Filed pursuant to Rule 424(b)(4)
Registration No. 333-267022
Registration No. 333-267428

10,900,000 Shares

Common Stock

Third Harmonic Bio, Inc. is offering 10,900,000 shares of its common stock. This is our initial public offering of shares of common stock, and prior to this offering, there has been no public market for our common stock. The initial public offering price is $17.00 per share.

We have been approved to list our common stock on the Nasdaq Global Market, or Nasdaq, under the symbol "THRD."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, we have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings. Investing in our common stock involves risks. See "Risk Factors" beginning on page 14.

PRICE $17.00 A SHARE

	Price to Public	Underwriting Discounts and Commissions(1)	Proceeds to Third Harmonic
Per Share	$ 17.00	$ 1.19	$ 15.81
Total	$ 185,300,000	$ 12,971,000	$ 172,329,000

(1) See "Underwriters" for a description of the compensation payable to the underwriters.

We have granted the underwriters the right to purchase up to an additional 1,635,000 shares of our common stock solely to cover over-allotments, if any.

The Securities and Exchange Commission and state regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on September 19, 2022.

MORGAN STANLEY ***JEFFERIES*** ***COWEN***

LIFESCI CAPITAL

September 14, 2022

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PROSPECTUS

Through and including October 9, 2022 (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 delivery requirement 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.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. 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 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 the time of any sale of shares of our common stock.

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 our common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes and the information set forth under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward—Looking Statements" for additional information. Unless the context otherwise requires, we use the terms "Third Harmonic Bio," "the Company," "we," "us" and "our" in this prospectus to refer to the consolidated operations of Third Harmonic Bio, Inc. and its wholly owned subsidiary, THB MS, Inc.

THIRD HARMONIC BIO, INC.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of the next wave of medicine for the treatment of allergic and inflammatory diseases. Our lead product candidate, THB001, is a highly selective, oral small molecule inhibitor of KIT, a cell surface receptor that acts as the master survival and functional regulator of mast cells. Mast cells are a part of the immune system, and dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders including urticaria, asthma and gastrointestinal disorders, among others. KIT inhibition has shown positive clinical responses in mast cell mediated diseases such as asthma and chronic urticaria. In our recently completed Phase 1a clinical trial, THB001 demonstrated dose-dependent reductions of serum tryptase, a key biomarker of mast cell activity which has been shown to correlate with clinical benefit in chronic urticaria patients. We submitted a clinical trial application, or CTA, in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024. We intend to submit both a CTA in Europe and an investigational new drug application, or IND, in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024. We are also exploring development opportunities across a range of other indications where THB001 may provide benefit to patients suffering from mast cell driven inflammation to demonstrate the "pipeline-in-a-product" potential of THB001.

Mast cells are a main driver of allergic inflammatory responses. They are present throughout the body in connective and vascularized tissues, most prominently along surface boundaries with exposure to the external environment: in the skin, the respiratory tract and the gastrointestinal tract. For many patients suffering from allergic conditions, inhibition of mast cell derived mediators, including histamines, leukotrienes, and prostaglandins, has demonstrated insufficient therapeutic value to-date given that many mast cell-driven disorders involve multiple pro-inflammatory mediators. As a result, we believe that targeting mast cells directly through highly selective inhibition of KIT is key to achieving the clinical efficacy needed for broad symptomatic relief across a range of allergic and other inflammatory disorders.

Since KIT is a cell surface receptor that acts as the master regulator of mast cell function and survival, our approach impacts mast cells directly and provides what we believe to be a favorable point of intervention. Furthermore, significant clinical and nonclinical data has been generated internally and by third parties that demonstrate that KIT is a potential target for broad and potentially clinically differentiated inhibition of mast cells. For example, an anti-KIT antibody demonstrated compelling clinical responses in chronic inducible urticaria patients in a third-party Phase 1 trial.

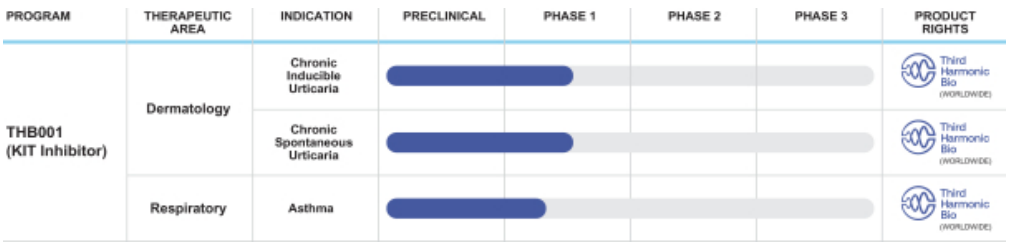
Our lead product candidate THB001 is a potent and highly selective, oral small molecule wild-type KIT inhibitor in development for the treatment of mast cell mediated inflammatory diseases. In nonclinical studies, THB001 demonstrated what we believe to be evidence of highly selective KIT inhibition and mast cell depletion in skin, respiratory and gastrointestinal tissues with a potent therapeutic profile. We believe that chronic

inducible urticaria represents an attractive initial clinical indication for THB001 as a precursor for chronic spontaneous urticaria, given the ability to efficiently evaluate clinical activity outcomes through provocation testing, in concert with biomarker measures of mast cell activity and safety data. Our goal is to be a leader in the oral KIT inhibitor space, and we continue to invest in formulation and discovery for next generation molecules. In addition to initially developing THB001 for treatment of chronic urticaria, we are exploring THB001 as a potential treatment for other indications where mast cell dysfunction plays a key role.

