ross. Michael Ross chairs the nominating and corporate governance committee. Our board of directors has determined that each member of the nominating and corporate governance committee satisfies the independence standards of the applicable rules of Nasdaq.

Our board of directors may establish other committees from time to time.

Role of the Board of Directors in Risk Oversight

Our board of directors has, and upon the completion of this offering, its committees will also have, an active role 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 will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee will be responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and governance committee 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, the entire board of directors will be regularly informed through discussions from committee members about such risks.

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Code of Business Conduct and Ethics

In connection with this offering, we have adopted a written Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at trex.bio. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our executive officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

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EXECUTIVE AND DIRECTOR COMPENSATION

The following discussion of compensation arrangements should be read with the compensation tables and related disclosures set forth below. 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 completion of this offering may differ materially from the currently planned programs summarized in this discussion.

Our named executive officers ("NEOs") for the year ended December 31, 2025, which consist of our principal executive officer during 2025 and our two most highly compensated executive officers other than our principal executive officer during 2025, were:

- M. Johnston Erwin, Jr., Chief Executive Officer and Director;
- Ali Zarrin, Chief Scientific Officer; and
- Laura Berner, Chief Operating Officer.

Summary Compensation Table

The following table sets forth the compensation awarded to, earned by, or paid to our named executive officers in respect of their service to us for fiscal year 2025.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	Non-equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)	Total ($)
M. Johnston Erwin, Jr.							
Chief Executive Officer	2025	569,039	—	490,274	287,282	52,635	1,399,230
Ali Zarrin							
Chief Scientific Officer	2025	377,737	200,000	223,860	122,636	11,884	936,117
Laura Berner							
Chief Operating Officer	2025	456,269	—	147,083	153,182	14,000	770,534

(1) The amount shown in this column for Mr. Zarrin reflects a retention bonus awarded in connection with his promotion to Chief Scientific Officer in August 2025.

(2) The amounts shown in this column reflect the grant date fair value of time-based stock option awards granted under the 2024 Plan (defined below) in fiscal year 2025, in each case computed in accordance with FASB ASC Topic 718 and excluding the effect of estimated forfeitures. The assumptions used to value the stock options for this purpose are set forth in Note 8 to our audited financial statements included elsewhere in this prospectus.

(3) The amounts shown in this column reflect the annual bonus awards paid to our NEOs in respect of 2025 performance.

(4) The amounts shown in the "All Other Compensation" column for fiscal year 2025 reflect Company matching contributions to our 401(k) plan and, in the case of Mr. Erwin, reimbursement for the cost of certain commuting expenses ($28,872) and a related tax gross-up on such reimbursements ($11,480).

Narrative to the Summary Compensation Table

Annual Base Salary

The employment agreement with Mr. Erwin, and the offer letters with each of Mr. Zarrin and Ms. Berner described below, establish an initial annual base salary for each named executive officer, which has been subsequently increased. As of the end of fiscal year 2025, Mr. Erwin's annual base salary was $574,564, Mr. Zarrin's annual base salary was $430,000 and Ms. Berner's annual base salary was $460,699.

Annual Bonus

With respect to fiscal year 2025, each of Messrs. Erwin and Zarrin and Ms. Berner was eligible to receive an annual short-term bonus award, with the initial target amount of such bonus set forth in each named executive officer's employment agreement or offer letter, each of which has been subsequently increased. For fiscal year 2025, the target bonus amount, expressed as a percentage of base salary, for our named executive officers was as follows: Mr. Erwin, 50%; Mr. Zarrin, 30% for the portion of the year preceding his promotion and 35% for the period thereafter; and Ms. Berner, 35%. The actual bonus amounts paid to our named executive officers for 2025, which were determined by our board of directors based on the attainment of company performance objectives related to product development milestones, are set forth in the Summary Compensation Table above.

Equity Awards

Each of our named executive officers received a stock option grant during fiscal year 2025, the amount and terms of which are included in the "Outstanding Equity Awards as of December 31, 2025" table below.

Agreements with our Named Executive Officers; Severance Upon Termination of Employment

Each of our named executive officers is party to an amended employment agreement or amended offer letter (each agreement or offer letter, as most recently amended in connection with this offering, an "amended agreement") that sets forth the terms and conditions of the named executive officer's employment with us and provides for the named executive officer's entitlement to an initial base salary and an initial target bonus amount, as described above. In addition, each of our named executive officers is bound by certain restrictive covenant and related obligations, as set forth (i) in the case of Mr. Erwin, in an Employee Invention Assignment and Confidentiality Agreement, and (ii) in the case of Mr. Zarrin and Ms. Berner, in a Confidentiality, Proprietary Rights, Restrictive Covenant and Arbitration Agreement, including non-disclosure obligations with respect to confidential information, assignment of work product and intellectual property rights and non-solicitation obligations with respect to company employees and consultants during the named executive officer's employment and for 12 months after the termination of such employment.

If the employment of our named executive officers is terminated by us without cause (as defined in the executive's amended agreement) or by the named executive officer in connection with the occurrence of certain events constituting "good reason" (as defined in the executive's amended agreement) (each, a "qualifying termination"), the named executive officer will be entitled to receive continued payment of his or her base salary for nine months (12 months in the case of Mr. Erwin) following termination and reimbursement for the cost of COBRA continuation coverage during the applicable severance period. In addition, in the event the employment of a named executive officer is terminated as a result of a qualifying termination during the period beginning three months before and continuing for twelve months following the occurrence of a change in control, the named executive officer will be entitled to receive (i) continued payment of his or her base salary for 12 months (18 months in the case of Mr. Erwin) following termination; (ii) reimbursement for the cost of COBRA continuation coverage during the applicable severance period; (iii) a lump sum payment equal to 100% of the executive's then-current target annual bonus (150% in the case of Mr. Erwin); and (iv) accelerated vesting with respect to all of his or her outstanding equity-based incentive compensation awards. All severance benefits are subject to the applicable named executive officer's execution and non-revocation of a general release of claims in favor of the Company.

Outstanding Equity Awards as of December 31, 2025

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2025.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
M. Johnston Erwin, Jr.	299,491	—(1)	$ 1.09	11/22/2031
	113,485	13,196(1)	$ 1.09	5/24/2032
	76,602	383,011(2)	$ 1.24	4/10/2035
Ali Zarrin	4,715	549(1)	$ 1.09	5/24/2032
	3,485	17,428(2)	$ 1.24	4/10/2035
	15,501	170,514(2)	$ 1.24	9/30/2035
Laura Berner	24,579	—(1)	$ 1.09	11/22/2031
	39,817	4,630(1)	$ 1.09	5/24/2032
	9,056	3,729(1)	$ 1.09	2/25/2033
	3,906	4,617(1)	$ 1.09	2/26/2034
	22,980	114,904(2)	$ 1.24	4/10/2035

(1) Reflects options that vested as to 25% of the underlying shares on the first anniversary of the grant date, and that vest in 36 equal monthly installments thereafter, generally subject to the named executive officer's continued employment with or service to us through the applicable vesting date. Options have a term of ten years from the grant date.

(2) Reflects options that vest as to 1/48 of the underlying shares on each monthly anniversary of the grant date, generally subject to the named executive officer's continued employment with or service to us through the applicable vesting date. Options have a term of ten years from the grant date.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to the disclosure of executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Retirement Plan and Other Benefits

We currently provide broad-based health and welfare benefits that are available to our full-time employees, including our named executive officers, including health, life, disability, vision, and dental insurance. In addition, we participate in a 401(k) retirement plan for the benefit of our full time employees under which a matching contribution equal to 4% is provided. Other than the 401(k) plan, we do not provide any qualified or nonqualified retirement or deferred compensation benefits to our employees, including our named executive officers.

Clawback Policy

In connection with this offering, we have adopted a compensation recovery policy as required by Nasdaq Listing Rules and the Dodd-Frank Act.

Equity Incentive Plans

2024 Plan

On December 31, 2024, our board of directors adopted, and our stockholders approved, the Company's 2024 Equity Incentive Plan (the "2024 Plan"). The 2024 Plan permits the grant of awards to employees, officers, directors and consultants of the Company or any parent or subsidiary of the Company. As of June 30, 2026, 2,980,123 shares of our common stock were subject to outstanding awards under the 2024 Plan and 768,560 shares remained available for future issuance. This summary is not a complete description of all provisions of the 2024 Plan and is qualified in its entirety by reference to the terms of such plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

Plan Administration

The compensation committee of our board of directors administers the 2024 Plan. The compensation committee has the discretionary authority to interpret the 2024 Plan and awards granted thereunder, to approve the individuals to whom awards may from time to time be granted, to grant awards, and to determine the terms and conditions of any award. Our compensation committee may also delegate any or all of its powers to a subcommittee consisting of one or more directors or executive officers, as permitted by applicable law. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

Eligibility

Employees, officers, directors and consultants of the Company or any parent or subsidiary of Company are eligible to participate in the 2024 Plan. Eligibility for incentive stock options is limited to our employees and those of any parent or subsidiary.

Transferability of Awards

The 2024 Plan generally does not allow for the transfer of awards other than by will or by the laws of descent or distribution, and with respect to non-statutory stock options for participants in the U.S., by instrument to an inter vivos or testamentary trust in which the non-statutory stock options are to be passed to beneficiaries upon the death of the trustor (settlor), or by gift to a "family member" as that term is defined in the applicable securities laws. Unless an award is transferred as described above, during the lifetime of the participant an award will be exercisable only by the participant or the participant's legal representative.

Certain Adjustments

In the event that the Company's common stock is changed by a stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or other change in the capital structure of the Company affecting shares without consideration, then in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2024 Plan, the number and class of shares covered by each outstanding award, the number of shares that have been authorized for issuance under the 2024 Plan, and the price per share covered by each outstanding award will be proportionately adjusted.

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Effect of a Corporate Transaction

In the event of an Acquisition or Other Combination, as each term is defined below, each outstanding award will be assumed or substituted by the successor entity; settled in cash, cash equivalents, or securities of the successor entity (or its parent, if any), followed by the cancellation of such awards; or cancelled without consideration if not exercised in accordance with its terms upon or prior to consummation of the Acquisition or Other Combination. The vesting of outstanding awards may also be accelerated in connection with such transaction. For purposes of the 2024 Plan, an "Acquisition" means (i) any consolidation or merger in which the voting stock of the Company that is outstanding immediately prior to the consummation of such consolidation or merger represents less than 50% of the total voting power of the surviving entity that is outstanding immediately after the consummation of such consolidation or merger; (ii) a sale or other transfer in which more than 50% of the total voting power of the company, whether in one transaction or in a series of related transactions, is sold or transferred to a single person or entity or more than one such person(s) or entities acting in concert; or (iii) a sale, lease, transfer or other disposition, in a single transaction or series of related transactions, of all or substantially all of the company's assets. The consummation of the contemplated offering will not constitute an Acquisition. For purposes of the 2024 Plan, an "Other Combination" means (a) any consolidation or merger in which the Company is a constituent entity and is not the surviving entity of such consolidation or merger or (b) any conversion of the Company into another form of entity; *provided* that such consolidation, merger or conversion does not constitute an Acquisition.

Amendments and Termination

Our board of directors may, at any time, (a) terminate or amend the 2024 Plan in any respect, including without limitation amendment of any form of award agreement issued thereunder, and (b) terminate any and all outstanding awards upon a dissolution or liquidation of the Company. No amendment or termination of the 2024 Plan will affect any share previously issued or any award previously granted under the 2024 Plan.

2026 Equity Incentive Plan

In connection with this offering, our board of directors has adopted and our stockholders have approved the 2026 Plan, which is effective in connection with this offering. The following summary describes the material terms of the 2026 Plan. This summary is not a complete description of all provisions of the 2026 Plan and is qualified in its entirety by reference to the 2026 Plan, which has been filed as an exhibit to the registration statement of which this prospectus is a part. The Company has granted options to purchase up to approximately 46,188 shares of common stock to non-executive officer employees in connection with this offering, with an exercise price equal to the offering price.

Purpose

The purpose of the 2026 Plan is to advance our interests by providing for the grant to our employees, directors, consultants and advisors of stock and stock-based awards.

Plan Administration

The 2026 Plan is administered by the compensation committee of our board of directors (the "compensation committee"), except with respect to matters that are not delegated to our compensation committee by our board of directors. Our compensation committee (or our board of directors, as applicable) has the discretionary authority to interpret the 2026 Plan and any awards granted under it, determine eligibility for and grant awards, determine the exercise price, base value from which appreciation is measured or purchase price, if any, applicable to any award, determine, modify, accelerate and waive the terms and conditions of any award, determine the form of settlement of any award, prescribe forms, rules and procedures relating to the 2026 Plan and awards and otherwise do all things necessary or desirable to carry out the purposes of the 2026 Plan or any award. Our compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board and, to the extent permitted by law, our officers and may delegate to employees and other persons such ministerial tasks as it deems appropriate. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

Eligibility

Our employees, directors, consultants and advisors are eligible to participate in the 2026 Plan. Eligibility for stock options intended to be incentive stock options ("ISOs"), is limited to our employees or employees of certain affiliates. Eligibility for stock options, other than ISOs, and stock appreciation rights ("SARs"), is limited to individuals who are providing direct services to us or certain affiliates on the date of grant of the award.

Authorized Shares

Subject to adjustment as described below, the maximum number of shares of our common stock that may be delivered in satisfaction of awards under the 2026 Plan is 2,757,753 shares (the "share pool"). The share pool will automatically increase on January 1 of each year from 2027 to 2036 by the lesser of (i) five percent of the number of shares of diluted stock outstanding

as of the close of business on the immediately preceding December 31 (which, for this purpose, includes shares of stock and unexercised pre-funded warrants to purchase shares of stock) and (ii) the number of shares determined by our board of directors on or prior to such date for such year. Up to a maximum of 16,546,521 shares may be delivered in satisfaction of ISOs. The number of shares of our common stock delivered in satisfaction of awards under the 2026 Plan is determined (i) by excluding shares withheld by us in payment of the exercise price or purchase price of the award or in satisfaction of tax withholding requirements with respect to the award, (ii) by including only the number of shares delivered in settlement of a SAR that is settled in shares of our common stock and (iii) by excluding any shares underlying awards settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by us without the delivery of shares of our common stock (or retention, in the case of restricted stock or unrestricted stock). The number of shares available for delivery under the 2026 Plan will not be increased by any shares that have been delivered under the 2026 Plan and are subsequently repurchased using proceeds directly attributable to stock option exercises.

Shares that may be delivered under the 2026 Plan may be authorized but unissued shares, treasury shares or previously issued shares acquired by us.

Types of Awards

The 2026 Plan provides for the grant of stock options, SARs, restricted and unrestricted stock and stock units, performance awards and other awards that are convertible into or otherwise based on our common stock. Dividend equivalents may also be provided in connection with awards under the 2026 Plan. Dividends and dividend equivalents relating to an award that remains subject to a risk of forfeiture will be subject to the same risk of forfeiture as the underlying award, and no dividends or dividend equivalents will be payable with respect to stock options or SARs.

- *Stock Options and SARs*. The Administrator may grant stock options, including ISOs, and SARs. A stock option is a right entitling the holder to acquire shares of our common stock upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price per share of each stock option, and the base value of each SAR, granted under the 2026 Plan will be no less than 100% of the fair market value of a share on the date of grant (generally defined as the closing price of a share of common stock on the date of grant) (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, stock options and SARs granted under the 2026 Plan may not be repriced, amended or substituted for with new stock options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any stock options or SARs that have a per share exercise or base price greater than the fair market value of a share on the date of such cancellation, in each case, without shareholder approval. Each stock option and SAR will have a maximum term of not more than ten years from the date of grant (or five years, in the case of certain ISOs).
- *Restricted and Unrestricted Stock and Stock Units*. The Administrator may grant awards of stock, stock units, restricted stock and restricted stock units. A stock unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted stock unit is a stock unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted stock consists of shares subject to restrictions requiring that they be forfeited, redelivered or offered for sale to us if specified performance or other vesting conditions are not satisfied.
- *Performance Awards*. The Administrator may grant performance awards, which are awards subject to the achievement of performance criteria.
- *Other Share-Based Awards*. The Administrator may grant other awards that are convertible into or otherwise based on shares of our common stock, subject to such terms and conditions as it determines.
- *Substitute Awards*. The Administrator may grant substitute awards in connection with certain corporate transactions, which may have terms and conditions that are different from the terms and conditions of the 2026 Plan.

Director Limits

The aggregate value of all compensation granted or paid to any director with respect to any calendar year, including awards granted under the 2026 Plan and cash fees or other compensation paid by us to such director outside of the 2026 Plan for his or her services as a director during such calendar year (which, for the avoidance of doubt, will not include compensation granted or paid to a director for services other than as a director, including, without limitation, for services as a consultant or advisor to the company), is subject to a limit of $750,000 in the aggregate ($1,000,000 in the aggregate with respect to a director's first year of service on our board of directors).

Vesting; Terms of Awards

The Administrator determines the terms and conditions of all awards granted under the 2026 Plan, including the time or times an award vests or becomes exercisable, the terms and conditions on which an award remains exercisable and the effect of termination of a participant's employment or service on an award. The Administrator may at any time accelerate the vesting or exercisability of an award (or any portion thereof).

Non-transferability of Awards

Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

Adjustments upon Certain Covered Transactions

In the event of certain covered transactions (including the consummation of a consolidation, merger or similar transaction, the sale of all or substantially all of our assets or shares of our common stock or our dissolution or liquidation), the Administrator may, with respect to outstanding awards, provide for (in each case, on such terms and subject to such conditions as it deems appropriate):

- The assumption, substitution or continuation of some or all awards (or any portion thereof) by the acquiror or surviving entity;
- The acceleration of exercisability or delivery of shares in respect of any award, in full or in part; and/or
- The cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the Administrator may otherwise determine, each award will automatically terminate or be forfeited immediately upon the consummation of the covered transaction, other than awards that are substituted for, assumed or that continue following the covered transaction.

Adjustments upon Changes in Capitalization

In the event of certain corporate transactions, including a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure, the Administrator shall make appropriate adjustments to the maximum number of shares that may be delivered under the 2026 Plan, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of outstanding awards, and any other provisions affected by such event.

Recovery of Compensation

The Administrator may provide that any outstanding award, the proceeds of any award or shares acquired thereunder and any other amounts received in respect of any award or shares acquired thereunder will be subject to forfeiture and disgorgement to us, with interest and other related earnings, if the participant to whom the award was granted is not in compliance with any provision of the 2026 Plan or any award, any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant or any Company policy that relates to trading on non-public information and permitted transactions with respect to shares of our common stock or that provides for forfeiture, disgorgement or clawback, including, to the extent applicable, the Company's Policy for Recoupment of Incentive Compensation or as otherwise required by law.

Amendment and Termination

The Administrator may at any time amend the 2026 Plan or any outstanding award and may at any time terminate the 2026 Plan as to future awards. However, except as expressly provided in the 2026 Plan, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent (unless the Administrator expressly reserved the right to do so in the 2026 Plan or at the time the award was granted). Any amendments to the 2026 Plan will be conditioned on shareholder approval to the extent required by applicable law or stock exchange requirements.