In our recently completed Phase 1a trial in healthy volunteers, we have observed dose dependent increases in THB001 serum concentration levels above the protein binding adjusted KIT cellular IC_{50} value. As signs of the potential efficacy of THB001, we observed that dose levels of 200 mg once daily, or QD, 200 mg twice daily, or BID, and 400 mg BID resulted in dose dependent declines in serum tryptase. The twice daily dose at the 400 mg level of THB001 resulted in a decreased mean serum tryptase level that was at the lower limit of quantification. Reductions in serum tryptase have been associated with a robust clinical response in a clinical trial of an anti-KIT antibody in chronic inducible urticaria patients conducted by a third party. Furthermore, THB001 was well-tolerated, with no serious adverse events, or SAEs, in the trial to-date.

We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, which has been cleared in the Netherlands and Germany. We initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024. We intend to submit both a CTA in Europe and an IND in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024.

There remains a large unmet need in chronic urticaria. Epidemiological studies indicate that up to 25% of the population suffers from urticaria at some point in their lifetime, with 0.5-1% of the population suffering from the disease at any point in time, suggesting a point prevalence of over 1.5 million patients in the United States. Approximately 70% to 80% of patients with urticaria are women. Many patients are first provided H1 antihistamine therapy when diagnosed with urticaria; however, there remains a large unmet need. Approximately 50% of chronic spontaneous urticaria patients continue to experience itch and hives despite H1 antihistamine treatment at FDA-approved doses. There have been no new approved therapies to treat chronic urticaria in eight years, and the most recently approved treatment, the injectable biologic Xolair, provided complete hive and itch symptom relief to approximately 36% of patients in clinical trials. We believe Xolair is currently addressing less than 20% of eligible patients whose symptoms have failed to be controlled by H1 antihistamine therapy. There is a clear unmet need for chronic urticaria treatments that provide higher levels of complete hive and itch symptom relief, while also providing improved patient comfort and convenience via an oral route of administration. We believe an oral therapy offers clear advantages over an injectable therapy, and an oral therapy with the potential to improve upon the results of the existing standard of care offers a significant opportunity to address a large unmet need. While the potential market opportunity within urticaria alone is vast, dysfunctional mast cell activity has also been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders, including respiratory and gastrointestinal disorders. Furthermore, in nonclinical studies, THB001 has demonstrated the ability to deplete mast cells across different tissue types, which we believe supports its ability to potentially treat a range of mast cell mediated skin, respiratory and gastrointestinal conditions supporting our ultimate goal of THB001 achieving its potential as a "pipeline-in-a-product." The table below reflects our initial targeted indications for THB001.



Our Team and Investors

Founded by Atlas Venture in 2019, we are led by a strong management team with diverse backgrounds and significant experience in drug discovery, development and company building, as well as a demonstrated track record of delivering breakthrough therapeutic approaches for patients. Our management team are industry veterans with extensive experience at biopharmaceutical companies such as Audentes, Cadent Therapeutics, Genentech/Roche, Gilead Sciences, Morphic Therapeutic and Pfizer. Together, our team has a proven track record in the discovery, development and commercialization of numerous approved therapeutics.

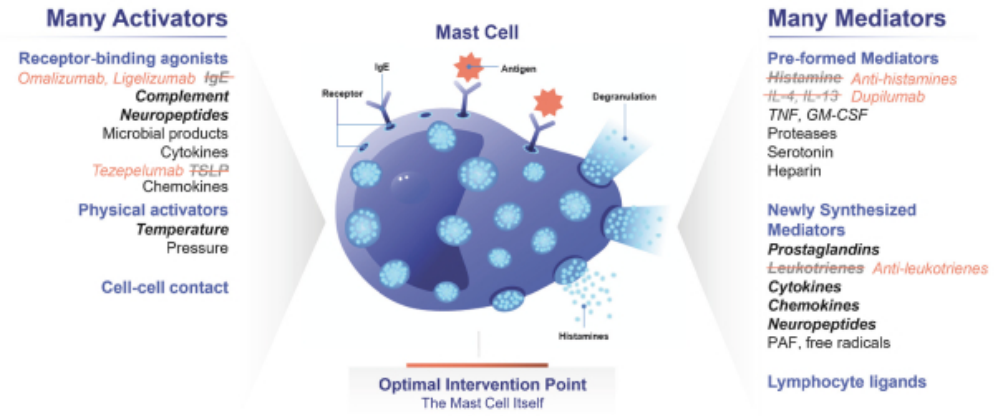
Since our inception, we have been supported by and have raised approximately $155 million of capital from a group of premier life science investors including Atlas Venture, OrbiMed, BVF Partners L.P., General Atlantic, RA Capital, RTW Investments, Boxer Capital, Deep Track Capital, Commodore Capital and Ajax Health|Zeus.

Mast Cells and Their Role in Immunity

Mast cells derive from KIT-positive hematopoietic progenitors in the bone marrow and are present throughout the body in connective and vascularized tissues, most prominently along surface boundaries with exposure to the external environment such as the skin, the respiratory tract and the gastrointestinal tract. Their numerous physiological functions include regulation of inflammation, vasodilation, vascular homeostasis and angiogenesis as well as involvement in the control of other elements of the immune response. Dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders, including urticaria, asthma and gastrointestinal disorders, among others.

The cytoplasm of mast cells stores inflammatory mediators including histamine, the proteolytic enzyme tryptase and various cytokines, such as interleukins IL-4, IL-5 and IL-13, and Tumor Necrosis Factor-a, or TNF-a. Mast cells express multiple cell-surface receptors, one of which is FceR that has particularly high affinity for immunoglobin E, or IgE, antibodies. As shown in the figure below, upon the stimulation of IgE, change of temperature, or pressure, a signaling cascade leads to activation of the mast cell and its degranulation resulting in the release of tryptase, histamine and other inflammatory mediators. In addition to IgE dependent activation, other IgE independent stimuli can also trigger mast cell activation. The release of inflammatory mediators can manifest into a broad range of allergic or inflammatory diseases. Moreover, mast cell activation and degranulation lead to the recruitment of other progenitor cells to the specific tissue site and the propagation of the inflammatory response.

Mast cells mediate multiple pro-inflammatory activities



The receptor tyrosine kinase KIT, also known as CD117, is recognized as a master regulator of mast cell activity. Under normal physiological conditions, mast cell progenitors circulate in an immature form and only fully develop into mature mast cells upon migration to a specific tissue type. Mature mast cells remain localized to a designated destination. Stem cell factor, or SCF, which is also referred as the c-kit ligand, binds to KIT on the surface of the mast cell, enables signal transduction into the mast cell and activates the KIT-mediated signaling cascade critical to mast cell survival, propagation and differentiation via pathways such as PLCg, JAK2/STAT, PI3K/AKT and RAS/RAF/MEK/ERK. As the master regulator of mast cell function and survival, we believe that the KIT-SCF signaling axis is the optimal intervention point to treat many mast cell mediated diseases. Inhibition of KIT drives both mast cell inactivation and depletion, independent of mast cell activation status.

Our Solution: The KIT Inhibitor THB001

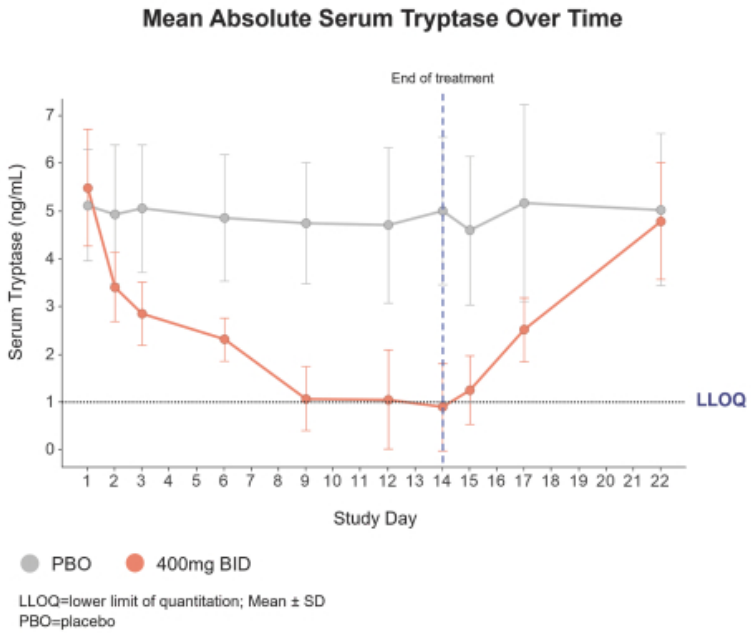
THB001 is a highly potent and selective, small molecule wild-type KIT inhibitor in development for the treatment of mast cell mediated inflammatory diseases. THB001 is designed to offer attractive drug-like properties, including high potency and oral bioavailability, and high selectivity for the wild-type KIT receptor. Based on nonclinical and available clinical data to date, we believe THB001 differentiates from other KIT-targeting therapeutics in the following designed aspects:

- The small molecule modality is anticipated to provide more refined dose titration capabilities than anti-KIT mAbs.
- Oral administration offers improved patient convenience while avoiding mAb-related injection events.
- Higher selectivity for wild-type KIT relative to other small molecule inhibitors.
- THB001 binds intracellularly to an inactive conformation of KIT, avoiding the risk of paradoxical mast cell activation that can result from a KIT mAb binding to the extracellular portion of the KIT receptor.

In our recently completed Phase 1a clinical trial in healthy volunteers, THB001 demonstrated dose-dependent reductions of serum tryptase, a key biomarker of mast cell activity which has been shown to correlate with clinical benefit in chronic urticaria.

As reflected in the chart presented below, which shows absolute serum tryptase levels in patients over time, twice daily dosing of the higher 400 mg level of THB001 resulted in mean serum tryptase which was at the lower limit of quantitation.

The higher 400 mg BID dose resulted in a serum tryptase level at the lower limit of quantitation.



"Pipeline-in-a-Product" Potential of THB001

Dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders that impact the skin, respiratory tract and gastrointestinal tract. Given KIT is the master regulator of mast cell function and survival, we believe that KIT inhibition is the optimal approach to treat many of these mast cell mediated diseases. As such, we believe THB001 represents a "pipeline-in-a-product" opportunity.