2026 Employee Stock Purchase Plan

In connection with this offering, our board of directors has adopted and our stockholders have approved the ESPP, which is effective in connection with this offering. The initial offering period under the ESPP is expected to commence in connection therewith. The following summary describes the material terms of the ESPP. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which has been filed as an exhibit to the registration statement of which this prospectus is a part.

Purpose

The purpose of the ESPP is to enable eligible employees of us and our participating subsidiaries to use payroll deductions to purchase shares of our common stock and thereby acquire an interest in us. The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code.

Plan Administration

The ESPP is administered by the compensation committee, which has the discretionary authority to administer and interpret the ESPP, determine eligibility under the ESPP, prescribe forms, rules and procedures relating to the ESPP and otherwise do all things necessary or desirable to carry out the purposes of the ESPP. The compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board of directors and our officers and employees, in each case, to the extent permitted by law. As used in this summary, the term "Administrator" refers to the compensation committee and its authorized delegates, as applicable.

Eligibility

Participation in the ESPP will generally be limited to our employees and employees of our subsidiaries who are employed by us or one of our subsidiaries, as applicable, as of the first day of an applicable offering period and who satisfy the requirements set forth in the ESPP. The Administrator may establish additional or other eligibility requirements, or change the requirements set forth in the ESPP, to the extent consistent with Section 423 of the Code. Any employee who owns (or is deemed under statutory attribution rules to own) shares possessing five percent or more of the total combined voting power or value of all classes of shares of us or our parent or subsidiaries, if any, will not be eligible to participate in the ESPP.

Shares Subject to the ESPP

Subject to adjustment as described below, the aggregate number of shares of our common stock available for purchase pursuant to the exercise of options under the ESPP is 275,775 shares, plus an automatic annual increase, as of January 1st of each year beginning in 2027, equal to the lesser of (i) one percent of the number of shares of diluted stock outstanding as of the close of business on the immediately preceding December 31 (which, for this purpose, includes shares of stock and unexercised pre-funded warrants to purchase shares of stock) and (ii) the number of shares determined by our board of directors on or prior to such date for such year (up to a maximum of 3,033,529 shares). Shares to be delivered upon exercise of options under the ESPP may be authorized but unissued shares, treasury shares or previously issued shares acquired by us. If any option granted under the ESPP expires or terminates for any reason without having been exercised in full or ceases for any reason to be exercisable in whole or in part, the unpurchased shares subject to such option will remain available for purchase under the ESPP.

General Terms of Participation

The ESPP allows eligible employees to purchase shares of our common stock during specified offering periods. On the first day of each offering period, eligible employees will be granted an option to purchase shares of our common stock on the last business day of the offering period. A participant may purchase a maximum of 5,000 shares with respect to any offering period (or such lesser number as the Administrator may prescribe). No participant will be granted an option under the ESPP that permits the participant's right to purchase shares of our common stock under the ESPP and under all other employee stock purchase plans of us or our parent or subsidiaries, if any, to accrue at a rate that exceeds $25,000 in fair market value (or such other maximum as may be prescribed by the Code) for each calendar year during which any option granted to the participant is outstanding at any time, determined in accordance with Section 423 of the Code.

The purchase price of each share issued pursuant to the exercise of an option under the ESPP on an exercise date will be 85% (or such greater percentage as specified by the Administrator) of the lesser of: (a) the closing price of a share of our common stock on the date the option is granted (or, if no closing price is reported on that date, the reported closing price of a share of our common stock for the immediately preceding day that is a trading day), which will be the first day of the offering period, and (b) the closing price of a share of our common stock on the exercise date (or, if no closing price is reported on that date, the reported closing price of a share of our common stock for the immediately preceding day that is a trading day), which will be the last business day of the offering period.

The Administrator may change the commencement and exercise dates of offering periods, the purchase price, the maximum number of shares that may be purchased with respect to any offering period, the duration of any offering periods and other terms of the ESPP, in each case, without stockholder approval, except as required by law.

Participants in the ESPP will pay for shares purchased under the ESPP through payroll deductions. Participants may elect to authorize payroll deductions in an amount equal to a pre-established percentage of the participant's eligible compensation each payroll period.

Restrictions on Transfer

For participants who have purchased shares under the ESPP, the Administrator may impose restrictions prohibiting the transfer, sale, pledge or alienation of such shares, other than by will or by the laws of descent and distribution, for such period as may be determined by the Administrator.

Covered Transactions

In the event of a sale or transfer of all or substantially all of our stock or assets, or a merger or similar transaction in which we are not the surviving entity or which results in our acquisition by another person, the Administrator may provide that each outstanding option will be assumed or substituted for or will be cancelled and the balances of participants' accounts returned or that the option period will end before the date of the proposed covered transaction.

Adjustments upon Changes in Capitalization

In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure that constitutes an equity restructuring, the Administrator will make appropriate adjustments to the maximum number and type of shares available for purchase under the ESPP, the number and type of shares granted under any outstanding options, the maximum number and type of shares purchasable under any outstanding option and/or the purchase price per share under any outstanding option.

Amendment and Termination

The Administrator has discretion to amend the ESPP to any extent and in any manner it may deem advisable, provided that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 of the Code will require stockholder approval. The Administrator may suspend or terminate the ESPP at any time.

Non-Employee Director Compensation

The following table sets forth the compensation awarded to, earned by, or paid to all individuals who served as non-employee directors during the year ended December 31, 2025. Mr. Erwin, our Chief Executive Officer, does not receive any compensation for his service as a director. The compensation awarded to, earned by or otherwise paid to Mr. Erwin for 2025 is included with that of our other named executive officers above.

Name	Fees Earned or Paid in Cash ($)[1]	Option Awards ($)[2][3]	All Other Compensation ($)[4]	Total ($)
Carol G. Gallagher	70,000	107,193	—	177,193
Alexandra Cantley	—	—	—	—
Travis Coy	7,500	38,471	—	45,971
Julie Gilmore	—	—	—	—
Peter Hirth	40,000	—	20,000	60,000
Eric Huang	—	—	—	—
Joel S. Marcus	—	—	—	—
Sanjay Mistry	—	—	—	—
Christopher O'Donnell	—	—	—	—
Eric Pham	—	—	—	—
Michael Ross	—	—	—	—
Nikola Trbovic	—	—	—	—

(1) Amounts reported in this column reflect cash fees earned for services provided as a director during the year ended December 31, 2025.

(2) The amounts shown in this column reflect the grant date fair value of options to purchase shares of our common stock granted under the 2024 Plan to certain of our directors in fiscal year 2025 computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the stock option grants for this purpose are set forth in Note 8 to our audited financial statements included elsewhere in this prospectus.

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(3) As of December 31, 2025, certain of our directors held options to purchase shares of our common stock as follows: Mr. Hirth, 7,520; and Mr. Coy, 35,431. In addition, Ms. Gallagher holds 83,741 restricted shares that resulted from the early exercise of options granted to her in 2025.

(4) Amounts reported in this column reflect fees paid for the provision of advisory services by Mr. Hirth pursuant to his consulting agreement with the Company, as described below.

Mr. Hirth entered into a consulting agreement with the Company in 2025 pursuant to which he provided specified services to the Company, including advice on scientific, portfolio and business matters, in exchange for a quarterly fee of $5,000. Mr. Hirth's consulting agreement was terminated in September 2026. Prior to 2025, Ms. Gallagher had been subject to a consulting agreement with the Company pursuant to which she provided specified services to the Company. She received no amounts under this agreement in 2025.

In connection with this offering, our board of directors has adopted and our stockholders have approved a non-employee director compensation policy, which became effective in connection with this offering. Under the policy, our non-employee directors will be compensated as follows:

- each non-employee director will receive an annual cash retainer of $40,000 ($65,000 for the lead director);
- each non-employee director who is a member of the audit committee will receive an additional annual cash retainer of $10,000 ($20,000 for the audit committee chair);
- each non-employee director who is a member of our compensation committee will receive an additional annual cash retainer of $7,500 ($15,000 for our compensation committee chair); and
- each non-employee director who is a member of the nominating and corporate governance committee will receive an additional annual cash retainer of $5,000 ($10,000 for the nominating and corporate governance committee chair);

Under the policy, each non-employee director who is first elected or appointed to our Board following the completion of this offering will be granted an option under the 2026 Plan to purchase 35,000 shares of our common stock, such stock option to vest in monthly installments over three years from grant. In connection with this offering, each non-employee director who is providing services to our Board as of the effectiveness of such offering has been granted an option under the 2026 Plan to purchase 17,500 shares of our common stock with an exercise price equal to the offering price, such stock options to vest on the one-year anniversary of the date of grant. Commencing in fiscal year 2027, each non-employee director who is not first elected or appointed to the Board during the fiscal year of the annual meeting of our stockholders will be granted an annual option under the 2026 Plan to purchase 17,500 shares of our common stock, such stock option to vest in full on the first anniversary of grant (or the next annual meeting, if earlier). Each stock option grant will vest in full on a change in control, subject to the non-employee director's services to our Board through such change in control.

Each non-employee director is also entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of our Board and any committee on which he or she serves.

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CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a summary of transactions since January 1, 2024, to which we have been a party in which the amount involved exceeded the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus captioned "Executive and Director Compensation." We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions with unrelated third parties.

Series B Preferred Stock Financing

In November 2024, we issued and sold an aggregate of 13,683,972 shares of Series B preferred stock at a price per share of $3.0897 in cash, for an aggregate purchase price of approximately $42.3 million. In March 2025, we issued and sold an aggregate of 13,522,143 shares of Series B preferred stock in an additional closing of our Series B preferred stock at the same price per share as at the first closing for an aggregate purchase price of approximately $41.8 million. In January 2026, we issued and sold an aggregate of 16,182,795 shares of Series B preferred stock in an extension of our Series B preferred stock financing at the same price per share as at the first and second closings for an aggregate purchase price of approximately $50.0 million. Each share of our Series B preferred stock will convert into shares of our common stock immediately prior to the consummation of this offering, including adjustments in connection with the 1-for-3.8649 reverse stock split of our common stock, which was effected on October 2, 2026.

The following table sets forth the aggregate numbers of shares of our Series B preferred stock that we sold to our 5% stockholders and their affiliates in the first closing, second closing and extension, and the aggregate amount of consideration for such shares:

Participants	Series B Preferred Stock	Total Purchase Price
Eli Lilly and Company	8,098,748	$ 25,022,702
Entities affiliated with SV Health Investors[(1)]	8,213,495	$ 25,377,236
Pfizer Ventures (US) LLC[(2)]	2,232,960	$ 6,899,177
Johnson & Johnson Innovation – JJDC, Inc.	2,217,311	$ 6,850,826
Janus Henderson Biotech Innovation Master Fund Limited	4,854,840	$ 14,999,999
Entities affiliated with Joel S. Marcus[(3)]	3,642,215	$ 11,253,352
Delos Capital Fund III, LP[(4)]	4,442,357	$ 13,725,550
Polaris Partners X, L.P.[(5)]	1,870,573	$ 5,779,509

(1) Michael Ross and Nikola Trbovic, who serve as members of our board of directors, are managing partners at SV Health Investors, LLC.

(2) Christopher O'Donnell, a member of our board of directors, is a partner at Pfizer Ventures (US) LLC.

(3) Joel S. Marcus, a member of our board of directors, is the executive chairman of Alexandria Real Estate Equities, Inc. Alexandria Real Estate Equities, Inc. is the managing member of Alexandria Venture Investments, LLC. Alexandria Venture Investments, LLC holds more than 5% of our capital stock.

(4) Eric Huang, a member of our board of directors, is a partner at Delos Capital.

(5) Alexandra Cantley, a member of our board of directors, is a partner at Polaris Partners.

See the section titled "Principal Stockholders" for additional information regarding beneficial ownership of our capital stock and Series B preferred stock. See the sections titled "Description of Capital Stock—Common Stock" and "Description of Capital Stock—Preferred Stock" for additional information regarding these securities.

Agreements with Eli Lilly and Company

We were party to a Laboratory License Agreement with Lilly for office and laboratory space in South San Francisco, California, dated December 12, 2019, as amended (the "Lab License"), which term expired in August 2026. During the years ended December 31, 2024 and 2025, and the six months ended June 30, 2026, we paid Lilly approximately $1.3 million, $1.4 million and $0.7 million, respectively, pursuant to the Lab License.

We are also party to a Master Management Services Agreement with Lilly, dated July 17, 2025 (the "Lilly Services Agreement"), pursuant to which we retained Lilly to provide preclinical research and development services in support of one or more of our research projects. During the year ended December 31, 2025 and the six months ended June 30, 2026, we paid Lilly approximately $0.1 million and less than $0.1 million, respectively, pursuant to the Lilly Services Agreement.

For information regarding the Lilly Collaboration Agreement, see "Business—Intellectual Property—License and Collaboration Agreements—Our Research Collaboration and License Agreement with Lilly."

Lilly owns more than 5% of our capital stock and owned more than 5% of our capital stock during the years ended December 31, 2024 and 2025.

Agreements with Johnson & Johnson

We had been party to a Collaboration and License Agreement with Janssen Pharmaceutica NV ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson and an affiliate of Johnson & Johnson Innovation – JJDC, Inc. ("JJDC"), dated as of December 28, 2021 (the "Janssen Agreement"), pursuant to which Janssen exercised an option in January 2024 to obtain exclusive and non-exclusive licenses with respect to for up to three targets arising out of the parties' research collaboration. In connection with this option exercise, we received a $1.0 million option exercise fee during the year ended December 31, 2024. Janssen delivered a notice of termination of the Janssen Agreement for convenience in July 2025. There are no programs currently in development under the Janssen Agreement and all licenses under the Janssen Agreement terminated in October 2025, 90 days after receipt of the notice of termination.

JJDC owns more than 5% of our capital stock and owned more than 5% of our capital stock during the years ended December 31, 2024 and 2025.

Alexandria Real Estate Lease

On April 15, 2026, the Company entered into a lease agreement with ARE-San Francisco No. 46, LLC for research laboratory and office space (the "ARE Lease"). Alexandria Venture Investments, LLC, is affiliated with ARE-San Francisco No. 46, LLC. The lease commenced in August 2026 and expires in November 2028. During the six months ended June 30, 2026, we paid ARE-San Francisco No. 46, LLC approximately $0.2 million in prepaid rent for the first full month in which base rent is payable under the ARE Lease.

For information regarding the ARE Lease, see "Business—Facilities."

Alexandria Venture Investments, LLC owns more than 5% of our capital stock and owned more than 5% of our capital stock during the years ended December 31, 2024 and 2025.

Investor Rights Agreement

We are party to an Amended and Restated Investors' Rights Agreement (the "Investors' Rights Agreement") with our current stockholders. Pursuant to the terms of the Investors' Rights Agreement, we granted certain stockholders certain management, observer information rights and a right of first offer for future stock issuances, which rights terminate upon this offering. The Investors' Rights Agreement also grants these stockholders certain registration rights. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights. Certain other provisions of the Investors' Rights Agreement will terminate upon completion of this offering.

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors' and officers' liability insurance. We also maintain a general liability insurance policy which covers certain liabilities of directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. See the section titled "Executive and Director Compensation—Limitations on Liability and Indemnification."

Directed Share Program

At our request, the underwriters have reserved up to 250,000 shares of common stock offered by this prospectus for sale (approximately 3%) at the initial public offering price to certain individuals through a directed share program, including our directors, officers, employees and certain other individuals identified by management. The directed share program will not limit the ability of our directors, officers and their family members, or holders of more than 5% of our capital stock, to purchase more than $120,000 in value of our common stock. We do not currently know the extent to which these related persons will participate in our directed share program, if at all, or the extent to which they will purchase more than $120,000 in value of our common stock. See the section titled "Underwriting-Directed Share Program."

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Related Person Transactions Policy

Our board of directors has adopted a written related person transaction policy, which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds in any fiscal year the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years and a related person had, has or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked with considering all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

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PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of September 30, 2026 (i) immediately prior to the completion of this offering and (ii) as adjusted to reflect the sale of shares of our common stock offered by this prospectus by:

- each person or group of affiliated persons who we know beneficially owns more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Our calculation of beneficial ownership and percentage ownership prior to and after this offering is based on 19,244,201 shares of our common stock outstanding as of September 30, 2026, after giving effect to the Preferred Stock Conversion. For further information, see the section titled "Prospectus Summary—The Offering."

Beneficial ownership and percentage ownership are determined in accordance with the rules and regulations of the SEC. Under SEC rules, a person is deemed to be a "beneficial owner" of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has a right to acquire beneficial ownership within 60 days. Securities that can be so acquired are deemed to be outstanding for purposes of computing such person's ownership percentage, but not for purposes of computing any other person's percentage. Under these rules, more than one person may be deemed to be a beneficial owner of the same securities, and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest. Except as indicated in the footnotes to the following table or pursuant to applicable community property laws, we believe, based on information furnished to us, that each shareholder named in the table has sole voting and investment power with respect to the shares set forth opposite such shareholder's name.

The table below does not reflect any shares of our common stock that our directors, executive officers, or other shareholders may purchase through our directed share program or in this offering.

For further information regarding material transactions between us and certain of our shareholders, see the section titled "Certain Relationships and Related Person Transactions."

Name of Beneficial Owner[1]	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or Greater Stockholders:			
Eli Lilly and Company[2]	4,605,872	23.9%	16.8%
Entities affiliated with SV Health Investors[3]	3,882,485	20.2%	14.1%
Pfizer Ventures (US) LLC[4]	1,265,066	6.6%	4.6%
Johnson & Johnson Innovation – JJDC, Inc. [5]	1,261,017	6.6%	4.6%
Janus Henderson Biotech Innovation Master Fund Limited[6]	1,256,136	6.5%	4.6%
Alexandria Venture Investments, LLC[7]	1,167,929	6.1%	4.3%
Delos Capital Fund III, LP[8]	1,149,411	6.0%	4.2%
Polaris Partners X, L.P.[9]	1,018,825	5.3%	3.7%
Directors and Named Executive Officers:			
M. Johnston Erwin, Jr.[10]	656,339	3.3%	2.3%
Ali Zarrin[11]	102,323	*	*
Laura Berner[12]	193,437	1.0%	*
Carol G. Gallagher[13]	251,471	1.3%	*
Alexandra Cantley[14]**	—	—%	—%
Travis Coy[15]	19,885	*	*
Julie Gilmore[16]	—	—%	—%
Peter Hirth[17]	45,722	*	*
Eric Huang[18]**	—	—%	—%
Joel S. Marcus [19]	41,871	*	*
Sanjay Mistry [20]**	—	—%	—%
Christopher O'Donnell[21]**	—	—%	—%
Eric Pham**	—	—%	—%
Michael Ross[22]	—	—%	—%
Nikola Trbovic[22]**	—	—%	—%
All executive officers and directors as a group (17 persons)	1,515,915	7.5%	5.3%

* Represents beneficial ownership of less than 1%.

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** Drs. Cantley, Huang, Mistry, O'Donnell, Pham and Trbovic have each resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(1) Except as otherwise noted, the business address of each of the named individuals in this table is c/o TRex Bio, Inc., 269 East Grand Avenue, Suite 300, South San Francisco, CA 94080.