Our Strategy

Our goal is to develop the next wave of medicine for the treatment of allergic and inflammatory diseases. The key components of our strategy are to:

- Continue to advance THB001 through clinical development in chronic urticaria.
- Continue to advance THB001 into our second indication in asthma.
- Develop THB001 in a broad range of indications across therapeutic areas where mast cell driven inflammation can benefit from THB001's product profile, including in the skin, respiratory and gastrointestinal tracts.
- Continue to innovate and potentially expand the pipeline through our internal discovery efforts and selectively evaluate strategic collaborations.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

- We have a limited operating history, have not completed any clinical trials beyond Phase 1, and none of THB001 or any future product candidates have been approved for commercial sale. We have a history of significant net losses since our inception and expect to continue to incur significant losses for the foreseeable future.
- Even if we complete this offering, we will need substantial additional funds to pursue our business objectives, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.
- We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock.
- Our future performance is substantially dependent on the success of our lead product candidate, THB001, which is currently in clinical development and which has not completed a pivotal trial.
- Drug development is a lengthy and expensive process, and the outcome of clinical testing is inherently uncertain, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of THB001 or any future product candidates.
- Our future clinical trials may reveal significant adverse events not seen in our nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- The COVID-19 pandemic could adversely impact our business, including the conduct of our clinical trials.
- We face competition from entities that have made substantial investments into the rapid development of novel treatments for allergic and inflammatory diseases, including large and specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize, if approved, product candidates may be adversely affected.
- We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform all of our research and nonclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

- If we are not able to obtain, maintain and enforce patent protection for our technologies or product candidates, development and commercialization, if approved, of our product candidates may be adversely affected.

- The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

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

We were incorporated under the laws of the State of Delaware on April 25, 2019, originally under the name Project Ige, Inc. We changed our name on June 28, 2019 to Third Harmonic Bio, Inc.

Our principal executive offices are located at 300 Technology Square, 8th Floor, Cambridge, Massachusetts 02139, and our telephone number is (617) 915-6680. Our website address is www.thirdharmonicbio.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this prospectus. We have included our website in this prospectus solely as a textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

The mark "Third Harmonic Bio" is our registered or common law trademarks. All other service marks, trademarks and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

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

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies. These provisions include, but are not limited to:

- being permitted to present only two years of consolidated financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, on the effectiveness of our internal controls over financial reporting;

- reduced disclosure obligations regarding executive compensation arrangements; 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.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer,"

with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of this offering.

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

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, until those standards apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with such new or revised accounting standards. Until the date that we are no longer an emerging growth company or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, upon issuance of a new or revised accounting standard that applies to our consolidated financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that the market value of our capital stock held by non-affiliates plus the proposed 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 capital 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 capital 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 consolidated financial statements in our Annual Report on Form 10-K, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

For certain risks related to our status as an emerging growth company and a smaller reporting company, see the section titled "Risk Factors—Risks Related to Our Common Stock and This Offering—We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors."

THE OFFERING

Common stock offered by us	10,900,000 shares
Underwriters' over-allotment option of common stock offered by us	1,635,000 shares
Common stock to be outstanding immediately after this offering	38,693,935 shares (or 40,328,935 shares, if the underwriters exercise their over-allotment option in full)
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $169.0 million (or approximately $194.9 million if the underwriters exercise their over-allotment option in full), based upon the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the continued clinical development of THB001 for the treatment of urticaria, including through completion of our Phase 1b clinical trial for chronic inducible urticaria and initiation of our Phase 2 clinical trial for chronic spontaneous urticaria; to advance the continued clinical development of THB001 in additional indications, including through completion of a Phase 1b clinical trial for asthma and to fund further development or acquisition of future programs to advance nonclinical and clinical development; and the remainder for potential expansion of our pipeline and other research and development activities, as well as for working capital and other general corporate purposes. See the section titled "Use of Proceeds" for additional information.
Risk factors	You should read the section titled "Risk Factors" in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq trading symbol	We have been approved to list our common stock on Nasdaq under the symbol "THRD."

The number of shares of our common stock to be outstanding after this offering is based on 27,793,935 shares of our common stock outstanding as of June 30, 2022 (including (i) 1,410,565 shares of unvested restricted common stock subject to repurchase and (ii) after giving effect to the automatic conversion of all of our shares of convertible preferred stock outstanding as of June 30, 2022, into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering), and excludes:

- 1,803,079 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2022 under our 2019 Stock Incentive Plan, or the 2019 Plan, with a weighted-average exercise price of $7.50 per share;

- 753,139 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after June 30, 2022 under our 2019 Plan, with a weighted-average exercise price of $8.60 per share; and
- 5,079,624 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of:
  - 283,808 shares of our common stock reserved for future issuance under our 2019 Plan as of August 31, 2022,
  - 4,426,737 shares of our common stock to be reserved for future issuance under our 2022 Equity Incentive Plan, or the 2022 Plan, which became effective immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part, and
  - 369,079 shares of our common stock to be reserved for future issuance under our 2022 Employee Stock Purchase Plan, or the ESPP, which became effective immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part.

Our 2022 Plan and our ESPP provide for automatic annual increases in the number of shares of our common stock reserved thereunder, and our 2022 Plan provides for increases to the number of shares that may be granted thereunder based on shares under our 2019 Plan that expire, are tendered to or withheld by us for payment of an exercise price or for satisfying tax withholding obligations or are forfeited or otherwise repurchased by us. Upon completion of this offering, any remaining shares of our common stock available for issuance under our 2019 Plan will be added to the shares reserved under our 2022 Plan and we will cease granting awards under our 2019 Plan. See the section titled "Executive Compensation—Equity Compensation Plans and Other Benefit Plans" for additional information.

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

- the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2022 into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering;
- a 1-for-2.259 reverse stock split of our outstanding common stock, which was effected on September 7, 2022;
- the filing, and effectiveness of our restated certificate of incorporation and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise of outstanding options referred to above; and
- no exercise by the underwriters of their over-allotment option.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statements of operations and consolidated balance sheet data. The summary consolidated statement of operations data presented below for the years ended December 31, 2020 and 2021 are derived from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the summary consolidated statement of operations data for the six months ended June 30, 2021 and 2022, and the consolidated balance sheet data as of June 30, 2022, from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as our annual audited summary consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the unaudited interim condensed consolidated financial statements. The following summary consolidated financial data should be read in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period and results for the six months ended June 30, 2022 are not necessarily indicative of results to be expected for the full year ending December 31, 2022 or any other period. The summary consolidated financial data in this section are not intended to replace our consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this prospectus.

(in thousands, except share and per share amounts)	Year Ended December 31, 2020	Year Ended December 31, 2021	Six Months Ended June 30, 2021	Six Months Ended June 30, 2022
			(unaudited)	
Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	$ 9,953	$ 15,748	$ 6,546	$ 10,393
General and administrative	1,166	3,256	1,010	5,177
Total operating expenses	11,119	19,004	7,556	15,570
Loss from operations	11,119	19,004	7,556	15,570
Total other (income) expense, net	1,688	10,605	(1,110)	(110)
Net loss	$ 12,807	$ 29,609	$ 6,446	$ 15,460
Per share information:				
Net loss per share of common stock, basic and diluted[1]	$ 3.49	$ 7.32	$ 1.64	$ 3.58
Weighted-average common shares outstanding, basic and diluted[1]	3,668,072	4,043,416	3,939,670	4,321,267
Pro forma net loss per share of common stock, basic and diluted (unaudited)[2]		$ 1.73		$ 0.59
Pro forma weighted-average shares outstanding, basic and diluted (unaudited)[2]		17,111,011		26,288,583

(1) See Note 10 to our audited consolidated financial statements and our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for further details on the calculation of historical net loss per share and the weighted-average number of shares of common stock used in the computation of the per share amounts.
(2) The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2021 and for the six months ended June 30, 2022 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock on the later of January 1, 2021 or the date the shares were issued.

(in thousands)	As of June 30, 2022		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
		(unaudited)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$112,731	$ 112,731	$ 281,760
Working capital[3]	108,537	108,537	274,266
Total assets	114,431	114,431	282,370
Total convertible preferred stock	170,184	—	—
Total stockholders' (deficit) equity	(60,557)	109,627	274,266

(1) Pro forma amounts give effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2022 into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering.
(2) Pro forma as adjusted amounts reflect pro forma adjustments described in footnote (1) above as well as the sale of 10,900,000 shares of our common stock in this offering, based upon the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.
(3) We define working capital as current assets less current liabilities. See our audited consolidated financial statements and our unaudited interim condensed consolidated financial statements and the related notes thereto included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making your decision 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 consolidated financial statements and the related notes included elsewhere in this prospectus. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position, Limited Operating History and Need for Additional Capital

We have a limited operating history, have not completed any clinical trials beyond Phase 1, and none of THB001 or any future product candidates have been approved for commercial sale. We have a history of significant net losses since our inception and expect to continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history on which to base your investment decision. We commenced operations in 2019, and none of THB001 or any future product candidates have completed clinical trials beyond Phase 1 or have been approved for commercial sale. Biopharmaceutical product development is a highly speculative undertaking because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable.

Since our inception, we have focused substantially all of our efforts and financial resources on the development of our lead product candidate, THB001. We have not yet demonstrated an ability to successfully complete any late-stage trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately evaluate the performance of our business to date or to predict our viability than it would be if we had a longer operating history.

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through private placements of our preferred stock. Our net losses were $12.8 million and $29.6 million for the years ended December 31, 2020 and 2021, respectively, and $6.4 million and $15.5 million for the six months ended June 30, 2021 and 2022, respectively. As of June 30, 2022, we had an accumulated deficit of $63.7 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of THB001 and any future product candidates. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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

- advance THB001 and any future product candidates through clinical development for chronic inducible urticaria, chronic spontaneous urticaria, and asthma;
- conduct additional nonclinical studies and clinical trials for THB001 in additional potential indications;
- discover and develop new product candidates;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;

- manufacture, or have manufactured, nonclinical, clinical and potentially commercial supplies of THB001 and any future product candidates;
- seek regulatory approvals for THB001 or any future product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize THB001 or any future product candidates, if approved;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses;
- hire additional clinical, scientific and management personnel, as well as administrative staff to support the growth of our business;
- add operational, financial and management information systems and personnel;
- incur additional legal, accounting and other costs associated with operating as a public company following the completion of this offering;
- experience delays related to the COVID-19 pandemic in the United States and in other countries in which we have planned or have active clinical trial sites and where our third-party contract development and manufacturing organizations, or CDMOs operate; and
- establish licenses, collaborations or strategic partnerships.