(2) Consists of (i) 2,510,411 shares of common stock issuable upon the conversion of Series A redeemable convertible preferred stock and (ii) 2,095,461 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Lilly. Lilly has the sole power to vote or direct the vote of an aggregate of 4,605,872 shares and has the sole power to dispose or direct the disposition of an aggregate of 4,605,872 shares. As of December 31, 2025, the board of directors of Lilly was comprised of the following individuals: David A. Ricks, Ralph Alvarez, Katherine Baicker, Carolyn R. Bertozzi, J. Erik Fyrwald, Mary Lynne Hedley, Jamere Jackson, Kimberly H. Johnson, William G. Kaelin Jr., Juan R. Luciano, Jon Moeller and Gabrielle Sulzberger. Lilly is a publicly traded company. The address of Lilly is Lilly Corporate Center Indianapolis, Indiana 46285.

(3) Consists of an aggregate of 3,882,485 shares managed by SV Health Investors, LLC and SV Health Managers LLP (together, "SV Health"), including (i) 74,451 shares of common stock issued or issuable upon the conversion of Series A and Series B redeemable convertible preferred stock held by SV Life Sciences Fund VI Strategic Partners L.P. ("SV Strategic Partners VI"), (ii) 2,174,571 shares of common stock issued or issuable upon the conversion of Series A and Series B redeemable convertible preferred stock held by SV Life Sciences Fund VI, L.P., ("SV Fund VI") and (iii) 669,939 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by SV TRex Coinvestment, L.P. ("SV Coinvestment") and (iv) 963,524 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by SV Biotech Crossover Opportunities Fund LP ("SV Crossover"). SV Health Investors, LLC is the manager of SV Fund VI, SV Strategic Partners VI and SV Coinvestment. SVLSF VI, LLC is the general partner of SV Life Sciences Fund VI (GP), L.P., which is the general partner of each of SV Fund VI, SV Strategic Partners VI and SV Coinvestment. Investment and voting decisions with respect to securities held by SV Fund VI, SV Strategic Partners VI and SV Coinvestment are made by the investment committee of SVLSF VI, LLC, which consists of Kate Bingham, Thomas Flynn, Eugene D. Hill, III, Paul LaViolette and Michael Ross, Ph.D. ("Dr. Ross"). Approval of four of the five members of the investment committee is required for such decisions, and no individual member has separate or delegated authority to vote or dispose of such securities. SV Health Managers is the manager of SV Crossover, and SV BCO I GP LLP is the general partner of SV Crossover. Investment and voting decisions with respect to securities held by SV Crossover are made by the four-member investment committee of SV BCO I GP LLP, which includes Dr. Ross and Nikola Trbovic, Ph.D. ("Dr. Trbovic"). All such investment committee decisions require unanimous approval of all four members. The securities held by the foregoing entities are aggregated in the table above for purposes of presentation only, and such aggregation is not intended to constitute an admission that any such entity or person beneficially owns securities held by any other such entity or that any of the foregoing entities or persons constitutes a "group" for purposes of Section 13(d) of the Exchange Act. The address of the principal business for SV Health Investors, LLC, SV Fund VI, SV Strategic Partners VI, SV Coinvestment and Dr. Ross is c/o SV Health Investors, 28 State Street, Suite 980, Boston, MA 02109. The principal business address of SV Health Managers LLP and SV Crossover is 71 Kingsway, London WC2B 6ST, United Kingdom.

(4) Consists of (i) 687,312 shares of common stock issuable upon the conversion of Series A redeemable convertible preferred stock and (ii) 577,754 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Pfizer Ventures (US) LLC. The address of Pfizer Ventures (US) LLC is c/o Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001. Pfizer Inc. is the parent company of Pfizer Ventures (US) LLC and may be deemed to beneficially own the shares directly owned by Pfizer Ventures (US) LLC. As of December 31, 2025, the board of directors of Pfizer Inc. was comprised of the following individuals: Dr. Albert Bourla, Shantanu Narayen, Ronald E. Blaylock, Mortimer J. Buckley, Susan Desmond-Hellmann, Joseph J. Echevarria, Scott Gottlieb, Susan Hockfield, Dan R. Littman, Suzanne Nora Johnson, James Quincey, James C. Smith and Cyrus Taraporevala. Pfizer Inc. is a publicly traded company. The address for Pfizer Inc. is 66 Hudson Blvd. East, New York, NY 10001.

(5) Consists of (i) 687,312 shares of common stock issuable upon the conversion of Series A redeemable convertible preferred stock held by Johnson & Johnson Innovation—JJDC, Inc. ("JJDC") and (ii) 573,705 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by JJDC. JJDC is a wholly-owned subsidiary of Johnson & Johnson ("J&J"). J&J may be deemed to indirectly beneficially own the shares that are directly beneficially owned by JJDC. As of December 31, 2025, the board of directors of J&J was comprised of the following individuals: Mary C. Beckerle, Jennifer A. Doudna, Joaquin Duato, Marillyn A. Hewson, Paula A. Johnson, Hubert Joly, Mark B. McClellan, John G. Morikis, Daniel E. Pinto, Mark A. Weinberger, Nadja Y. West and Eugene A. Woods. J&J is a publicly traded company. The principal business address of J&J is One Johnson & Johnson Plaza, New Brunswick, NJ 08933, and the principal business address of JJDC is 410 George Street, New Brunswick, NJ 08901.

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(1) Consists of 1,256,136 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock directly held by Janus Henderson Biotech Innovation Master Fund Limited ("Master Fund"). Such shares may be deemed to be beneficially owned by Janus Henderson Investors US LLC ("Janus"), an investment adviser to the Master Fund, and, in such capacity, has the ability to make decisions with respect to the voting and disposition of the shares subject to the oversight of the board of directors of the Master Fund. Under the terms of its management contract with the Master Fund, Janus has overall responsibility for directing the investments of the Master Fund in accordance with the Master Fund's investment objective, policies and limitations. The Master Fund has one or more portfolio managers appointed by and serving at the pleasure of Janus whom makes decisions with respect to the disposition of the shares of common stock offered hereby. The principal address for the Master Fund is c/o Janus Henderson Investors US LLC, 151 Detroit Street, Denver, Colorado 80206. The portfolio managers for the Master Fund are Andrew Acker, Daniel S. Lyons and Agustin Mohedas.

(7) Consists of (i) 267,417 shares of common stock issuable upon the conversion of Series A redeemable convertible preferred stock and (ii) 900,512 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Alexandria Venture Investments, LLC ("Alexandria"). The managing member of Alexandria is Alexandria Real Estate Equities, Inc., which has full voting and investment power with respect to the shares owned by Alexandria. Joel S. Marcus is the Executive Chairman of Alexandria Real Estate Equities, Inc., however Mr. Marcus does not have voting or investment power with respect to the shares owned by Alexandria. The address of Alexandria is 26 North Euclid Avenue, Pasadena, CA 91101.

(8) Consists of 1,149,411 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Delos Capital Fund III, LP ("Delos Capital Fund"). Delos Capital GP III, LLC ("Delos GP") is the general partner of Delos Capital Fund and holds voting and dispositive power over the shares held by Delos Capital Fund. Voting, investment and dispositive power with respect to the shares held by Delos Capital Fund are made collectively by the managers of Delos GP, Henry Chen and Frank Chen. Dr. Huang is a partner at Delos Advisors Inc., an entity affiliated with Delos Capital Fund and Delos GP, and a former member of our board of directors. Dr. Huang has no voting or dispositive power with respect to any of the above referenced shares and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. The address of Delos Capital Fund is c/o Delos Advisors Inc., 201 Broadway, Suite 330, Cambridge, MA 02139.

(9) Consists of (i) 534,835 shares of common stock issuable upon the conversion of Series A redeemable convertible preferred stock and (ii) 483,990 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Polaris Partners X, L.P. ("PP X"). Polaris Partners GP X, L.L.C. ("PP GP X") is the general partner of PP X and may be deemed to have sole voting and dispositive power with respect to the shares held by PP X. Brian Chee, and Amy Schulman (together, the "PP GP X Managing Members") are the managing members of PP GP X. Dr. Cantley is a partner at Polaris Partners, an entity affiliated with PP X and PP GP X, and a former member of our board of directors. Dr. Cantley holds an interest in PP GP X. Each of the PP GP X Managing Members and Dr. Cantley, in their respective capacities with respect to PP GP X, may be deemed to have shared voting and dispositive power with respect to the shares held by PP X. The principal business address for all entities and individuals affiliated with Polaris Partners is c/o Polaris Partners, One Marina Park Drive, 8th Floor, Boston, MA 02210.

(10) Consists of 656,339 shares of common stock subject to options exercisable within 60 days of September 30, 2026, held by M. Johnston Erwin, Jr.

(11) Consists of (i) 18,111 shares of common stock and (ii) 84,212 shares of common stock subject to options exercisable within 60 days of September 30, 2026, held by Ali Zarrin.

(12) Consists of (i) 168,574 shares of common stock and (ii) 24,863 shares of common stock subject to options exercisable within 60 days of September 30, 2026, held by Laura Berner.

(13) Consists of 251,471 shares of common stock held by Carol G. Gallagher.

(14) Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by PP X. Dr. Cantley is a partner at Polaris Partners. Dr. Cantley has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(15) Consists of 19,885 shares of common stock subject to options exercisable within 60 days of September 30, 2026, held by Travis Coy.

(16) Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by Lilly. Dr. Gilmore is a vice president and Global Head of Lilly Gateway Labs at Lilly.

(17) Consists of (i) 38,202 shares of common stock and (ii) 7,520 shares of common stock subject to options exercisable within 60 days of September 30, 2026, held by Peter Hirth.

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(18) Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by Delos Capital Fund III, LP. Dr. Huang is a partner at Delos Advisors Inc. Dr. Huang has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(19) Consists of 41,871 shares of common stock issuable upon the conversion of Series B redeemable convertible preferred stock directly held by Joel S. Marcus. Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by Alexandria**.**

(20) Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by Johnson & Johnson Innovation – JJDC Inc. Dr. Mistry is a vice president at Johnson & Johnson Innovation – JJDC Inc. Dr. Mistry has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(21) Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by Pfizer Ventures (US) LLC. Dr. O'Donnell is a partner at Pfizer Ventures (US) LLC and is a vice president of worldwide business development at Pfizer Inc. Dr. O'Donnell has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(22) Does not include shares of common stock issuable upon conversion of redeemable convertible preferred stock held by funds affiliated with SV Health. Dr. Ross and Dr. Trbovic are managing partners at certain funds affiliated with SV Health. As a result, by virtue of the relationships described in footnote 3 above, Dr. Ross and Dr. Trbovic may be deemed to share beneficial ownership of such securities held by certain funds affiliated with SV Health. Dr. Trbovic has resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

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DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our Restated Charter and Restated Bylaws as they will be in effect prior to the completion of this offering are summaries and are qualified in their entirety by reference to our Restated Charter and Restated Bylaws that will be in effect prior to the completion of this offering. Copies of these documents are filed as exhibits to the registration statement of which this prospectus is a part.

General

Following the completion of this offering, our authorized capital stock will consist of 225,000,000 shares of common stock, par value $0.0001 per share, and 25,000,000 shares of preferred stock, par value $0.0001 per share, all of which preferred stock will be undesignated.

As of June 30, 2026, after giving effect to the Preferred Stock Conversion, there were 19,112,348 shares of our common stock outstanding, held of record by 119 stockholders. No shares of preferred stock will be issued and outstanding immediately after completion of this offering.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a majority of the votes cast by the stockholders entitled to vote on the election, except in the case of a contested election, in which case the election shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our Restated Charter that will be in effect in connection with the completion of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the completion of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of June 30, 2026, options to purchase 2,980,123 shares of our common stock were outstanding, of which options to purchase 1,077,146 shares were vested and exercisable. For additional information regarding the terms of our Incentive Plans, see the sections titled “Executive and Director Compensation—Equity Incentive Plans.”

Registration Rights

Our Investors’ Rights Agreement grants the parties thereto certain registration rights in respect of the “registrable securities” held by them, which securities include (i) the Common Stock issuable or issued upon conversion of the Preferred Stock; (ii) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors; and (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) through (iii) above. The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Investors’ Rights Agreement, we will pay all expenses relating to such registrations, including the fees of one counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Investors’ Rights Agreement includes customary indemnification and procedural terms.

The demand and piggyback registration rights granted under the Investors' Rights Agreement will terminate, as to any particular holder, upon the earliest to occur of (i) the closing of a Deemed Liquidation Event (as defined in our Restated Charter), (ii) such time after consummation of this offering as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period without registration and (iii) the fifth anniversary of this offering.

Demand Registration Rights

At any time after the earlier of (i) five years after the date of the Investors' Rights Agreement or (ii) 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of the majority of the registrable securities then outstanding may request that we file a registration statement on Form S-1 with respect to at least 60% of the registrable securities or a lesser percent if the anticipated aggregate offering price would exceed $50,000,000 net of selling expenses, as defined in the Investors' Rights Agreement.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders (other than (i) a registration relating to the demand or S-3 registration rights described herein, (ii) a registration relating to the sale or grant of securities to our employees or consultants pursuant to a stock option, stock purchase, equity incentive or similar plan, (iii) a registration relating to a SEC Rule 145 transaction, (iv) 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 registrable securities, or (v) a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered, the holders of registrable securities will be entitled to certain "piggyback" registration rights pursuant to the Investors' Rights Agreement , allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act covered by these piggyback rights, the holders of registrable securities are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the offering, to include their registrable securities in the registration.

S-3 Registration Rights

At any time when we are eligible to use a registration statement on Form S-3, the holders of at least 60% of the registrable securities then outstanding may request that we file a Form S-3 registration statement with respect to outstanding registrable securities of such holders having an anticipated aggregate offering price, net of selling expenses, of at least $5.0 million. Within ten days after such request is given, we are required to give a demand notice to all other holders of registrable securities, and use commercially reasonable efforts to file, as soon as practicable and in any event within 45 days after the request is given by the initiating holders, a Form S-3 registration statement covering all registrable securities that the initiating holders and any other holders requested to be registered (with such other holders' notices to be given within 20 days of the demand notice). The right to request a Form S-3 demand registration is not available to any holder that is a "Foreign Person". We are not obligated to effect more than two Form S-3 registrations in any 12-month period, and may defer such registration in certain circumstances

Anti-takeover Effects of Our Restated Charter and Our Restated Bylaws

Our Restated Charter and Restated Bylaws, which will be in effect in connection with the completion of this offering, will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Classified board. Our Restated Charter will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board of directors. Our Restated Charter will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have seven directors.

Action by written consent; special meetings of stockholders. Our Restated Charter will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our Restated Charter and the Restated Bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of our board of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require our board of directors to call a special meeting.

Removal of directors. Our Restated Charter will provide that our directors may be removed only for cause by the affirmative vote of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote of at least sixty-six and two-thirds percent (66-2/3%) of the vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board of directors.

Advance notice procedures. Our Restated Bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the Restated Bylaws will not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the Restated Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Supermajority approval requirements. The Delaware General Corporation Law (the "DGCL"), generally provides that the affirmative vote of sixty-six and two-thirds percent (66-2/3%) of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our Restated Charter and bylaws will provide that the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the total votes eligible to be cast in the election of directors will be required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our Restated Charter and Restated Bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but unissued shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum. Our Restated Charter will provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if, and only if, the Court of Chancery of the State of Delaware dismisses a Covered Claim (as defined above) for lack of subject matter jurisdiction, any other state or federal court in the State of Delaware that does have subject matter jurisdiction) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for Covered Claims. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our Restated Charter will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Restated Charter will provide that any person or entity purchasing or otherwise acquiring any interest in the shares of capital stock of the Company will be deemed to have notice of and consented to these choice-of-forum provisions and waived any argument relating to the inconvenience of the forums in connection with any Covered Claim.

The choice of forum provisions to be contained in our Restated Charter may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions to be contained in our Restated Charter are inapplicable or unenforceable if they are challenged in a proceeding or otherwise, which could cause us to incur additional costs associated with resolving such action in other jurisdictions. See the section titled "Risk Factors—Risks Related to This Offering and Our Common Stock—Our Restated Charter will designate the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees."

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Section 203 of the DGCL

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the corporation's board of directors approved either the business combination or the transaction which resulted in the stockholder becoming 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, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Limitations of Liability and Indemnification Matters

Our Restated Charter provides that no director will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except as required by applicable law, as in effect from time to time. Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to our company or our stockholders;
- any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; and
- any transaction from which the director derived an improper personal benefit.

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages against a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior, except in the situations described above. Our Restated Charter also provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our director or officer or served any other enterprise at our request as a director or officer. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

For a discussion of liability and indemnification, see the section titled "Executive and Director Compensation—Limitations on Liability and Indemnification."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 150 Royall Street, Canton, Massachusetts 02021, and its telephone number is (781) 575-2000.

Nasdaq Listing

Our common stock has been approved for listing on the Nasdaq under the symbol "TRXB."

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SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See the section titled "Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—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." Furthermore, although our common stock has been approved for listing on Nasdaq, we cannot assure you that there will be an active public trading market for our common stock.

Upon the completion of this offering, based on the number of shares of our common stock outstanding as of June 30, 2026, after giving effect to the conversion of all of the shares of our redeemable convertible preferred stock into an aggregate of 17,742,217 shares of our common stock, we will have an aggregate of 27,445,682 shares of our common stock outstanding (or 28,695,682 shares of our common stock if the underwriters exercise their option to purchase additional shares in full). Of these shares of our common stock, all of the 8,333,334 shares sold in this offering (or 9,583,334 shares if the underwriters exercise their option to purchase additional shares in full) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately 19,112,348 shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed with the underwriters that, among other things and subject to certain exceptions, 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 J.P. Morgan Securities LLC and Evercore Group L.L.C.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the Investor Rights Agreement and our standard form of option agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell, or transfer our equity securities for such period of time as may be requested by us or the underwriters (not to exceed 180 days) following the date of this prospectus.

Upon the expiration of the lock-up period set forth in the agreements described above, and assuming that J.P. Morgan Securities LLC and Evercore Group L.L.C. do not release any parties from these agreements, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see the section titled "Underwriting."

Rule 10b5-1 Plans

After the date of the initial public filing of the prospectus, 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.

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Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell (subject to the lock-up agreement referred to above, if applicable) in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 274,456 shares (or 286,956 shares if the underwriters exercise their option to purchase additional shares in full) of our common stock immediately after this offering; or
- the average weekly trading volume in shares of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

An "affiliate" is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by or is under common control with an issuer. Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us (as well as the lock-up agreement referred to above, if applicable). If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and shares of our common stock issued or issuable under our incentive plans. We expect to file the registration statement covering shares offered pursuant to our incentive plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the completion of this offering, the holders of 17,541,654 shares of our common stock or their transferees, after giving effect to the Preferred Stock Conversion, will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See the section titled "Description of Capital Stock—Registration Rights" for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

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MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-UNITED STATES HOLDERS OF OUR COMMON STOCK

The following is a summary of the material United States federal income tax considerations relating to the purchase, ownership and disposition of our common stock by Non-U.S. Holders (defined below). This summary does not purport to be a complete analysis of all the potential tax considerations relevant to Non-U.S. Holders of our common stock. This summary is based on the Code, Treasury Regulations promulgated thereunder, published rulings and administrative pronouncements of the Internal Revenue Service (the "IRS") and judicial decisions, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in United States federal income tax consequences different from those discussed below. We have not requested, nor do we intend to request, a ruling from 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 discussion is limited to Non-U.S. Holders that acquire our common stock pursuant to this offering and hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). For purposes of this summary, a "Non-U.S. Holder" means a beneficial owner of common stock that for U.S. federal income tax purposes is not classified as a partnership and is not:

- an individual who is a citizen or resident of the United States;
- a corporation or any other organization taxable as a corporation for United States federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is included in gross income for United States federal income tax purposes regardless of its source; or
- a trust if (1) a United States court is able to exercise primary supervision over the trust's administration and one or more "United States persons" (as defined in the Code) have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person for United States federal income tax purposes.

This discussion does not address all United States federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or non-United States tax laws or any other United States federal tax laws. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- United States expatriates and former citizens or long term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid United States federal income tax;
- partnerships or other entities or arrangements treated as partnerships or other pass-through entities for United States federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- persons who hold common stock that constitutes "qualified small business stock" under Section 1202 of the Code, or "Section 1244 stock" under Section 1244 of the Code;

- persons who acquired our common stock in a transaction subject to the gain rollover provisions of the Code (including Section 1045 of the Code);
- persons that acquired our common stock pursuant to the exercise of warrants or conversion rights under convertible instruments;
- persons who have elected to mark securities to market;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- 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.

If an entity that is classified as a partnership for United States federal income tax purposes holds our common stock, the tax treatment of persons treated as its partners for United States federal income tax purposes will generally depend upon the status of the partner and the activities of the partnership. Partnerships and other entities that are classified as partnerships for United States federal income tax purposes and persons holding our common stock through a partnership or other entity classified as a partnership for United States federal income tax purposes are urged to consult their own tax advisors.

THIS SUMMARY IS FOR GENERAL INFORMATION ONLY AND IS NOT INTENDED TO BE TAX ADVICE. NON-U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS CONCERNING THE UNITED STATES FEDERAL INCOME TAXATION, STATE, LOCAL AND NON-UNITED STATES TAXATION AND OTHER TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, INCLUDING CONSEQUENCES ARISING UNDER ANY APPLICABLE INCOME TAX TREATY.

Distributions on Our Common Stock

We do not currently expect to make distributions with respect to our common stock. If we make a distribution of cash or property with respect to our common stock, any such distributions generally will constitute dividends for United States federal income tax purposes to the extent of our current and accumulated earnings and profits, if any, as determined under United States federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will constitute a return of capital and will first reduce the holder's adjusted tax basis in our common stock, but not below zero. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock." Any such distribution would also be subject to the discussion below under the section titled "—Additional Withholding and Reporting Requirements."

Dividends paid to a Non-U.S. Holder generally will be subject to a 30% United States federal withholding tax unless such Non-U.S. Holder provides the applicable withholding agent with the appropriate IRS Form W-8, such as:

- IRS Form W-8BEN or W-8BEN-E (or successor form) certifying, under penalties of perjury, a reduction in withholding under an applicable income tax treaty, or
- IRS Form W-8ECI (or successor form) certifying that a dividend paid on our common stock is not subject to withholding tax because it is effectively connected with a trade or business in the United States of the Non-U.S. Holder (in which case such dividend generally will be subject to regular graduated United States tax rates as described below).

The certification requirement described above must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. The certification also may require a Non-U.S. Holder that provides an IRS form or that claims treaty benefits to provide its United States taxpayer identification number. Special certification and other requirements apply in the case of certain Non-U.S. Holders that hold shares of our common stock through intermediaries or are pass-through entities for United States federal income tax purposes.

Each Non-U.S. Holder is urged to consult its own tax advisor about the specific methods for satisfying these requirements. A claim for exemption will not be valid if the person receiving the applicable form has actual knowledge or reason to know that the statements on the form are false.

If dividends are effectively connected with a trade or business in the United States of a Non-U.S. Holder (and, if required by an applicable income tax treaty, are attributable to a permanent establishment maintained by such Non-U.S. Holder in the United States), the Non-U.S. Holder, although exempt from the withholding tax described above (provided that the certifications described above are satisfied), generally will be subject to United States federal income tax on such dividends on

a net income basis in the same manner as if it were a resident of the United States. In addition, if a Non-U.S. Holder is treated as a corporation for United States federal income tax purposes, the Non-U.S. Holder may be subject to an additional "branch profits tax" equal to 30% (unless reduced by an applicable income tax treaty) of its earnings and profits in respect of such effectively connected dividend income.

Non-U.S. Holders that do not timely provide the applicable withholding agent with the required certification, but which are eligible for a reduced rate of United States federal withholding tax pursuant to an income tax treaty, may obtain a refund or credit of any excess amount withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable tax treaties.

Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under the section titled "—Additional Withholding and Reporting Requirements," in general, a Non-U.S. Holder will not be subject to United States federal income tax or withholding tax on gain realized upon such holder's sale, exchange or other taxable disposition of shares of our common stock, unless (1) such Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition, and certain other conditions are met, (2) we are or have been a "United States real property holding corporation," as defined in the Code ("USRPHC"), at any time within the shorter of the five-year period preceding the disposition and the Non-U.S. Holder's holding period in the shares of our common stock, and certain other requirements are met, or (3) such gain is effectively connected with the conduct by such Non-U.S. Holder of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by such Non-U.S. Holder in the United States).

If the first exception applies, the Non-U.S. Holder generally will be subject to United States federal income tax at a rate of 30% (or at a reduced rate under an applicable income tax treaty) on the amount by which such Non-U.S. Holder's capital gains realized upon the sale, exchange or other taxable disposition of shares of our common stock exceed capital losses allocable to United States sources during the taxable year of the disposition. If the third exception applies, the Non-U.S. Holder generally will be subject to United States federal income tax with respect to such gain on a net income basis in the same manner as if it were a resident of the United States and a Non-U.S. Holder that is a corporation for United States federal income tax purposes may also be subject to a branch profits tax with respect to any earnings and profits attributable to such gain at a rate of 30% (or at a reduced rate under an applicable income tax treaty).

With respect to the second exception, generally, a corporation is a USRPHC only if the fair market value of its United States real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not, and do not anticipate becoming, a USRPHC. Even if we became a USRPHC, a Non-U.S. Holder would not be subject to United States federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as USRPHC so long as our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market at any time during the calendar year in which the disposition occurs and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly and constructively) more than 5% of our common stock at any time during the shorter of the five year period ending on the date of disposition and the holder's holding period. There can be no assurances that our common stock will continue to be regularly traded on an established securities market. Non-U.S. Holders should consult their tax advisors regarding the tax consequences if the company is or becomes a USRPHC.

Additional Withholding and Reporting Requirements

The Foreign Account Tax Compliance Act, Sections 1471 through 1474 of the Code, and related Treasury Regulations, together with other Treasury Department and IRS guidance issued thereunder, and intergovernmental agreements, legislation, rules and other official guidance adopted pursuant to such intergovernmental agreements, or commonly referred to as FATCA, impose a United States federal withholding tax of 30% on certain payments, including dividends paid on our common stock, paid to (1) a "foreign financial institution" (as defined under FATCA) unless such institution furnishes proper documentation (typically on IRS Form W-8BEN-E) evidencing either (i) an exemption from FATCA withholding, (ii) its compliance (or deemed compliance) with specified due diligence, reporting, withholding and certification obligations under FATCA or (iii) residence in a jurisdiction that has entered into an intergovernmental agreement with the United States relating to FATCA and compliance with the diligence and reporting requirements of the intergovernmental agreement and local implementing rules; or (2) a "non-financial foreign entity" (as defined under FATCA) unless such institution furnishes proper documentation (typically on IRS Form W-8BEN-E) evidencing either (i) an exemption from FATCA, (ii) that it does not have any substantial United States beneficial owners or (iii) adequate information regarding substantial United States beneficial owners of such entity. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements.

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The IRS and the U.S. Department of Treasury have issued proposed regulations on which taxpayers may rely providing that these withholding rules will not apply to the gross proceeds of a sale or other disposition of shares of property of a type that can produce U.S. source dividends or interest. Prospective investors should consult their own tax advisors regarding the effect of FATCA on their ownership and disposition of our common stock.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions on our common stock paid to the holder and the tax withheld, if any, with respect to the distributions, regardless of whether such distributions constitute dividends. Non-U.S. Holders may have to comply with specific certification procedures (such as the provision of a properly completed W-8BEN, W-8BEN-E or W-8ECI) to establish that the holder is not a United States person in order to avoid backup withholding at the applicable rate, currently 24%, with respect to dividends on our common stock. Dividends paid to Non-U.S. Holders subject to the United States withholding tax, as described above under the section titled "— Distributions on Our Common Stock," generally will be exempt from United States backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a Non-U.S. Holder effected by or through the United States office of any broker, United States or foreign, unless the holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-United States office of a broker. However, for information reporting purposes, dispositions effected through a non-United States office of a broker with substantial United States ownership or operations generally will be treated in a manner similar to dispositions effected through a United States office of a broker. Prospective investors should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them, including the availability of and procedure for obtaining an exemption from backup withholding.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or, in which the Non-U.S. Holder is incorporated, under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder's United States federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

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UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Evercore Group L.L.C. are acting as book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	3,083,334
Evercore Group L.L.C.	2,083,334
Cantor Fitzgerald & Co.	1,250,000
Stifel, Nicolaus & Company, Inc.	1,250,000
Wedbush Securities Inc.	666,666
Total	8,333,334

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.588 per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $0.588 per share from the initial public offering price. After the initial offering of the shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 1,250,000 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

Lilly has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount, when combined with shares of common stock beneficially owned by Lilly prior to the initial public offering, that does not exceed 19.9% of the number of shares of common stock issued and outstanding after this offering. Because this indication of interest is not a binding agreement or commitment to purchase, Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Lilly. The number of shares of common stock available for sale to the public will be reduced to the extent that Lilly purchases shares of common stock in the offering.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $0.98 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$ 0.98	$ 0.98
Total	$ 8,166,667	$ 9,391,667

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $5.0 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $40,000.

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A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) 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, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Evercore Group L.L.C. for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; or (iii) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers, and substantially all of our shareholders (such persons, the "lock-up parties") have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the "restricted period"), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities LLC and Evercore Group L.L.C., (1) 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, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the common stock, the "lock-up securities")), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which would reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers, distributions, dispositions or surrenders of lock-up securities: (i) as bona fide gifts, including to a charitable organization or educational institution, or for bona fide estate planning purposes, (ii) by will, other testamentary document or intestacy, (iii) to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, (iv) to a corporation, trust, partnership, limited liability company or other entity of which the lock-up party and/or one or more members of the immediate family are the, direct or indirect, legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business

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entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates or (B) as part of a distribution to stockholders, partners, members or other equityholders of the lock-up party; (vii) by operation of law, (viii) to us (A) from an employee or other service provider upon death, disability or termination of employment or service or (B) pursuant to a right of first refusal with respect to transfers of such shares of common stock or other securities, (ix) as part of a sale of lock-up securities acquired in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrant received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC and Evercore Group L.L.C., in their joint 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.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock has been approved for listing/quotation on Nasdaq under the symbol "TRXB."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. 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 the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on Nasdaq, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Directed Share Program

At our request, the underwriters have reserved up to 3% of the shares of common stock to be issued by us and offered by this prospectus for sale, at the initial public offering price, to certain of our directors and officers and certain of our employees, business associates, investors and friends and family of our directors, officers, employees, business associates and investors. The sales will be made at our direction by J.P. Morgan Securities LLC and its affiliates through a directed share program. Any shares sold in the directed share program to our directors or officers who have entered into lock-up agreements described above will be subject to the provisions of such lock-up agreements. The number of shares of common stock available for sale to the general public will be reduced to the extent such persons 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.

Selling Restrictions

General

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

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European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering 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 legal entity which is a 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 us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 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.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA;

provided that no such offer of the shares shall require us or any manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom 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 "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The securities may be sold in Canada 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 securities 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.

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Hong Kong

No shares have been offered or sold, and the shares may not be offered or sold in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (the "SFO") and any rules made under the SFO; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions Ordinance (Cap. 32) of Hong Kong (the "C(WUMP)O")) or which do not constitute an offer or invitation to the public within the meaning of the C(WUMP)O. No document, invitation or advertisement relating to the shares has been or will be issued or has been or will be in the possession of any person for the purpose of issue (in each case 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 under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under the SFO.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act 2001 of Singapore, as modified or amended from time to time (the "SFA")) under 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, in each case subject to conditions set forth in the SFA.

The shares are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948 of Japan, as amended) (the "FIEA"). The securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEA and any other applicable laws, regulations and ministerial guidelines of Japan.

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LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Ropes & Gray LLP. Certain legal matters relating to this offering will be passed upon for the underwriters by Latham & Watkins LLP.

EXPERTS

The financial statements of TRex Bio, Inc. as of December 31, 2024 and 2025, and for each of the years in the two-year period ended December 31, 2025, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

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 common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto.

Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is *www.sec.gov*.

Upon the effectiveness of the registration statement, we became subject to the informational requirements of the Exchange Act and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be accessed at the SEC's website referenced above. We also maintain a website at trex.bio, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

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TRex Bio, Inc.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
TRex Bio, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of TRex Bio, Inc. (the Company) as of December 31, 2024 and 2025, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2025, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2025, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2022.

San Francisco, California
June 26, 2026, except for the effects of the reverse stock split discussed in Note 13, as to which the date is October 5, 2026.

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TRex Bio, Inc.
BALANCE SHEETS
(in thousands, except share data)

	As of December 31,	
	2024	2025
Assets		
Current assets:		
Cash and cash equivalents	$ 47,469	$ 15,192
Marketable securities	17,836	52,533
Prepaid expenses and other current assets	1,469	3,707
Total current assets	66,774	71,432
Property and equipment, net	632	482
Operating lease right-of-use assets, net	657	681
Other assets	3	538
Total assets	$ 68,066	$ 73,133
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 527	$ 371
Accrued liabilities	6,316	3,906
Lease liabilities	696	717
Total current liabilities	7,539	4,994
Income taxes payable - long-term	1,253	1,171
Other liabilities	—	72
Total liabilities	8,792	6,237
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock:		
Series A-1 redeemable convertible preferred stock, $0.0001 par value per share; 5,000,000 shares authorized, issued and outstanding as of December 31, 2024 and 2025; liquidation preference of $9,806 as of December 31, 2024 and 2025	6,530	6,530
Series A-2 redeemable convertible preferred stock, $0.0001 par value per share; 7,700,000 shares authorized, issued and outstanding as of December 31, 2024 and 2025; liquidation preference of $42,721 as of December 31, 2024 and 2025	25,181	25,181
Series A-3 redeemable convertible preferred stock, $0.0001 par value per share, 12,482,976 shares authorized, issued and outstanding as of December 31, 2024 and 2025; liquidation preference of $61,844 as of December 31, 2024 and 2025	43,730	43,730
Series B redeemable convertible preferred stock, $0.0001 par value per share; 27,510,762 shares authorized as of December 31, 2024 and 2025; 13,683,972 and 27,206,115 shares issued and outstanding as of December 31, 2024 and 2025, respectively; liquidation preference of $42,279 and $84,059 as of December 31, 2024 and 2025	41,805	83,574
Stockholders' deficit:		
Common Stock, $0.0001 par value; 72,213,000 shares authorized as of December 31, 2024 and 2025; 1,019,195 and 1,285,835 shares issued and outstanding as of December 31, 2024 and 2025, respectively; and 0 and 83,741 shares subject to repurchase as of December 31, 2024 and 2025, respectively	—	—
Additional paid-in capital	1,473	2,123
Accumulated other comprehensive income	8	17
Accumulated deficit	(59,453)	(94,259)
Total stockholders' deficit	(57,972)	(92,119)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 68,066	$ 73,133

See accompanying notes to the financial statements.

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TRex Bio, Inc.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands)

	For the Year Ended December 31,	
	2024	2025
Collaboration revenue	$ 39,108	$ —
Operating expenses:		
Research and development	34,989	29,809
General and administrative	6,500	8,036
Total operating expenses	41,489	37,845
Loss from operations	(2,381)	(37,845)
Interest income	2,007	3,154
Other expense, net	(70)	(69)
Total other income, net	1,937	3,085
Loss before provision for income taxes	(444)	(34,760)
Provision for income taxes	2,700	46
Net loss	(3,144)	(34,806)
Series A preferred stock dividends	(5,745)	—
Net loss attributable to common stockholders	$ (8,889)	$ (34,806)
Net loss per share attributable to common stockholders, basic and diluted	$ (8.92)	$ (33.20)
Weighted-average shares outstanding, basic and diluted	996,143	1,048,231
Comprehensive loss:		
Net loss	(3,144)	(34,806)
Unrealized gain on marketable securities	8	9
Comprehensive loss	$ (3,136)	$ (34,797)

See accompanying notes to the financial statements.

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TRex Bio, Inc.
STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands, except share data)

	Redeemable Convertible Preferred Stock													
	Series A-1		Series A-2		Series A -3		Series B		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Share	Amount	Share	Amount	Share	Amount	Share	Amount	Share	Amount				
Balances as of December 31, 2023	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	—	$ —	964,091	$ —	$ 1,179	$ —	$ (56,309)	$ (55,130)
Issuance of common stock	—	—	—	—	—	—	—	—	55,104	—	46	—	—	46
Issuance of Series B preferred stock, net of issuance costs of $474	—	—	—	—	—	—	13,683,972	41,805	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	248	—	—	248
Unrealized gain on marketable securities		—		—		—		—		—	—	8	—	8
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(3,144)	(3,144)
Balances as of December 31, 2024	5,000,000	6,530	7,700,000	25,181	12,482,976	43,730	13,683,972	41,805	1,019,195	—	1,473	8	(59,453)	(57,972)
Issuance of common stock	—	—	—	—	—	—	—	—	266,640	—	182	—	—	182
Vesting of early exercised common stock	—	—	—	—	—	—	—	—	—	—	16	—	—	16
Issuance of Series B preferred stock, net of issuance costs of $10	—	—	—	—	—	—	13,522,143	41,769	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	452	—	—	452
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	9	—	9
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(34,806)	(34,806)
Balances as of December 31, 2025	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	27,206,115	$ 83,574	1,285,835	$ —	$ 2,123	$ 17	$ (94,259)	$ (92,119)

See accompanying notes to the financial statements.