Even if we succeed in commercializing one or more product candidates, we may continue to incur substantial research and development expenses 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, financial condition, results of operations and prospects. The size of our future losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have never generated revenue, may never generate any revenue from product sales and may never be profitable.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, THB001, or any other future product candidates we may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for these product candidates, manufacturing, marketing and selling those products for which we, or any future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for THB001 or any future product candidates from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenue, if any, the extent of any further losses or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenue in an amount sufficient for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the U.S. Food and Drug Administration, or the FDA, European Medicines Agency, or EMA, or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of THB001 or any future product candidates.

Our failure to become and remain profitable would decrease the value of our Company and depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

Even if we complete this offering, we will need substantial additional funds to pursue our business objectives, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.

Identifying and developing potential product candidates and conducting nonclinical and clinical studies is a time consuming, capital-intensive and uncertain process that takes years to complete. If THB001 or any future product candidates enter and advance through nonclinical studies and clinical trials, as applicable, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial amounts of cash since inception to develop THB001 and will require significant funds to conduct further research and development and nonclinical testing and clinical trials of THB001 and any future product candidates, to seek regulatory approvals for THB001 or any future product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

Nonclinical studies and clinical trials for THB001 and any future product candidates, as applicable, will require substantial funds to complete. As of June 30, 2022, we had $112.7 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through 2025. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund continued growth of our operations, research and development of product candidates, or otherwise respond to competitive pressures, may vary significantly from what we expect and we may need to seek additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of THB001 or any future product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements for THB001, any future product candidates and our ongoing operations, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of nonclinical and clinical development activities;
- the cost of regulatory submissions and timing of regulatory approvals;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we are obligated to make under our Novartis Agreement or any future license agreements;
- the cash requirements of any future acquisitions or discovery of product candidates;

- 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, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved product candidates;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing product candidates by third parties;
- the cost of commercialization activities if THB001 or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of product candidates;
- the continued effect of the COVID-19 pandemic on our business; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and nonclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before THB001 and any future product candidates are clinically tested, approved for commercialization and successfully marketed, if ever.

We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, additional licensing agreements and/or collaborations, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our future debt financings, if available, are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to THB001 or any future product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms, or at all, may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for the year ended December 31,

2021, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that we identified related to the lack of segregation of duties, certain system limitations in our accounting software and the overall control environment as we had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process.

We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel and engaging financial consultants to enable the implementation of internal control over financial reporting and segregating duties amongst accounting and finance personnel. In addition, we are in the process of implementing an accounting software system with the design and functionality to segregate incompatible accounting duties, which we currently expect will be fully implemented in our 2023 fiscal year.

While we are implementing these measures, we cannot assure you that these efforts will remediate our material weaknesses and significant deficiencies in a timely manner, or at all, or prevent restatements of our financial statements in the future. In particular, we do not currently expect that our material weakness related to our certain system limitations in our accounting software will be fully remediated for the fiscal year ended December 31, 2022 as we expect to implement new software in 2023. If we are unable to successfully remediate our material weaknesses, or identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our common stock may decline as a result.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. We expect to incur additional costs to remediate these control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the Securities and Exchange Commission, or SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our products to new and existing customers.

Risks Related to Discovery, Development and Commercialization

Our future performance is substantially dependent on the success of our lead product candidate, THB001, which is currently in clinical development and which has not completed a pivotal trial.

Our future performance is substantially dependent on our ability to timely complete successful clinical trials, obtain regulatory approval for, and then successfully commercialize THB001 and any future product

candidates. We are early in our development efforts and our lead product candidate, THB001, recently completed a Phase 1a clinical trial in healthy volunteers. While we are devoting significant resources to research and development activities, we have not yet identified additional product candidates. We currently have no products that are approved for sale in any jurisdiction. There can be no assurance that THB001 or any future product candidates we develop will achieve success in their clinical trials or obtain regulatory approval.

We plan to seek regulatory approval to commercialize THB001 or any future product candidates in the United States, the European Union and in selected foreign countries, including the United Kingdom and Japan. In order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of THB001 or any future product candidates, and we will be required to expend significant resources to obtain regulatory approval, which may not be successful, and to comply with ongoing regulations in these jurisdictions.

Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and commercialization of THB001. The success of THB001 will depend on several factors, including the following:

- successful completion of necessary nonclinical studies to enable the initiation of clinical trials;
- acceptance of INDs by the FDA or other similar clinical trial applications from foreign regulatory authorities for our future clinical trials for our pipeline product candidates;
- enrollment of patients in, and the completion of, our clinical trials;
- completion of successful clinical trials with positive risk/benefit profiles;
- receiving required regulatory authorizations for the development and obtaining approvals for the commercialization of THB001 or any future product candidates;
- establishing and maintaining arrangements with third-party manufacturers;
- ability to perform drug manufacturing and maintain consistent supply of drugs which meets specifications across various jurisdictions;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for THB001 or any future product candidates and their components and related filings;
- enforcing and defending our intellectual property rights and claims;
- achieving desirable therapeutic properties for THB001 or any future product candidates' intended indications;
- launching commercial sales of THB001 or any future product candidates, if approved, whether alone or in collaboration with third parties;
- acceptance of THB001 or any future product candidates, if approved, by patients, the medical community and third-party payors;
- addressing any delays in our clinical trials resulting from factors related to the COVID-19 pandemic or other major natural disaster or significant political event;
- effectively competing with other therapies; and

- maintaining an acceptable safety profile of THB001 or any future product candidates through clinical trials and following regulatory approval.

Many of these factors are beyond our control, and it is possible that none of THB001 or any future product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize THB001 or any future product candidates, which would materially harm our business.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of THB001 or any future product candidates may be delayed and, as a result, our stock price may decline and you may lose all or part of your investment.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of THB001 or any future product candidates may be delayed or never achieved and, as a result, our stock price may decline. A decline in our stock price and in the value of our Company could cause you to lose all or part of your investment.

Drug development is a lengthy and expensive process, and the outcome of clinical testing is inherently uncertain, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of THB001 or any future product candidates.

We currently have only one product candidate, THB001, which is in Phase 1 clinical development in Europe and the risk of failure is high. Additionally, we have not submitted an IND for THB001 in the United States for any indication. It is impossible to predict when or if THB001 or any future product candidate will prove effective and safe in humans or will receive regulatory approval. While certain treatments have been approved for chronic spontaneous urticaria, to date no products have been approved specifically for the treatment of chronic inducible urticaria, our first indication. To obtain the requisite regulatory approvals to commercialize any product candidate, we must demonstrate through extensive nonclinical studies and lengthy, complex and expensive clinical trials that our product candidate is safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials of THB001 or any future product candidates may not be predictive of the results of later-stage clinical trials. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support clinical development of THB001 or any future product candidates.

We or any future collaborators may experience delays in initiating or completing clinical trials. We or any future collaborators also may experience numerous unforeseen events during, or as a result of, any future clinical

trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize THB001 or any future product candidates, including:

- regulators or institutional review boards, or IRBs, the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may halt or suspend an ongoing clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of THB001 or any future product candidates may be greater than we anticipate;
- the quality of THB001 or any future product candidates or other materials necessary to conduct clinical trials of THB001 or any future product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of THB001 or any future product candidates for use in clinical trials;
- our inability to meet drug specifications suitable for use in clinical trials and commercial applications;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about THB001 or any future product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or nonclinical data for such product candidate as well as data emerging from other molecules in the same class as THB001 or any future product candidate; and
- the FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

Patient 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 we enroll, the proximity of

patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, 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 therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we may in the future rely on collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of THB001 or any future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of THB001 or any future product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize THB001 or any future product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize THB001 or any future product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, results of operations and prospects significantly.

Results of nonclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of nonclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, nonclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for THB001 or any future product candidates warrant marketing approval, the FDA, EMA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of THB001 or any future product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in

protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of THB001 or any future product candidates, the development timeline and regulatory approval and commercialization prospects for such product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

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

From time to time, we may publish preliminary or topline data or data from planned interim analyses of our clinical trials. Preliminary or topline data remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data that we previously published. Data from planned interim analyses of our clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary data and interim analyses should be viewed with caution until the final data are available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our reputation and business prospects.

Our future clinical trials may reveal significant adverse events not seen in our nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of THB001 or any future product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. For example, KIT inhibition is known to produce certain on-target side effects, including inhibition of spermatogenesis, effects on hematopoietic progenitor cells resulting in reductions in neutrophils, reticulocytes, red blood cells and white blood cells, changes in taste and reduced hair pigmentation. In our Phase 1a trial in healthy volunteers, one moderate adverse effect, or AE, determined to be likely related to THB001 was low neutrophil levels, which resolved after discontinuation in the trial. While we believe that such side effects will be reversible following discontinuation of THB001 with sufficient recovery periods, we will need to monitor the severity and duration of side effects in our clinical trials. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide or be required to perform additional nonclinical studies or to halt or delay further clinical development of THB001, which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities. We also expect that, similar to other approved KIT inhibitor drugs, THB001 will be teratogenic as KIT mutations are embryo lethal and, if approved, THB001 will require the concomitant use of appropriate birth control measures. We have not yet tested THB001 on non-vasectomized male subjects in multiple doses, so we have not yet been able to evaluate the effect on spermatogenesis. AEs and serious adverse events, or SAEs, that emerge during clinical investigation of or treatment with THB001 or any future product candidates or other compounds acting through similar biological pathways may be deemed to be related to THB001 or any future product candidate. This may require longer and more extensive Phase 3 clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain THB001 or any future product candidates and could result in warnings and precautions in our product labeling or a restrictive risk evaluation and mitigation strategy, or REMS. This may also result in an inability to obtain approval of THB001 or any future product candidates. We, the FDA, EMA 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 subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects, including the potential effects on fertility, may inhibit market

acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

Clinical trials of THB001 or any future our product candidates may not uncover all possible AEs that patients may experience.

Clinical trials are conducted in representative samples of healthy volunteers and the potential patient population, which may have significant variability. By design, clinical trials are based on a limited number of subjects and are of limited duration of exposure to the product, to determine whether the product candidate demonstrates the substantial evidence of efficacy and safety necessary to obtain regulatory approval. As with the results of any statistical sampling, we cannot be sure that all side effects of THB001 or any future product candidates may be uncovered. It may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare SAEs, and the duration of such studies may not be sufficient to identify when those events may occur. Other products have been approved by the regulatory authorities for which safety concerns have been uncovered following approval. Such safety concerns have led to labeling changes, restrictions on distribution through use of a REMS, or withdrawal of products from the market, and THB001 or any future product candidates may be subject to similar risks.