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TRex Bio, Inc.
STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31,	
	2024	2025
Cash flows from operating activities:		
Net loss	$ (3,144)	$ (34,806)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,259	218
Stock-based compensation	248	452
Reduction in carrying amount of right-of-use assets	1,267	1,322
Net amortization of premiums and discounts on marketable securities	(592)	(1,767)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	577	(2,238)
Other assets	—	(535)
Accounts payable	(588)	(156)
Accrued liabilities	490	(2,441)
Deferred revenue	(24,108)	—
Lease liabilities	(1,268)	(1,325)
Income taxes payable - long-term	277	(82)
Net cash used in operating activities	(25,582)	(41,358)
Cash flows from investing activities:		
Purchase of property and equipment	(68)	(68)
Purchase of investments in marketable securities	(41,236)	(130,921)
Proceeds from maturities of marketable securities	24,000	98,000
Net cash used in investing activities	(17,304)	(32,989)
Cash flows from financing activities:		
Proceeds from issuance of common stock	46	301
Proceeds from sales of Series B redeemable convertible preferred stock	42,279	41,779
Payment of issuance costs of Series B redeemable convertible preferred stock	(474)	(10)
Net cash provided by financing activities	41,851	42,070
Net decrease in cash and cash equivalents	(1,035)	(32,277)
Cash and cash equivalents - beginning of year	48,504	47,469
Cash and cash equivalents - end of year	$ 47,469	$ 15,192
Supplemental disclosure:		
Cash paid for income taxes	$ 2,487	$ —
Supplemental disclosure of non-cash transactions:		
Right-of-use assets acquired in exchange for lease obligations	$ —	$ 1,346
Vesting of early exercised common stock	$ —	$ 16

See accompanying notes to the financial statements.

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TRex Bio, Inc.
Notes to Financial Statements
As of and for the years ended December 31, 2024 and 2025

1. Organization

Description of the Business

TRex Bio, Inc. (the "Company") is a company focusing on studying the regulation of tissue inflammation to develop breakthrough medicines. To date, the Company has created a multi-faceted discovery platform to gain insights into regulatory T cell biology through transcriptomic analyses. The Company has translated these findings into drug discovery campaigns, including collaboration with Eli Lilly and Company ("Lilly"). In June 2025, the Company initiated dosing for its first clinical trial for TRB-061, a novel TNFR2 agonist initially being developed for the treatment of atopic dermatitis.

The Company was incorporated in Delaware, United States of America in November 2021 as TRex Holdings, Inc. On December 29, 2021, TRex Bio Limited ("TBL") executed a Business Transfer Arrangement pursuant to which TRex Holdings Inc., the newly incorporated company for the purpose of effecting the re-domiciliation (the "Re-domiciliation"), acquired all TBL shares and TBL became a wholly-owned subsidiary of TRex Holdings Inc. TBL stockholders received one TRex Holdings, Inc. share for one TBL share. On December 31, 2024, the Company entered into the Agreement and Plan of Merger, in an effort to simplify and consolidate the corporate structure, with TRex Bio, Inc. (a Delaware corporation) remaining as the sole surviving entity. All directors of TRex Holdings, Inc. transferred to TRex Bio, Inc. upon closing of the merger. All preferred stock, common stock and stock option grants of TRex Holdings, Inc. were exchanged on a one for one basis for preferred stock, common stock and stock options of TRex Bio, Inc.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company is subject to risks inherent in operating an early-stage biotechnology business. These risks include, but are not limited to, dependence on the development of marketable products, the ability to attract, retain, and motivate qualified personnel, rapid technological changes and the rapidly evolving nature of the biotechnology industry.

As of December 31, 2025, the Company had cash and cash equivalents and marketable securities of $67.7 million and accumulated deficit of $94.3 million. The Company has incurred net losses and negative cash flows from operations since inception, except for the year ended December 31, 2023, during which it commenced a Research Collaboration and License Agreement (the "Lilly Collaboration Agreement"), received a one-time upfront payment of $55.0 million from Lilly, and recognized total collaboration revenue of $41.9 million across its collaboration agreements, resulting in net income for the year and positive cash flows from operations. The Company has incurred net losses of $3.1 million and $34.8 million for the years ended December 31, 2024 and 2025, respectively. The net cash used in operating activities was $25.6 million and $41.4 million for the years ended December 31, 2024 and 2025, respectively.

The Company has historically funded its operations primarily through the issuances of redeemable convertible preferred stock. In January 2026, the Company issued and sold an aggregate of 16,182,795 Series B preferred stock in an extension of its Series B preferred stock financing for an aggregate purchase price of approximately $50.0 million, as discussed in Note 13. The Company believes that its existing cash, cash equivalents and marketable securities as of December 31, 2025, together with the net proceeds received from the extension of the Series B financing, will be sufficient to fund its operations for at least twelve months from the date of issuance of these financial statements.

The Company expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval and commercialization of any product candidates it may develop, and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, it will need to continue to raise additional capital to fund ongoing research and development activities and maintain future operations. The Company's management plans to monitor expenses and may raise additional capital through a combination of public and private equity. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts, needed, on the terms which are favorable, the Company could be required to delay, scale back, or abandon some or all of its planned development product candidates and other operations, which could materially harm the Company's business, financial condition and results of operations.

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2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), stated in U.S. dollars. As a result of the corporate reorganization detailed in Note 1, the Company operates as a single legal entity without subsidiaries. Accordingly, the financial statements for the year ended December 31, 2025, represent the standalone operations of the Company. For the year ended December 31, 2024, the financial statements reflect the consolidated operations of the Company and its former subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation for this period.

The financial statements include all adjustments necessary for the fair presentation of the Company's financial statements as of and for the years ended December 31, 2024 and 2025. For all non-functional currency balances, the remeasurement of such balances to functional currency results in a foreign exchange transaction gain or loss, which is recorded as a component of other income (expense), net in the statement of operations and comprehensive loss. 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").

Reverse Stock Split

On October 2, 2026, the Company amended its certificate of incorporation to effect a 1-for-3.8649 reverse stock split of the Company's common stock. The par value of the Company's common stock was not adjusted as a result of the reverse stock split. The conversion prices of the Company's redeemable convertible preferred stock were proportionately adjusted, thereby reducing the number of shares of common stock issuable upon conversion. All issued and outstanding common stock, options to purchase common stock, and related share and per-share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent liabilities and the reported amounts of expenses in the financial statements and the accompanying notes. These estimates form the basis for judgments the Company makes about the carrying values of assets and liabilities that are not readily apparent from other sources. The Company bases its estimates using historical experience, Company forecasts and future plans, current economic conditions, and information from third-party professionals that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources and adjusts those estimates and assumptions when facts and circumstances dictate. Estimates are used in accounting for, among other things, useful lives of property and equipment, the rate used in determining the present value of lease payments, fair value of assets and liabilities, accrued liabilities, the fair value of common stock and stock-based compensation, the allocation of a revenue contract's transaction price to each distinct performance obligation on a relative standalone selling price basis, uncertain tax positions and the valuation allowance for deferred income tax assets. Actual results may differ from these estimates and assumptions.

The Company utilizes estimates and assumptions in determining the fair value of its common stock, including stock-based awards. The Company has granted stock options at exercise prices that represented the fair value of its common stock on the specific grant dates. The Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of the redeemable convertible preferred stock senior to the Company's common stock at the time, and a probability analysis of various liquidity events, such as a public offering or sale of the Company, under differing scenarios. Changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The Company's results can also be affected by economic, political, legislative, regulatory and legal actions. Economic conditions, such as recessionary trends, inflation, interest, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can have a significant effect on operations. While the Company maintains reserves for anticipated liabilities, the Company could be affected by civil, criminal, regulatory or administrative actions, claims or proceedings.

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Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment. As of December 31, 2024 and 2025, all of the Company's property and equipment was maintained in the United States. For the year ended December 31, 2024, all of the Company's revenue was generated in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist of amounts invested in money market funds exclusively composed of U.S. government obligations.

Marketable Securities

All marketable securities have been classified as "available-for-sale" and are carried at fair value, based upon quoted market prices. The Company considers its available-for-sale portfolio as available for use in current operations. Accordingly, the Company may classify certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. For available-for-sale debt securities, unrealized gains, net of any related tax effects, are excluded from earnings and are included in other comprehensive income and reported as a separate component of stockholders' equity until realized. The Company assesses available-for-sale debt securities on a quarterly basis to see if any unrealized loss is due to credit-related factors. Factors considered in determining whether an impairment is credit-related include the extent to which the investment's fair value is less than its cost basis, declines in published credit ratings, changes in interest rates, and any other adverse factors related to the security. If it is determined that a credit-related impairment exists, the Company will measure the credit loss based on a discounted cash flows model. Credit-related impairments on available-for-sale debt securities are recognized as an allowance for credit losses with a corresponding adjustment to other income, net in the Company's statement of operations. The unrealized loss position that is not credit-related is recorded, net of any related tax effects, in other comprehensive income until realized. There were no credit-related losses recognized for the periods presented.

The cost of securities sold is based on the specific-identification method. The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. In accordance with our investment policy, management invests in money market funds, U.S. treasury securities, and corporate bonds. The Company has not experienced any losses on its deposits of cash, cash equivalents, and marketable securities.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of financial instruments, including prepaid expenses and other current assets, accounts payable, accrued compensation, accrued expenses, and other liabilities, approximate fair value due to their short-term maturities. The cash invested in money-market funds is carried at fair value.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company's cash and cash equivalents are deposited in accounts with major financial institutions and amounts may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institution in which the cash and cash equivalents are held. The Company has not experienced any losses on deposits of cash and cash equivalents.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: management of growth; fluctuations in foreign currency; the ability to obtain future financing; regulatory clearance and market acceptance of the Company's products; development of sales channels; protection of the intellectual property; litigation or claims against the Company based on intellectual property, or other factors; and the Company's ability to attract and retain employees necessary to support its growth.

The Company is dependent on contract manufacturers to supply products for research and development activities in its product candidates. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the drug substance and drug products related to these product candidates. Disruption or interruption of these partners and contract manufacturers could adversely affect the supply of active pharmaceutical ingredients and formulated drugs for the Company's product candidates.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years. Repair and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred.

Leases

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For each lease, the Company determines the classification as either an operating lease or a financing lease. Lease recognition occurs at the lease commencement date and lease liability amounts are determined based on the present value of lease payments over the lease term. The lease term may include options to extend or terminate the lease only when it is reasonably certain that the Company will exercise that option.

The Company uses its incremental borrowing rate based on the information available at lease commencement date in determining the present value of lease payments if the Company's leases do not provide an implicit rate. The Company determines its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Right-of-use (ROU) assets represent the Company's right to use underlying assets for the lease term and operating lease liabilities represent the Company's obligation to make lease payments under the lease.

ROU assets are measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor. The Company elected to apply the practical expedient of combining lease and non-lease components for the real estate lease asset class. Fixed lease payments on operating leases are recognized as lease expense over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are recognized as incurred.

In addition, the Company elected the short-term lease practical expedient that allows the lessee to not record a lease liability and ROU asset for all leases with a term of 12 months or less.

As of December 31, 2024 and 2025, the Company did not have any finance leases.

Intangible Assets

Intangible assets with finite lives are amortized over their estimated useful lives using the straight-line method. As of December 31, 2024 and 2025, the Company does not have any intangible assets.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Recoverability is measured by comparing the carrying amount of each asset to the future undiscounted cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment is measured as the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows generated by the assets. The Company has not recorded impairment of any long-lived assets.

Redeemable Convertible Preferred Stock

The Company recorded all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. In the event of a deemed liquidation event, such as a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company's certificate of incorporation unless the holders of the redeemable convertible preferred stock have converted their shares of redeemable convertible preferred stock into shares of common stock. Redeemable convertible preferred stock is therefore classified outside of stockholders' deficit on the balance sheet as events triggering redemption are not solely within the Company's control.

The Company has not adjusted the carrying values of its redeemable convertible preferred stock to the liquidation preferences because of the uncertainty of whether or when such an event would occur. As of December 31, 2024 and 2025, it was not probable that such a deemed liquidation event would occur.

Comprehensive Loss

Comprehensive loss is the change in stockholders' deficit from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. The Company's other comprehensive income is comprised solely of unrealized gains on marketable securities. The Company has not recorded any reclassifications from other comprehensive income to net loss during the periods presented.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the period plus the potential dilutive effects of potential dilutive shares outstanding during the period. Potential dilutive securities include stock options and redeemable convertible preferred stock. The dilutive effect of stock options is computed using the treasury stock method and the dilutive effect of redeemable convertible preferred stock is calculated using the "if-converted method." For all periods presented in a net loss position, diluted net loss per share is the same as basic net loss per share since the effect of including potential common shares is anti-dilutive.

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company considers all series of its redeemable convertible preferred stock to be participating securities. Under the two-class method, the net loss attributable to common stockholders is not allocated to the redeemable convertible preferred stock as the holders of its redeemable convertible preferred stock do not have a contractual obligation to share in the Company's losses. Net income is attributed to common stockholders and participating securities based on their participation rights.

Research and Development Expenses

Research and development costs are expensed as incurred and consist of new product development. Research and development costs include salaries, bonuses, benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to other non-employees and entities that conduct certain research and development activities on the Company's behalf. Amounts incurred in connection with license agreements are also included in research and development expenses. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred. The deferred amounts are expensed as the related goods are delivered or the services are performed.

Revenue Recognition

As part of its ongoing activities, the Company enters into collaboration agreements with counterparts. The terms of the collaborative agreements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development or commercial goals; (iii) royalties on net sales of licensed products; and (iv) reimbursement of cost-sharing of research and development ("R&D") expenses.

When the Company enters into collaboration agreements, it assesses whether the arrangements fall within the scope of Accounting Standards Codification 808, *Collaborative Arrangements* ("ASC 808") based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and its collaboration partner fall within the scope of other accounting literature. If it concludes that payments from the collaboration partner to the Company represent consideration from a customer, such as license fees and contract research and development activities, the Company accounts for those payments within the scope of Accounting Standards Update No. 2014-09 (Topic 606), *Revenue from Contracts with Customers* ("ASC 606").

The Company has no products approved for commercial sale and has not generated any revenue from commercial product sales. The total revenue to date has been generated principally from collaboration agreements.

The Company determines revenue recognition through the following five-step framework: (i) identification of contract with a customer; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) each performance obligation has been satisfied.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation. For arrangements that include multiple performance obligations, the Company allocates the transaction price to the identified performance obligations based on the standalone selling price of each distinct performance obligation. In instances where standalone selling price is not directly observable, the Company develops assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract using a cost plus margin approach, which is an estimation method used when standalone selling price is not directly observable. Key assumptions used within this estimation method may include full-time equivalent personnel effort and estimated external costs associated with the performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, such as milestone and royalties payments, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in management's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation.

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance, (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or (iii) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer.

Consideration received prior to revenue recognition is recorded as deferred revenue in the balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying condensed balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current. For its current contracts, the Company recognizes revenue as the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and, if over time, revenue recognized is based on the use of an input method. As of December 31, 2024 and 2025, the Company did not have any deferred revenue.

Stock-Based Compensation Expense

Stock-based compensation expense related to awards to employees and nonemployees is recognized based on the grant-date fair value of the award. The Company uses the Black-Scholes valuation model as the method for determining the estimated fair value of underlying stock options.

The fair value of the Company's common stock is determined by the Company's Board of Directors with the assistance of management and an independent third-party valuation specialist. The valuation methodologies used to determine the fair value of the Company's common stock utilize certain assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability. In determining the fair value of the Company's common stock, the methodologies used to estimate the enterprise value of the Company were performed using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Technical Practice Aid, "*Valuation of Privately Held Company Equity Securities Issued as Compensation,"* to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require management judgment. These estimates and assumptions include a number of objective and subjective factors, including external market

conditions, the prices at which the Company sold shares of redeemable convertible preferred stock, the superior rights and preferences of the redeemable convertible preferred stock senior to the Company's common stock at the time, the status of clinical developments, the composition and ability of the current research and management team, and a probability analysis of various liquidity events, such as a public offering or sale of the Company, under different scenarios. Changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date. The Company has certain awards that allow the holder to purchase unvested stock options. The shares issued for unvested stock options are subject to repurchase by the Company at the original issuance price in the event of the holder's termination of their relationship with the Company. Consideration received for shares associated with the unvested stock options is initially recorded as a liability and subsequently reclassified into stockholders' equity as the related awards vest over the requisite service period.

The fair value of the award is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are recognized as they occur.

Expected Term—Expected term represents the weighted-average period that the Company's options are expected to be outstanding and is determined using the simplified method, as the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

Expected Volatility—Expected volatility is estimated by using an average historical price volatility of comparable publicly traded companies to be representative of its expected future stock price volatility, as the Company does not have sufficient trading history for its common stock. For the purpose of identifying these peer companies, the Company considers the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, the Company measures historical volatility over a period equivalent to the expected term. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected Dividend—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.

Risk-Free Interest Rate—The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for periods approximately equal to the expected term of the award.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse and are classified as non-current.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period when such determination is made. As of December 31, 2024 and 2025, the Company has recorded a full valuation allowance on its net federal and state deferred tax assets.

The calculation of tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes potential liabilities based on an estimate of whether, and the extent to which, additional taxes will be due. The Company utilizes a two-step approach for evaluation of uncertain tax positions. The first step is to determine if the weight of available evidence indicates a tax position is more likely than not to be sustained upon audit. The second step is to measure the tax benefit as the largest amount that is more likely than not to be realized on ultimate settlement. A liability is reported for unrecognized tax benefits resulting from uncertain tax positions taken or expected to be taken in a tax return. Any interest and penalties related to unrecognized tax benefits are recorded as income tax expense.

Emerging Growth Company Status and Smaller Reporting Company Status

The Company is an "emerging growth company," as defined in the Securities Act of 1933, as amended (Securities Act). Under the Jumpstart Our Business Startups Act of 2012, an emerging growth company has the option to adopt new or revised accounting guidance either (i) within the same periods as otherwise applicable to public business entities, or (ii) within the same time periods as non-public business entities, including early adoption when permissible. With the exception of accounting guidance the Company elected to early adopt, when permissible, the Company has elected to adopt new or revised accounting guidance within the same time periods as non-public business entities.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures,* aimed at enhancing the clarity and usefulness of segment disclosure. This update requires public business entities to disclose significant segment expenses that contribute to profitability measures and provide more detailed reconciliations to enhance user understanding. The disclosures required under ASU 2023-07 are also required for public entities with a single reportable segment. The Company adopted ASU 2023-07 for its fiscal year ended December 31, 2024.

Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, an accounting standard update that requires public business entities to disclose more detailed information about the types of expenses (including employee compensation, depreciation, and amortization) included in each relevant income statement expense caption. The ASU is effective for fiscal years 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 this standard will have on its financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 requires public business entities to provide annual disclosures of specific categories in the rate reconciliation and to disclose income taxes paid, disaggregated by jurisdiction. For public business entities that are not emerging growth companies using the extended transition period, ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. Because the Company is an emerging growth company and has elected to take advantage of the extended transition period for complying with new or revised accounting standards, ASU 2023-09 is effective for the Company for fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact that this standard will have on its financial statements and related disclosures.

3. Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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. These reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair

value hierarchy. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

All marketable securities were considered available-for-sale as of December 31, 2024 and 2025. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type are summarized in the tables below (in thousands):

	December 31, 2024			
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Fair Value
Cash equivalents:				
Money market funds	Level 1	$ 43,444	$ —	$ 43,444
Marketable securities:				
U.S. treasury securities	Level 1	17,828	8	17,836
Total		$ 61,272	$ 8	$ 61,280

	December 31, 2025			
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Fair Value
Cash equivalents:				
Money market funds	Level 1	$ 14,925	$ —	$ 14,925
Marketable securities:				
U.S. treasury securities	Level 1	$ 52,516	$ 17	$ 52,533
Total		$ 67,441	$ 17	$ 67,458

Interest receivable as of December 31, 2024 and 2025 was $0.2 million and $0.1 million, respectively, and is recorded as a component of prepaid expenses and other current assets on the Company's balance sheets.

4. Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets as of December 31, 2024 and 2025 consists of the following (in thousands):

	As of December 31,	
	2024	2025
Prepaid manufacturing costs	$ —	$ 1,106
Prepaid clinical costs	329	1,109
Other prepaid expenses	1,140	1,492
Total prepaid expenses	$ 1,469	$ 3,707

Property and Equipment

Property and equipment as of December 31, 2024 and 2025 consists of the following (in thousands):

	Life (in years)	As of December 31,	
		2024	2025
Laboratory equipment	3 - 5	$ 4,835	$ 4,903
Computer equipment	3	9	9
Total Property and equipment		4,844	4,912
Less: Accumulated depreciation		(4,212)	(4,430)
Property and equipment, net		$ 632	$ 482

Depreciation expense for the years ended December 31, 2024 and 2025 was $0.9 million and $0.2 million, respectively.

The Company reviews the estimated useful lives of its property and equipment on an ongoing basis. Effective January 1, 2025, the Company changed its estimated useful life of lab equipment from three to five years and this change has been accounted for as a change in accounting estimate. The change in estimated useful life decreased depreciation expense by approximately $0.7 million for the year ended December 31, 2025.

Accrued Liabilities

Accrued liabilities as of December 31, 2024 and 2025 consist of the following (in thousands):

	As of December 31,	
	2024	2025
Accrued payroll related expenses	$ 2,422	$ 2,369
Accrued research and development expenses	1,754	1,109
Income tax payable	1,987	148
Other current liabilities	153	280
Total accrued liabilities	$ 6,316	$ 3,906

5. Significant Agreements

Lilly

In January 2023, the Company and Lilly entered into a Research Collaboration and License Agreement which was amended by the First Amendment to the Research Collaboration and License Agreement dated June 24, 2026 (the "Lilly Collaboration Agreement"), wherein the Company granted to Lilly exclusive worldwide rights to develop and commercialize certain program molecules and products. The Lilly Collaboration Agreement terminated and replaced the earlier research agreement that was entered into in October 2018 and amended in September 2020 and October 2022. The Company received a $55.0 million upfront payment and, in July 2024, received a $15.0 million development milestone payment. After giving effect to the milestone payment received, the Company is eligible to receive up to an additional $577.5 million in development, commercialization and sales milestone payments. The Company is also eligible for tiered royalties ranging from six to ten percent on annual aggregate net sales of licensed products, subject to specified adjustments under the Lilly Collaboration Agreement. All milestone and royalty payments are subject to customary terms and conditions as described in the Lilly Collaboration Agreement.

Unless earlier terminated by either party, the Lilly Collaboration Agreement will expire on a product-by-product and country-by-country basis upon the expiration of all of Lilly's payment obligations under the Lilly Collaboration Agreement. Either party may terminate the Lilly Collaboration Agreement pursuant to customary termination provisions. The Company concluded that the Lilly Collaboration Agreement is a contract with a customer and accounted for it under ASC 606 revenue recognition guidance. The Company's performance obligations in the Lilly Collaboration Agreement relate to research and development activities under the applicable research plan and the transfer of related license rights and know-how. Based on the evaluation of the terms of the arrangement, the Company concluded that the transfer of related license rights and know-how and the research and development activities are not distinct within the context of the contract and, therefore, constitute a single performance obligation. The Company determined that the development and regulatory milestone payments represent variable consideration subject to constraint and excluded them from the initial transaction price. These payments will be included in the transaction price when it becomes probable that a significant reversal of cumulative revenue recognized will not occur and will be recognized as revenue based on the Company's progress toward satisfaction of the combined performance obligation.

For the year ended December 31, 2024, the Company recognized $39.1 million in collaboration revenue on its statements of operations and comprehensive loss related to the Lilly Collaboration Agreement. The $39.1 million consisted of approximately $24.1 million representing recognition of the remaining portion of the original $55.0 million upfront payment and $15.0 million of variable consideration associated with the achievement of a development milestone under the Lilly Collaboration Agreement that did not require additional research and development services by the Company. The upfront payment and milestone consideration were included in the transaction price for the single combined performance obligation comprising the license rights, related know-how and research and development services. Upon achievement of the milestone, the $15.0 million of variable consideration was no longer constrained and was included in the transaction price. Because the Company fully satisfied the combined performance obligation during the year ended December 31, 2024, the remaining upfront consideration and the full amount of the milestone consideration were recognized as revenue during 2024. The Company did not receive separate payments or cost reimbursements specifically for research and development services performed under the initial research plan during the year ended December 31, 2024, and no portion of the transaction price was allocated separately

to those services. The research term for the Lilly Collaboration Agreement expired during the year ended December 31, 2024 and the Company did not recognize any collaboration revenue during the year ended December 31, 2025. However, the Company's right to receive potential future milestone and royalty payments survives the expiration of the research term and remains in effect, unless earlier terminated in accordance with its terms.

6. Commitments and Contingencies

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2024 and 2025, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

Legal Proceedings

From time to time, the Company may have contingent liabilities that arise in the ordinary course of business activities. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable. As of December 31, 2024 and 2025, the Company did not have any material reserve estimates recorded.

7. Common Stock and Redeemable Convertible Preferred Stock

In November 2025, the Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware whereby the total number of shares of all classes of stock which the Company has authority to issue is (1) 72,213,000 shares of Common Stock, $0.0001 par value per share and (ii) 52,693,738 shares of Preferred Stock, $0.0001 par value per share.

Common Stock

The Company has common stock of 1,019,195 shares and 1,285,835 shares outstanding as of December 31, 2024 and 2025, respectively. The Company has the following shares reserved as of December 31, 2024 and 2025.

	As of December 31,	
	2024	2025
Options issued and outstanding under the 2021 Plan	769,984	—
Options issued and outstanding under the 2024 Plan	—	2,173,642
Shares reserved for future grants under 2021 Plan	2,371,404	—
Shares reserved for future grants under 2024 Plan	—	701,119
Total	3,141,388	2,874,761

Redeemable Convertible Preferred Stock

Between June 2018 and February 2022, the Company issued its Series A-1 redeemable convertible preferred stock, Series A-2 redeemable convertible preferred stock, and Series A-3 redeemable convertible preferred stock at the prices set in the tables below. Series A-1 redeemable convertible preferred stock, Series A-2 redeemable convertible preferred stock and Series A-3 redeemable convertible preferred stock are collectively defined as "Series A Preferred Stock."

In November 2024, the Company entered into a Series B redeemable convertible preferred stock financing arrangement in which 27,510,762 shares of Series B redeemable convertible preferred stock were authorized to be issued at an issuance price of $3.0897 per share for total proceeds of up to $85.0 million.

In November 2024, the Company issued an aggregate of 13,683,972 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share for net proceeds of $41.8 million related to the first tranche, with a potential second tranche of additional funding for up to $41.8 million based on approval of the Board of Directors and consent of the majority of the holders of the then-outstanding Series B redeemable convertible preferred stock. The Series B Preferred Stock Purchase Agreement provides that, upon the fulfillment of certain conditions, each investor will purchase its pro rata portion of the shares to be issued in additional Series B redeemable convertible preferred stock closings. Further, the Company agreed to sell and issue said shares of Series B redeemable convertible preferred stock on the same terms as the first tranche in the Purchase Agreement. The Company did not separately account for tranche purchase rights described above as they were not freestanding from the associated shares of redeemable convertible preferred stock. In March 2025, the Company issued an

aggregate of 13,522,143 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share for net proceeds of $41.8 million related to the second tranche.

In January 2026, the Company amended and restated the Certificate of Incorporation to increase the number of Series B redeemable convertible preferred stock authorized to be issued was increased to 43,388,910 shares and the Company issued an aggregate of approximately 16.2 million shares of Series B redeemable convertible preferred stock to multiple investors at an issuance price of $3.0897 per share for total proceeds of $50.0 million (the "Series B Extension").

As of December 31, 2024, redeemable convertible preferred stock consisted of the following (in thousands, except for share and per share amounts):

Redeemable Convertible Preferred Stock	Authorized Shares	Issued and Outstanding	Original Issue Price	Liquidation Preference	Carrying Value
Series A-1	5,000,000	5,000,000	$ 1.29	$ 9,806	$ 6,530
Series A-2	7,700,000	7,700,000	$ 3.87	42,721	25,181
Series A-3	12,482,976	12,482,976	$ 3.87	61,844	43,730
Series B	27,510,762	13,683,972	$ 3.09	42,279	41,805
Total	52,693,738	38,866,948		$ 156,650	$ 117,246

As of December 31, 2025, the Company's redeemable convertible preferred stock consisted of the following (in thousands, except for share and per share amounts):

Redeemable Convertible Preferred Stock	Authorized Shares	Issued and Outstanding	Original Issue Price	Liquidation Preference	Carrying Value
Series A-1	5,000,000	5,000,000	$ 1.29	$ 9,806	$ 6,530
Series A-2	7,700,000	7,700,000	$ 3.87	42,721	25,181
Series A-3	12,482,976	12,482,976	$ 3.87	61,844	43,730
Series B	27,510,762	27,206,115	$ 3.09	84,059	83,574
Total	52,693,738	52,389,091		$ 198,430	$ 159,015

The Series A and Series B redeemable convertible preferred stock (together, the "Preferred Stock") rights, privileges and preferences are as follows:

Dividends—The holders of the Series A Preferred Stock are entitled to receive cumulative dividends at a fixed rate of 8% per annum (calculated in respect of any partial year on a straight line, non-compounding, daily basis and on the basis of a 365-day year) calculated from the date on which such Series A Preferred Stock was first issued by TRex Bio Limited. The preferred dividend accrued on each Series A Preferred Stock from the date on which such stock was first issued until the first to occur of the completion of a Liquidation Event, Deemed Liquidation Event or a Qualified IPO (as defined below). In all cases, accruing dividends ceased to accrue on November 6, 2024, per the terms of the Series B Preferred Stock Purchase Agreement. Any accrued dividends on the Series A Preferred Stock are payable solely in the event of a Liquidation Event or Deemed Liquidation Event. Upon the conversion of the Series A Preferred Stock into Common Stock, including in connection with a Qualified IPO, the right to receive any such accrued dividends is automatically forfeited and no such amounts will be paid. The holders of Series B redeemable convertible preferred stock are not entitled to receive any dividends. As of December 31, 2024 and 2025, no dividends have been declared or paid by the Company on any series of redeemable convertible preferred stock.

Voting Rights—Each holder has the right to one vote for each share of common stock into which such Preferred Stock could be converted.

Conversion—Each share of Preferred Stock may at any time convert all, or any part of, its holding into a number of common stock by multiplying the applicable conversion rate by the number of the shares to be converted. The conversion price is initially equal to the respective redeemable convertible preferred stock original issuance price, and is subject to adjustments for stock splits, other dividends or distributions, merger or reorganization.

Qualified IPO—Unless this is waived by a simple majority of the Core Investors, as defined, in the event of a Qualified IPO, all outstanding Preferred Stock shall automatically be converted into Common Stock at the then-effective applicable Conversion Ratio, in each case immediately prior to the admission of Common Stock for trading as part of such Qualified IPO but conditional always on the Qualified IPO occurring. A Qualified IPO is defined as the Company's first offering of Common Stock to the public provided that: (1) the aggregate net proceeds are at least $50,000,000 and (2) the Common Stock are listed on any recognized public exchange.

Liquidation Event—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, the holder of shares of Series B Convertible Preferred Stock then outstanding shall be entitled to be paid out of the funds and assets of the Company before any payments shall be made to any holders of Series A Preferred Stock or Common Stock. If upon any such Liquidation Event or Deemed Liquidation Event, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid, on a *pari passu* basis, out of the funds and assets of the Company before any payments to the holders of Common Stock. From any remaining assets, the preferred dividends are distributed and if assets are insufficient, then the available assets are distributed ratably to the holders of the Series A Preferred Stock. Any remaining assets, after consideration of other amounts in arrears, are distributed pro rata based on the number of shares held on an as-converted basis.

8. Equity Incentive Plans

In November 2021, the Company's board of directors adopted the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan allows for the granting of incentive stock options, non-statutory stock options and restricted stock awards to the employees, members of the board of directors, and consultants of the Company.

In November 2024, the Board of Directors of the Company elected to amend the 2021 Plan to increase the number of shares available to be issued. The amendment allows for a total of 3,298,634 shares to be issued under the 2021 Plan.

In December 2024, the Board of Directors of the Company elected to adopt the 2024 Equity Incentive Plan (the "2024 Plan" and together with the 2021 Plan, the "Plans"). This was done contemporaneously with the merger of TRex Holdings, Inc. with TRex Bio, Inc. as discussed in Note 1. The 2024 Plan superseded the 2021 Plan and allows for the options issued under the 2021 Plan for TRex Holdings to be converted to options for TRex Bio, Inc. on a one-for-one basis.

Stock Options

Options under the Plans may be granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors provided that the exercise price of an option granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant.

Stock options issued under the Plans generally vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the individual award agreements.

The Company used the Black-Scholes option pricing model to estimate stock-based compensation expense for stock option awards granted during the periods presented, with the following assumptions:

	Year Ended December 31,	
	2024	2025
Expected volatility	95.26 - 95.95 %	107.3 - 123.25 %
Expected dividend yield	0.00 %	0.00 %
Expected term (in years)	5.48 - 6.08	5.70 - 6.08
Risk-free interest rate	4.33 %	4.16 %

The following summarizes stock option activity under the Stock Plans as follows:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	769,984	$ 1.09	7.16	$ 124
Granted	1,788,076	1.24		
Exercised	(266,627)	1.13		
Cancelled	(117,791)	1.17		
Outstanding as of December 31, 2025	2,173,642	1.20	8.48	93
Exercisable as of December 31, 2025	731,852	1.13	6.88	87
Exercisable and expected to vest as of December 31, 2025	2,173,642	$ 1.20	8.48	$ 93

The aggregate fair value of stock options that vested during the year ended December 31, 2025 was $0.2 million. The stock options granted in the year ended December 31, 2025 had a weighted-average grant-date fair value per share of $1.07 and a total grant-date fair value of $1.9 million. The total intrinsic value of stock options exercised during the year ended December 31, 2025 was immaterial.

Stock-based Compensation Expense

Stock-based compensation expense for stock options recognized in the Company's statements of operations and comprehensive loss is presented as follows (in thousands):

	Year Ended December 31,	
	2024	2025
General and administrative	$ 206	$ 324
Research and development	42	128
Total	$ 248	$ 452

As of December 31, 2025, total unrecognized stock-based compensation expense related to unvested restricted stock awards and unvested stock options was $1.5 million, which is expected to be recognized over a weighted-average period of 3.2 years.

9. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2024 and 2025 are as follows (in thousands):

	Year Ended December 31,	
	2024	2025
Current:		
Federal	$ 2,576	$ 26
State	124	20
Foreign	—	—
Total current	2,700	$ 46
Deferred:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred	—	—
Provision for income taxes	$ 2,700	$ 46

The Company had an effective tax rate of (0.1)% for the year ended December 31, 2025. The difference in the Company's effective tax rate and the U.S. Federal statutory tax rate is primarily due to recording a full valuation allowance on the Company's U.S. deferred tax assets.

The reconciliations of the statutory income tax rate to the Company's effective tax rate for the years ended December 31, 2024 and 2025, are as follows:

	Year Ended December 31, 2024	
	Amount	Percentage
U.S. federal taxes at statutory rate	$ (93)	21.0 %
State tax, net of federal benefit	565	(127.4)
Provision-to-return	198	(44.6)
U.S. R&D credits	(2,666)	600.1
Change in valuation allowance	4,398	(990.0)
Other	298	(67.0)
Provision for income taxes	$ 2,700	(607.9) %

	Year Ended December 31, 2025	
	Amount	Percentage
U.S. federal taxes at statutory rate	$ (7,300)	21.0 %
State tax, net of federal benefit	20	(0.1)
Provision-to-return	(5,765)	16.7
Uncertain tax positions - prior year positions	4,693	(13.5)
U.S. R&D credits	(1,005)	2.9
Change in valuation allowance	9,337	(26.9)
Other	66	(0.2)
Provision for income taxes	$ 46	(0.1) %

As of December 31, 2024 and 2025, the significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	Year Ended December 31,	
	2024	2025
Deferred Tax Assets:		
Accruals	$ 594	$ 474
Net operating losses	6	18,119
Lease liability	195	151
Stock-based compensation	7	20
Capitalized research and development expenditures	13,703	3,279
Credits	2,550	4,049
Gross deferred tax assets	17,055	26,092
Valuation allowance	(16,794)	(25,840)
Net deferred tax assets	261	252
Deferred Tax Liabilities:		
Depreciation	(77)	(105)
Acquired intangibles	—	—
Unrealized gain	—	(4)
Operating lease right-of-use assets	(184)	(143)
Total deferred tax liabilities	(261)	(252)
Net deferred tax liabilities	$ —	$ —

The Company has established a valuation allowance of $16.8 million and $25.8 million for December 31, 2024 and 2025, respectively, against its net deferred tax assets.

The Company determines its valuation allowance on deferred tax assets by considering both positive and negative evidence in order to ascertain whether it is more likely than not that deferred tax assets will be realized. Realization of deferred tax assets is dependent upon the generation of future taxable income, if any, the timing and amount of which are uncertain. Due to the history of losses the Company has generated in the past, the Company believes that it is not more likely than not that all of the deferred tax assets can be realized as of December 31, 2025. Accordingly, the Company has recorded a full valuation allowance on its deferred tax assets.

The valuation allowance on the Company's net deferred taxes increased by $4.9 million and $9.0 million during the years ended December 31, 2024 and 2025, respectively. The increase in valuation allowance is primarily attributable to the generation of net operating losses.

As of December 31, 2025, the Company has net federal net operating loss carryforwards of $96.1 million. The federal NOLs have an infinite carryforward period but are subject to 80% deduction limitation based upon pre-NOL deduction taxable income. As of December 31, 2025, the Company has no state net operating loss carryforwards.

As of December 31, 2025, the Company had federal and state research and development credit carryforwards of approximately $4.4 million and $3.9 million, respectively. As of December 31, 2025, the federal credits will begin to expire starting in 2041 if not utilized. The California credits have an indefinite carryforward period.

The Tax Reform Act of 1986 and similar state legislation impose substantial restrictions on the utilization of the net operating losses and tax credit carryforwards in the event there is a change in ownership as provided by Section 382 and Section 383 of the Internal Revenue Code and similar state provisions. The Company has completed an analysis of Section 382 ownership changes in the Company's stock through December 31, 2024 and has concluded that it has experienced ownership changes that will result in limitations in its ability to use certain net operating loss carryforwards, tax credit carryforwards and other tax attributes. The Company may experience ownership changes in the future as a result of future transactions in its stock. If it is determined that the Company undergoes one or more ownership changes in the future, then the Company's ability to utilize its U.S. federal and state net operating loss carryforwards, tax credit carryforwards or other tax attributes may be further limited or eliminated.

On July 4, 2025, the United States signed into law the One Big Beautiful Bill Act (the "OBBBA"), which, among other provisions, makes permanent the immediate expensing of domestic research and development expenditures, reinstates 100% bonus depreciation for certain qualified property, and modifies the international tax framework. The enactment of OBBBA did not have a material impact on the Company's income tax provision.

The Company's total amount of gross unrecognized tax benefits as of December 31, 2024 and 2025 was $1.9 million and $12.0 million, respectively, of which $1.1 million would impact the Company's effective tax rate if recognized.

For the years ended December 31, 2024 and 2025, the activity related to the unrecognized tax benefit was as follows (in thousands):

	Year Ended December 31,	
	2024	2025
Balance at beginning of the year	$ 1,527	$ 1,946
Decreases:		
For current year's tax positions	—	—
For prior year's tax positions	(52)	(166)
Increases:		
For current year's tax positions	610	410
For prior year's tax positions	—	9,829
Lapse of statute of limitations	(139)	—
Unrecognized tax benefit at December 31	$ 1,946	$ 12,019

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected as a reduction of the provision for income taxes in the period that such determination is made. As of December 31, 2024 and 2025, the Company did not recognize any material interest or penalties related to uncertain tax positions. The Company does not anticipate the recorded reserves to change significantly in the next twelve months.

The Company is subject to taxation in the U.S. and California. Due to certain tax attribute carryforwards, all tax years remain open to examination by the major taxing jurisdictions in which the Company is subject to tax. As of December 31, 2025, the Company was not under examination by the Internal Revenue Service or any state or foreign tax jurisdiction.

10. Related Parties

Lilly

In October 2018, Lilly entered into an agreement to subscribe for 2,366,992 shares of Series A-2 Convertible Preferred Stock at approximately $12.59 per share. Lilly purchased 1,183,496 shares in October 2018 and 1,183,496 shares in January 2020. On February 17, 2022, each share of issued Series A-2 Convertible Preferred Stock was reclassified into 3.253 shares of Series A-2 Convertible Preferred Stock, totaling 7,700,000 shares of Series A-2 Convertible Preferred Stock. In February 2022, Lilly also purchased 2,002,487 shares of Series A-3 Convertible Preferred Stock at $3.8702 per share.

Additionally, the Company and Lilly entered into the Lilly Collaboration Agreement in January 2023 (see Note 5). The Company previously executed an initial lab license agreement with Lilly in December 2019, which was subject to subsequent amendments executed in September 2020, April 2022, and July 2023 to incorporate additional leased space and modify certain contractual terms.

In November 2024, Lilly entered into an agreement to purchase 5,860,808 shares of Series B Convertible Preferred Stock at a price of $3.0897 per share. The investment is structured in two funding tranches, with two tranches of 2,930,404 shares issued in both November 2024 and March 2025.

Johnson & Johnson Innovation

In May 2019, Johnson & Johnson Innovation entered into an agreement to subscribe for 2,196,276 shares of Series A-3 Convertible Preferred Stock at approximately $3.8702 per share. Johnson & Johnson Innovation purchased 1,098,138 shares in May 2019 and 1,098,138 in June 2021.

In December 2021, the Company entered into a Collaboration and License Agreement with Janssen Pharmaceutica NV ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson and an affiliate of Johnson & Johnson Innovation, dated as of December 28, 2021 (the "Janssen Agreement") pursuant to which Janssen exercised an option in January 2024 to obtain exclusive and non-exclusive licenses with respect to for up to three targets arising out of the parties' research collaboration. In connection with this option exercise, we received a $1.0 million option exercise fee during the year ended December 31, 2024. The Janssen Agreement was terminated in October 2025.

During the year ended December 31, 2024, the Company received $1.0 million in connection with the Janssen Agreement for revenue recognized during the year ended December 31, 2023. The Company did not recognize any revenue during the years ended December 31, 2024 and 2025 in connection with the Janssen Agreement.

In February 2022, Johnson & Johnson Innovation purchased an additional 460,115 shares of Series A-3 Convertible Preferred Stock at $3.8702 per share.

In November 2024, Johnson & Johnson Innovation entered into an agreement to purchase 1,604,598 shares of Series B Convertible Preferred Stock at a price of $3.0897 per share, with two tranches of 802,299 shares issued in both November 2024 and March 2025.

Carol Gallagher, Pharm.D.

Carol Gallagher, Pharm.D., served as Executive Chair of the Company's Board of Directors from September 2020 to December 2024 and as the Chair of the Company's Board of Directors since January 1, 2025. In September 2020, Dr. Gallagher entered into an agreement with the Company to purchase 93,144 shares of common stock at $2.16 per share. In April 2025, Dr. Gallagher was granted 100,489 stock options under the Company's 2024 Plan as stock-based compensation for her services on the Board of Directors. In June 2025, Dr. Gallagher early exercised her options. As of December 31, 2025, 83,741 shares of Dr. Gallagher's early exercised stock options were unvested.

11. Net Loss Per Share

Through November 5, 2024, the holders of the Company's Series A redeemable convertible preferred stock were entitled to cumulative dividends based on the respective original issuance dates of the shares (see Note 7). Accordingly, the Company calculated its net loss attributable to common stockholders for the year ended December 31, 2024 by adjusting net loss for the aggregate cumulative dividends that accrued during this period. On November 6, 2024, the Series A preferred stock ceased accruing dividends, and no subsequent adjustments for preferred dividends were recognized. The holders of the Company's Series B redeemable convertible preferred stock are not entitled to receive dividends.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive were as follows (in common stock equivalent shares):

	Year Ended December 31,	
	2024	2025
Outstanding stock options	769,984	2,173,642
Unvested early exercised stock options	—	83,741
Series A-1 Convertible Preferred Stock	1,293,694	1,293,694
Series A-2 Convertible Preferred Stock	1,992,290	1,992,290
Series A-3 Convertible Preferred Stock	3,229,832	3,229,832
Series B Convertible Preferred Stock	3,540,577	7,039,280
Total	10,826,377	15,812,479

12. Segment Information

The Company operates as a single reportable segment focused on autoimmune and inflammatory disease discovery. The Company's Chief Executive Officer serves as the Chief Operating Decision Maker ("CODM"). The measure of segment profit or loss evaluated by the CODM to monitor spending, assess performance for the Company and management, evaluate the progress of completing corporate goals, allocate resources among the clinical and preclinical portfolios, and make strategic decisions regarding business development opportunities corresponds to the net loss presented on the statements of operations and comprehensive loss. Additionally, the measure of segment assets evaluated by the CODM corresponds to total assets as reported on the balance sheets.

The CODM is regularly provided with the following significant segment expenses:

	Year Ended December 31,	
	2024	2025
Collaboration revenue	$ 39,108	$ —
Operating expenses:		
Employee-related expenses, excluding stock-based compensation	13,658	13,676
Stock-based compensation	248	452
External research and development expenses	17,357	14,629
External general and administrative expenses	2,419	2,464
Other segment expenses*	7,807	6,624
Total operating expenses	41,489	37,845
Loss from operations	(2,381)	(37,845)
Interest income	2,007	3,154
Other expense, net	(70)	(69)
Total other income, net	1,937	3,085
Loss before provision for income taxes	(444)	(34,760)
Provision for income taxes	2,700	46
Net loss	$ (3,144)	$ (34,806)

(*) Other segment expenses include facility related and office costs, information technology costs, depreciation and amortization, and other operating expenses.

As of December 31, 2024 and 2025, all of the Company's property and equipment was maintained in the U.S.

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13. Subsequent Events

The Company has evaluated subsequent events through June 26, 2026, the date these financial statements were available to be issued (except for the effects of the reverse stock split, as to which the date is October 5, 2026). The Company has concluded that no subsequent events have occurred that require disclosure, except as described below.

Financing Transactions

In January 2026, the Company issued and sold an aggregate of 16,182,795 Series B preferred stock in an extension of the Company's Series B preferred stock financing at the same price per share as at the first and second tranches, for an aggregate purchase price of approximately $50.0 million.

Lease Agreement

In April 2026, the Company entered into an operating lease agreement with a related party for laboratory and office space in South San Francisco, California. The lease has an initial term of 27 months and is expected to commence in the third quarter of 2026. Total future minimum lease payments under this arrangement are approximately $3.3 million.

Reverse Stock Split

On October 2, 2026, the Company effected the reverse stock split described in Note 2. The accompanying financial statements and related notes give retroactive effect to the reverse stock split for all periods presented.

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TRex Bio, Inc.
CONDENSED BALANCE SHEETS
(in thousands, except share data)
(Unaudited)

	As of	
	December 31, 2025	**June 30, 2026**
Assets		
Current assets:		
Cash and cash equivalents	$ 15,192	$ 8,883
Marketable securities	52,533	81,971
Prepaid expenses and other current assets	3,707	2,405
Total current assets	71,432	93,259
Property and equipment, net	482	454
Operating lease right-of-use assets, net	681	212
Other assets	538	2,687
Total assets	$ 73,133	$ 96,612
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 371	$ 1,028
Accrued liabilities	3,906	6,431
Lease liabilities	717	197
Total current liabilities	4,994	7,656
Income taxes payable - long-term	1,171	1,211
Other liabilities	72	117
Total liabilities	6,237	8,984
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock:		
Series A-1 redeemable convertible preferred stock, $0.0001 par value per share; 5,000,000 shares authorized, issued and outstanding; liquidation preference of $9,806 as of December 31, 2025 and June 30, 2026.	6,530	6,530
Series A-2 redeemable convertible preferred stock, $0.0001 par value per share; 7,700,000 shares authorized, issued and outstanding as of December 31, 2025 and June 30, 2026; liquidation preference of $42,721 as of December 31, 2025 and June 30, 2026	25,181	25,181
Series A-3 redeemable convertible preferred stock, $0.0001 par value per share, 12,482,976 shares authorized, issued and outstanding as of December 31, 2025 and June 30, 2026; liquidation preference of $61,844 as of December 31, 2025 and June 30, 2026	43,730	43,730
Series B redeemable convertible preferred stock, $0.0001 par value per share; 27,510,762 and 43,388,910 shares authorized as of December 31, 2025 and June 30, 2026, respectively; 27,206,115 and 43,388,910 shares issued and outstanding as of December 31, 2025 and June 30, 2026, respectively; liquidation preference of $84,059 and $134,059 as of December 31, 2025 and June 30, 2026, respectively	83,574	133,397
Stockholders' deficit:		
Common Stock, $0.0001 par value; 72,213,000 and 89,000,000 shares authorized as of December 31, 2025 and June 30, 2026, respectively; 1,285,835 and 1,370,131 shares issued and outstanding as of December 31, 2025 and June 30, 2026, respectively; and 83,741 and 135,500 shares subject to repurchase as of December 31, 2025 and June 30, 2026, respectively	—	—
Additional paid-in capital	2,123	2,505
Accumulated other comprehensive income	17	(148)
Accumulated deficit	(94,259)	(123,567)
Total stockholders' deficit	(92,119)	(121,210)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 73,133	$ 96,612

See accompanying notes to the unaudited condensed financial statements.

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TRex Bio, Inc.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(Unaudited)

	For the Six Months Ended June 30,	
	2025	**2026**
Operating expenses:		
Research and development	$ 14,966	$ 26,030
General and administrative	4,258	4,988
Total operating expenses	19,224	31,018
Loss from operations	(19,224)	(31,018)
Interest income	1,568	1,755
Other expense, net	(66)	(3)
Total other income, net	1,502	1,752
Loss before provision for income taxes	(17,722)	(29,266)
Provision for income taxes	—	42
Net loss	(17,722)	(29,308)
Net loss per share attributable to common stockholders, basic and diluted	$ (17.33)	$ (24.08)
Weighted-average shares outstanding, basic and diluted	1,022,728	1,217,219
Comprehensive loss:		
Net loss	(17,722)	(29,308)
Unrealized loss on marketable securities	(11)	(165)
Comprehensive loss	$ (17,733)	$ (29,473)

See accompanying notes to the unaudited condensed financial statements.

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TRex Bio, Inc.
CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands, except share data)
(Unaudited)

	Redeemable Convertible Preferred Stock								Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A-1		Series A-2		Series A -3		Series B							
	Share	Amount	Share	Amount	Share	Amount	Share	Amount	Share	Amount				
Balances as of December 31, 2024	5,000,000	6,530	7,700,000	25,181	12,482,976	43,730	13,683,972	41,805	1,019,195	—	1,473	8	(59,453)	(57,972)
Issuance of common stock	—	—	—	—	—	—	—	—	105,989	—	10	—	—	10
Issuance of Series B preferred stock, net of issuance costs of $10	—	—	—	—	—	—	13,522,143	41,769	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	183	—	—	183
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(17,722)	(17,722)
Balances as of June 30, 2025	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	27,206,115	$ 83,574	1,125,184	$ —	$ 1,666	$ (3)	$ (77,175)	$ (75,512)

	Redeemable Convertible Preferred Stock								Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A-1		Series A-2		Series A -3		Series B							
	Share	Amount	Share	Amount	Share	Amount	Share	Amount	Share	Amount				
Balances as of December 31, 2025	5,000,000	6,530	7,700,000	25,181	12,482,976	43,730	27,206,115	83,574	1,285,835	—	2,123	17	(94,259)	(92,119)
Issuance of common stock	—	—	—	—	—	—	—	—	84,296	—	20	—	—	20
Vesting of early exercised common stock	—	—	—	—	—	—	—	—	—	—	18	—	—	18
Issuance of Series B preferred stock, net of issuance costs of $177	—	—	—	—	—	—	16,182,795	49,823	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	344	—	—	344
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(165)	—	(165)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(29,308)	(29,308)
Balances as of June 30, 2026	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	43,388,910	$ 133,397	1,370,131	$ —	$ 2,505	$ (148)	$ (123,567)	$ (121,210)

See accompanying notes to the unaudited condensed financial statements.

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TRex Bio, Inc.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	For the Six Months Ended June 30,	
	2025	2026
Cash flows from operating activities:		
Net loss	$ (17,722)	$ (29,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	108	115
Stock-based compensation	183	344
Reduction in carrying amount of right-of-use assets	655	645
Net amortization of premiums and discounts on marketable securities	(605)	(1,059)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(107)	1,302
Other assets	(554)	(61)
Accounts payable	594	294
Accrued liabilities	(4,022)	1,361
Lease liabilities	(660)	(696)
Income taxes payable - long-term	—	40
Net cash used in operating activities	(22,130)	(27,023)
Cash flows from investing activities:		
Purchase of property and equipment	(22)	(11)
Purchase of investments in marketable securities	(51,259)	(81,544)
Proceeds from maturities of marketable securities	18,000	53,000
Net cash used in investing activities	(33,281)	(28,555)
Cash flows from financing activities:		
Proceeds from issuance of common stock	130	106
Proceeds from sales of Series B redeemable convertible preferred stock	41,779	50,000
Payment of issuance costs of Series B redeemable convertible preferred stock	(10)	(177)
Payment of costs related to planned initial public offering	—	(500)
Net cash provided by financing activities	41,899	49,429
Net decrease in cash, cash equivalents and restricted cash	(13,512)	(6,149)
Cash, cash equivalents and restricted cash - beginning of period	47,469	15,192
Cash, cash equivalents and restricted cash - end of period	$ 33,957	$ 9,043
Supplemental disclosure:		
Cash paid for income taxes, net of refunds received	$ —	$ 100
Supplemental disclosure of non-cash transactions:		
Right-of-use assets acquired in exchange for lease obligations	$ 1,346	$ 176
Vesting of early exercised stock options	$ —	$ 18
Property and equipment included in accounts payable and accrued expenses and other current liabilities	$ —	$ 76
Unpaid deferred initial public offering costs included in accounts payable and accrued liabilities	$ —	$ 1,428

See accompanying notes to the unaudited condensed financial statements.

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TRex Bio, Inc.
Notes to Unaudited Condensed Financial Statements
As of December 31, 2025 and June 30, 2026 and for the Six Months Ended June 30, 2025 and 2026

1. Organization

Description of the Business

TRex Bio, Inc. (the "Company") is a biotechnology company focused on studying the regulation of tissue inflammation to develop breakthrough medicines. To date, the Company has created a multi-faceted discovery platform to gain insights into regulatory T cell biology through transcriptomic analyses. The Company has translated these findings into drug discovery campaigns, including a collaboration with Eli Lilly and Company ("Lilly"). In June 2025, the Company initiated dosing for its first clinical trial for TRB-061, a novel TNFR2 agonist initially being developed for the treatment of atopic dermatitis.

Liquidity and Capital Resources

The accompanying unaudited condensed financial statements have been prepared on a going concern-basis, which contemplates that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company is subject to risks inherent in operating an early-stage biotechnology business. These risks include, but are not limited to, dependence on the development of marketable products, the ability to attract, retain, and motivate qualified personnel, rapid technological changes and the rapidly evolving nature of the biotechnology industry.

As of June 30, 2026, the Company had cash and cash equivalents and marketable securities of $90.9 million and accumulated deficit of $123.6 million. The Company has incurred net losses and negative cash flows from operations since inception, except for the year ended December 31, 2023, during which it commenced a Research Collaboration and License Agreement (the "Lilly Collaboration Agreement"), received a one-time upfront payment of $55.0 million from Lilly, and recognized total collaboration revenue of $41.9 million across its collaboration agreements, resulting in net income for the year and positive cash flows from operations.

The Company has historically funded its operations primarily through the issuances of redeemable convertible preferred stock. In January 2026, the Company issued and sold an aggregate of 16,182,795 shares of Series B redeemable convertible preferred stock in an extension of its Series B preferred stock financing for aggregate gross proceeds of approximately $50.0 million, as discussed in Note 7. The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations for at least twelve months from the date these unaudited condensed financial statements are available to be issued.

The Company expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval and commercialization of any product candidates it may develop, and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, it will need to continue to raise additional capital to fund ongoing research and development activities and maintain future operations. The Company's management plans to monitor expenses and may raise additional capital through a combination of public and private equity. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts, needed, on the terms which are favorable, the Company could be required to delay, scale back, or abandon the development of one or more of its product candidates and other operations, which could materially harm the Company's business, financial condition and results of operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting by smaller reporting companies. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The balance sheet as of December 31, 2025 was derived from the audited financial statements as of that date but does not include all of the disclosures required by U.S. GAAP. These unaudited financial statements should be read in conjunction with the audited financial statements and accompanying notes for the years ended December 31, 2024 and 2025 included elsewhere in this prospectus.

In the opinion of management, the accompanying unaudited condensed financial statements include all adjustments, consisting only of normal recurring adjustments, considered necessary to present fairly the Company's financial position, results of operations and cash flows for the interim periods presented. The results of operations for the six months ended June 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other future annual or interim period.

Reverse Stock Split

On October 2, 2026, the Company amended its certificate of incorporation to effect a 1-for-3.8649 reverse stock split of the Company's common stock. The par value of the Company's common stock was not adjusted as a result of the reverse stock split. The conversion prices of the Company's redeemable convertible preferred stock were proportionately adjusted, thereby reducing the number of shares of common stock issuable upon conversion. All issued and outstanding common stock, options to purchase common stock, and related share and per-share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Significant Accounting Policies

During the six months ended June 30, 2026, there were no material changes to the Company's significant accounting policies from those described in Note 2 of the audited financial statements for the years ended December 31, 2024 and 2025, included elsewhere in this prospectus, except for the deferred offering costs policy described below.

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within condensed balance sheets to the amounts in the condensed statements of cash flows (in thousands):

	As of December 31, 2025	As of June 30, 2026
Cash and cash equivalents	$ 15,192	$ 8,883
Restricted cash included in other assets	—	160
Total cash, cash equivalents and restricted cash shown in the condensed statements of cash flows	$ 15,192	$ 9,043

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly attributable to in-process equity financings, including the Company's planned initial public offering ("IPO"), as deferred offering costs. Upon completion of the IPO, these costs will be recorded as a reduction of the proceeds from the offering within additional paid-in capital. If the planned IPO is abandoned, the deferred offering costs will be expensed. As of June 30, 2026, the Company had $1.9 million of deferred offering costs included in other assets on the condensed balance sheet.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 requires public business entities to provide annual disclosures of specific categories in the rate reconciliation and to disclose income taxes paid, disaggregated by jurisdiction. For emerging growth companies electing to use the extended transition period, the standard is effective for fiscal years beginning after December 15, 2025. The Company adopted ASU 2023-09 prospectively on January 1, 2026. Because the standard primarily requires enhanced annual disclosures, its adoption did not have a material impact on the Company's condensed financial statements for the six months ended June 30, 2026. The Company will include the required disclosures in its annual financial statements for the year ending December 31, 2026.

Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires public business entities to disclose more detailed information about the types of expenses (including employee compensation, depreciation, and amortization) included in each relevant income statement expense caption. The ASU is effective for the Company for fiscal years 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 this standard will have on its financial statements and related disclosures.

3. Fair Value Measurements

The Company measures its cash equivalents and marketable securities at fair value on a recurring basis. The authoritative guidance on fair value measurements establishes a three-level fair value hierarchy for measuring and disclosing fair value. There have been no changes to the Company's valuation methodologies from those described in the audited financial statements for the years ended December 31, 2024 and 2025.

The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type and fair value hierarchy level are summarized in the tables below (in thousands):

	December 31, 2025				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 14,925	$ —	$ —	$ 14,925
Marketable securities:					
U.S. treasury securities	Level 1	52,516	17	—	52,533
Total		$ 67,441	$ 17	$ —	$ 67,458

	June 30, 2026				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 8,883	$ —	$ —	$ 8,883
Marketable securities:					
U.S. treasury securities	Level 1	82,119	—	(148)	81,971
Total		$ 91,002	$ —	$ (148)	$ 90,854

Interest receivable was approximately $0.1 million and $0.3 million as of December 31, 2025 and June 30, 2026, respectively, and was included in prepaid expenses and other current assets.

4. Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets as of December 31, 2025 and June 30, 2026 consisted of the following (in thousands):

	As of December 31, 2025	As of June 30, 2026
Prepaid manufacturing costs	$ 1,106	$ 154
Prepaid clinical costs	1,109	967
Other prepaid expenses	1,492	1,284
Total prepaid expenses	$ 3,707	$ 2,405

Property and Equipment

Property and equipment, net, as of December 31, 2025 and June 30, 2026 consisted of the following (in thousands):

	Life (in years)	As of December 31, 2025	As of June 30, 2026
Laboratory equipment	5	$ 4,903	$ 4,942
Computer equipment	3	9	9
Construction in progress		—	48
Total property and equipment		4,912	4,999
Less: Accumulated depreciation		(4,430)	(4,545)
Property and equipment, net		$ 482	$ 454

Depreciation expense was $0.1 million for each of the six months ended June 30, 2025 and 2026.

Accrued Liabilities

Accrued liabilities as of December 31, 2025 and June 30, 2026 consisted of the following (in thousands):

	As of December 31, 2025	As of June 30, 2026
Accrued payroll related expenses	$ 2,369	$ 1,801
Accrued research and development expenses	1,109	3,022
Accrued initial public offering costs	—	1,104
Other current liabilities	428	504
Total accrued liabilities	$ 3,906	$ 6,431

5. Significant Agreements

Lilly

In January 2023, the Company entered into a Research Collaboration and License Agreement with Eli Lilly and Company ("Lilly"). Under the agreement, the Company granted Lilly exclusive worldwide rights to develop and commercialize certain program molecules and products. Under the terms of the agreement, the Company received a $55.0 million upfront payment and, in July 2024, received a $15.0 million development milestone payment. After giving effect to the $15.0 million milestone payment received, the Company is eligible to receive up to an additional $577.5 million in development, commercialization, and sales milestone payments, as well as royalties on net sales.

In June 2026, the Company and Lilly entered into the First Amendment to the Research Collaboration and License Agreement. The amendment modified the achievement criteria for certain development milestones related to specified product candidates under the collaboration and established related development reporting requirements. Under the amended terms, the applicable milestones are tied to specified clinical-development events. The amendment also modified certain rights and obligations of the parties in connection with Lilly's continuation or discontinuation of development of the applicable product candidates, including certain contingent rights of the Company following discontinuation. The amendment did not provide for any additional consideration, and no additional variable consideration was included in the transaction price upon execution of the amendment. The Company did not recognize any collaboration revenue under the Lilly Collaboration Agreement for the six months ended June 30, 2025 and 2026 because no development, commercialization, or sales milestones were achieved during those periods.

6. Commitments and Contingencies

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2025 and June 30, 2026, the Company did not have any material indemnification claims that were probable or reasonably possible and, consequently, had not recorded related liabilities.

Legal Proceedings

From time to time, the Company may have contingent liabilities that arise in the ordinary course of business activities. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable. As of December 31, 2025 and June 30, 2026, the Company did not have any material reserve estimates recorded.

Lease Commitment

In April 2026, the Company entered into an operating lease agreement with a related party for approximately 33,780 rentable square feet of laboratory and office space in South San Francisco, California. The lease has an initial term of 27 months and provides for total fixed lease payments of approximately $3.3 million over the 27-month lease term. As of June 30, 2026, the lease had not commenced, and the Company had not recognized a right-of-use asset or lease liability related to the lease. See Note 10 for additional information regarding the related-party nature of the lease agreement.

TRex Bio, Inc.
Notes to Unaudited Condensed Financial Statements
As of December 31, 2025 and June 30, 2026 and for the Six Months Ended June 30, 2025 and 2026

7. Common Stock and Redeemable Convertible Preferred Stock

In January 2026, the Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware, which increased the number of authorized shares of Series B redeemable convertible preferred stock from 27,510,762 shares to 43,388,910 shares. Following the amendment, the total number of shares of all classes of stock that the Company was authorized to issue consisted of (i) 89,000,000 shares of common stock, $0.0001 par value per share, and (ii) 68,571,886 shares of preferred stock, $0.0001 par value per share.

Common Stock

The Company had 1,285,835 and 1,370,131 shares of common stock outstanding as of December 31, 2025 and June 30, 2026, respectively. The Company had the following shares reserved for issuance as of December 31, 2025 and June 30, 2026:

	As of December 31, 2025	As of June 30, 2026
Options issued and outstanding under the 2024 Plan	2,173,642	2,980,123
Shares reserved for future grants under 2024 Plan	701,119	768,560
Total	2,874,761	3,748,683

Redeemable Convertible Preferred Stock

In March 2025, the Company issued an aggregate of 13,522,143 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share for net proceeds of $41.8 million related to the second tranche.

In January 2026, the Company issued an aggregate of 16,182,795 shares of Series B redeemable convertible preferred stock to multiple investors at an issuance price of $3.0897 per share for net proceeds of $49.8 million (the "Series B Extension").

As of December 31, 2025, the Company's redeemable convertible preferred stock consisted of the following (in thousands, except for share and per share amounts):

Redeemable Convertible Preferred Stock	Authorized Shares	Issued and Outstanding	Original Issue Price	Liquidation Preference	Carrying Value
Series A-1	5,000,000	5,000,000	$ 1.29	$ 9,806	$ 6,530
Series A-2	7,700,000	7,700,000	$ 3.87	42,721	25,181
Series A-3	12,482,976	12,482,976	$ 3.87	61,844	43,730
Series B	27,510,762	27,206,115	$ 3.09	84,059	83,574
Total	52,693,738	52,389,091		$ 198,430	$ 159,015

As of June 30, 2026, the Company's redeemable convertible preferred stock consisted of the following (in thousands, except for share and per share amounts):

Redeemable Convertible Preferred Stock	Authorized Shares	Issued and Outstanding	Original Issue Price	Liquidation Preference	Carrying Value
Series A-1	5,000,000	5,000,000	$ 1.29	$ 9,806	$ 6,530
Series A-2	7,700,000	7,700,000	$ 3.87	42,721	25,181
Series A-3	12,482,976	12,482,976	$ 3.87	61,844	43,730
Series B	43,388,910	43,388,910	$ 3.09	134,059	133,397
Total	68,571,886	68,571,886		$ 248,430	$ 208,838

No dividends have been declared or paid during the six months ended June 30, 2025 and 2026.

8. Equity Incentive Plans

Stock Options

The Company used the Black-Scholes option pricing model to estimate stock-based compensation expense for stock option awards granted during the periods presented, with the following assumptions:

	Six Months Ended June 30,	
	2025	2026
Expected volatility	107.30 - 116.54 %	123.26 - 138.74 %
Expected dividend yield	0.00 %	0.00 %
Expected term (in years)	5.95 - 6.07	5.92 - 6.08
Risk-free interest rate	4.23 %	3.78 %

The following summarizes stock option activity under the Plans and includes early exercised shares as part of the stock options exercised:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	2,173,642	$ 1.20	8.48	$ 93
Granted	890,770	1.28		
Exercised	(84,289)	1.26		
Cancelled	—	—		
Outstanding as of June 30, 2026	2,980,123	1.22	8.45	176
Exercisable as of June 30, 2026	1,077,146	1.16	7.15	129
Exercisable and expected to vest as of June 30, 2026	2,980,123	$ 1.22	8.45	$ 176

The aggregate fair value of stock options that vested during the six months ended June 30, 2026 was $0.4 million. Options granted during the six months ended June 30, 2026 had a weighted-average grant-date fair value per share of $1.12 and total grant-date fair value of $1.0 million. The total intrinsic value of stock options exercised during six months ended June 30, 2026 was immaterial.

Early Exercised Stock Options

Proceeds received in connection with early exercise of stock options are recorded as share repurchase liability and reclassified to additional paid-in capital as the underlying shares vest. As of December 31, 2025 and June 30, 2026, the Company had approximately $0.1 million and $0.2 million, respectively, of share repurchase liabilities related to unvested shares, which were classified within accrued liabilities and other noncurrent liabilities on the condensed balance sheets.

The following table summarizes the activity for the Company's early exercised shares for the six months ended June 30, 2026:

	Number of Shares	Weighted-Average Exercise Price Per Share
Unvested as of December 31, 2025	83,741	$ 1.24
Early exercised	67,242	$ 1.28
Vested	(15,483)	$ 1.23
Unvested as of June 30, 2026	135,500	$ 1.26

Stock-Based Compensation Expense

Stock-based compensation expense for stock options recognized in the Company's condensed statements of operations and comprehensive loss was as follows (in thousands):

	Six Months Ended June 30,	
	2025	2026
General and administrative	$ 146	$ 239
Research and development	37	105
Total	$ 183	$ 344

As of June 30, 2026, total unrecognized stock-based compensation expense related to unvested stock options was $2.2 million, which is expected to be recognized over a weighted-average period of 3.2 years.

9. Income Taxes

The Company recorded no significant income tax expense or benefit during the six months ended June 30, 2025. During the six months ended June 30, 2026, the Company recorded income tax expense of approximately $42,000, primarily related to interest and penalties associated with uncertain tax positions.

The difference between the Company's effective tax rate and the U.S. federal statutory tax rate of 21% was primarily attributable to the full valuation allowance maintained against its deferred tax assets. There were no material changes to the Company's valuation allowance or unrecognized tax benefits during the six months ended June 30, 2026.

10. Related Parties

Lilly

During the six months ended June 30, 2025, Lilly purchased 2,930,404 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share, for an aggregate purchase price of approximately $9.1 million, in connection with the second tranche under the Series B Preferred Stock Purchase Agreement. During the six months ended June 30, 2026, Lilly purchased 2,237,940 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share, for an aggregate purchase price of approximately $6.9 million, in connection with the Series B Extension. As of December 31, 2025, Lilly held 7,700,000 shares of Series A-2 redeemable convertible preferred stock, 2,002,487 shares of Series A-3 redeemable convertible preferred stock and 5,860,808 shares of Series B redeemable convertible preferred stock. As of June 30, 2026, Lilly held 7,700,000 shares of Series A-2 redeemable convertible preferred stock, 2,002,487 shares of Series A-3 redeemable convertible preferred stock and 8,098,748 shares of Series B redeemable convertible preferred stock.

In July 2025, the Company entered into a Master Management Services Agreement with Lilly (the "Lilly Services Agreement"), pursuant to which Lilly provides preclinical research and development services in support of the Company's research projects. The Company incurred no expense and approximately $0.1 million of expense under the Lilly Services Agreement for the six months ended June 30, 2025 and 2026, respectively. Amounts due to Lilly under the Lilly Services Agreement as of December 31, 2025 were immaterial, and approximately $0.2 million was due to Lilly as of June 30, 2026, which was included in accrued liabilities on the condensed balance sheets.

Additionally, the Company and Lilly entered into the Lilly Collaboration Agreement in January 2023, which was amended in June 2026 (see Note 5). The Company also leases certain laboratory and office space from Lilly under a lease agreement that expires in August 2026.

Johnson & Johnson Innovation

In January 2026, Johnson & Johnson Innovation purchased 612,713 shares of Series B Convertible Preferred Stock at a price of $3.0897 per share for aggregate proceeds of approximately $1.9 million in connection with the Series B Extension financing.

As of December 31, 2025, Johnson & Johnson Innovation held 2,656,391 shares of Series A-3 Convertible Preferred Stock and 1,604,598 shares of Series B Convertible Preferred Stock. As of June 30, 2026, Johnson & Johnson Innovation held 2,656,391 shares of Series A-3 Convertible Preferred Stock and 2,217,311 shares of Series B Convertible Preferred Stock, including the 612,713 shares purchased in January 2026.

The Company also had a Collaboration and License Agreement with Janssen Pharmaceutica NV ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson and an affiliate of Johnson & Johnson Innovation, dated as of December 28, 2021 (the "Janssen Agreement"), which was terminated in October 2025. The Company did not recognize any revenue in connection with the Janssen Agreement during either of the six months ended June 30, 2025 and 2026.

Carol Gallagher, Pharm.D.

Carol Gallagher, Pharm.D., served as Executive Chair of the Company's Board of Directors from September 2020 to December 2024 and as the Chair of the Company's Board of Directors since January 1, 2025. In September 2020, Dr. Gallagher entered into an agreement with the Company to purchase 93,144 shares of common stock at $2.16 per share. In April 2025 and February 2026, Dr. Gallagher was granted stock options to purchase 100,489 and 57,838 shares, respectively, under the Company's 2024 Plan as stock-based compensation for her services on the Board of Directors.

Alexandria Real Estate Equities, Inc.

Joel S. Marcus, a member of the Company's Board of Directors, serves as Executive Chairman of Alexandria Real Estate Equities, Inc. In addition, Alexandria Venture Investments, LLC, an affiliate of Alexandria Real Estate Equities, Inc., holds more than 5% of the Company's outstanding capital stock.

In April 2026, the Company entered into an operating lease agreement with ARE-San Francisco No. 46, LLC, an affiliate of Alexandria Real Estate Equities, Inc., for laboratory and office space in South San Francisco, California. During the six months ended June 30, 2026, the Company paid approximately $0.2 million in prepaid rent to ARE-San Francisco No. 46, LLC. See Note 6 for additional information regarding the lease arrangement.

11. Net Loss Per Share

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive (in common stock equivalent shares):

	Six Months Ended June 30,	
	2025	2026
Outstanding stock options	2,187,136	2,980,123
Unvested early exercised stock options	96,303	135,500
Series A-1 Convertible Preferred Stock	1,293,694	1,293,694
Series A-2 Convertible Preferred Stock	1,992,290	1,992,290
Series A-3 Convertible Preferred Stock	3,229,832	3,229,832
Series B Convertible Preferred Stock	7,039,280	11,226,401
Total	15,838,535	20,857,840

12. Segment Information

The Company operates as a single reportable segment focused on autoimmune and inflammatory disease discovery. The Company's Chief Executive Officer serves as the Chief Operating Decision Maker ("CODM"). The measure of segment profit or loss evaluated by the CODM to monitor spending, assess performance for the Company and management, evaluate the progress of completing corporate goals, allocate resources among the clinical and preclinical portfolios, and make strategic decisions regarding business development opportunities corresponds to the net loss presented on the condensed statements of operations and comprehensive loss. Additionally, the measure of segment assets evaluated by the CODM corresponds to total assets as reported in the condensed balance sheets.

The CODM is regularly provided with the following significant segment expenses:

	Six Months Ended June 30,	
	2025	2026
Operating expenses:		
Employee-related expenses, excluding stock-based compensation	$ 6,914	$ 8,021
Stock-based compensation	183	344
External research and development expenses	7,442	17,050
External general and administrative expenses	1,357	1,749
Other segment expenses*	3,328	3,854
Total operating expenses	19,224	31,018
Loss from operations	(19,224)	(31,018)
Interest income	1,568	1,755
Other expense, net	(66)	(3)
Total other income, net	1,502	1,752
Loss before provision for income taxes	(17,722)	(29,266)
Provision for income taxes	-	42
Net loss	$ (17,722)	$ (29,308)

(*) Other segment expenses include facility related and office costs, information technology costs, depreciation and amortization, and other operating expenses.

As of December 31, 2025 and June 30, 2026, all of the Company's property and equipment was located in the United States.

13. Subsequent Events

The Company evaluated subsequent events through August 21, 2026, the date these unaudited condensed financial statements were available to be issued (except for the effects of the reverse stock split, as to which the date is October 5, 2026). The Company concluded that no subsequent events were identified that required recognition or disclosure in these unaudited condensed financial statements, except as described below.

Reverse Stock Split

On October 2, 2026, the Company effected the reverse stock split described in Note 2. The accompanying unaudited condensed financial statements and related notes give retroactive effect to the reverse stock split for all periods presented.

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8,333,334 Shares



Common Stock

P R O S P E C T U S

J.P. Morgan
Evercore ISI
Cantor
Stifel
Wedbush PacGrow

October 8, 2026

Through and including November 2, 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.