In our Phase 1a trial in healthy volunteers to date, we have observed no SAEs, three moderate AEs and the remaining AEs categorized as mild. Although to date we have not seen evidence of significant safety concerns in our Phase 1a clinical trial with THB001, patients treated with our products, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of THB001 or any future product candidates. If safety problems occur or are identified after THB001 or any future product candidates, if any, reach the market, we may make the decision or be required by regulatory authorities to amend the labeling of our products, recall our products, or even withdraw approval for our products.

The COVID-19 pandemic could adversely impact our business, including the conduct of our clinical trials.

The ongoing COVID-19 pandemic could cause significant disruptions that could severely impact our business, including:

- delays or difficulties in screening, enrolling and maintaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- inability or unwillingness of subjects to travel to the clinical trial sites;
- delays, difficulties or incompleteness in data collection and analysis and other related activities;
- decreased implementation of protocol required clinical trial activities and quality of source data verification at clinical trial sites;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials and our other research and development activities, including because of sickness of employees or their families or mitigation measures such as lock-downs and social distancing;
- delays due to production shortages resulting from any events affecting raw material supply or manufacturing capabilities domestically and abroad;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global and domestic shipping that may affect the transport of clinical trial materials, such as investigational drug products used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, delays or require us to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of regulatory authorities such as FDA or EMA, to accept data from clinical trials in affected geographies; and
- adverse impacts on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

Such disruptions could impede, delay, limit or prevent completion of our ongoing clinical trials and nonclinical studies or commencement of new clinical trials and ultimately lead to the delay or denial of regulatory approval of THB001 or any future product candidates, which would increase our costs and expenses and seriously harm our business, financial condition, results of operations and prospects. Furthermore, if either we or any third party in the supply chain for materials used in the production of THB001 are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our clinical trials. We are in close contact with our clinical research organizations, or CROs, our CDMOs and clinical sites as we seek to mitigate the impact of the COVID-19 pandemic on our current timelines. Measures we have taken in response to the COVID-19 pandemic include, where feasible, conducting remote clinical trial site activations and data monitoring. However, despite these efforts, we have experienced delays in trial site initiations, patient participation and patient enrollment in our clinical trial and we may continue to experience some delays in our clinical trials and nonclinical studies and delays in data collection and analysis.

These delays so far have had a limited impact on our development prospects for THB001, but the negative impacts could be exacerbated as the COVID-19 pandemic and the response to it continue to evolve. The COVID-19 pandemic could also affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned or completed clinical trials and ultimately of reviews and approvals of THB001. The extent to which the COVID-19 pandemic impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the success of mass vaccination efforts globally, travel restrictions and social distancing in the United States and other countries, the impact of new COVID-19 variants, business closures or business disruptions and the effectiveness of actions taken by governmental authorities to contain and address the challenges posed by the ongoing COVID-19 pandemic.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

Patient 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 we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, 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 therapeutic biologics that may be approved for the indications being investigated by us. In addition, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as THB001, our lead clinical product candidate, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. The COVID-19 pandemic may also delay clinical trials if there are inadequate clinical resources for sites to safely conduct clinical research. Furthermore, we expect to rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of THB001 or any future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

If we are unable to enroll a sufficient number of patients for our clinical trials, it would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for THB001 or any future product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and to generate revenue, which would cause the value of our Company to decline and limit our ability to obtain additional financing if needed.

We face competition from entities that have made substantial investments into the rapid development of novel treatments for allergic and inflammatory diseases, including large and specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize, if approved, product candidates may be adversely affected.

The development and commercialization of drugs is highly competitive. Our lead product candidate, THB001, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunology and, furthermore, within the treatment of allergies and inflammatory conditions.

Our likelihood of success will depend partially on our ability to develop and commercialize therapeutics that are safer and more effective than competing products. Our commercial opportunity and likelihood of success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we are trying, or may try, to develop.

Our competitors have developed, are developing or will develop product candidates and processes competitive with our lead product candidate, and any future product candidates, and processes. therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. THB001, our lead product candidate, initially under development for treatment of chronic inducible urticaria, if approved, would face competition from existing approved urticaria treatments. In addition to the current standard of care treatments for patients with allergies and inflammatory diseases, numerous commercial and academic nonclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates. There are numerous other competitive approaches, including inhibitors of activators of mast cells such as IgE antibodies like omalizumab, inhibitors of mediators such as anti-histamines and anti-IL-4 /IL-13 therapies, other small molecule approaches such as Bruton's tyrosine kinase inhibitors, and other small molecule and biologic KIT inhibitors such as Celldex's CDX-0159 or monoclonal antibody KIT inhibitor, among others.

Many of these competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of THB001 or any future product candidates, the ease with which THB001 or any future product candidates can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing THB001 or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

THB001 or any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success, if approved, and we may not generate any future revenue from the sale or licensing of product candidates.

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt THB001 or any future product candidates, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or future collaborators. Market acceptance of THB001 or any future product candidates, if approved, will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of THB001 or any future product candidates as demonstrated in clinical trials;
- the prevalence and severity of any adverse side effects associated with THB001 or any future product candidates;
- limitations or warnings contained in any labeling approved by the FDA, EMA or other regulatory authority;
- relative convenience and ease of administration of THB001 or any future product candidates;

- the willingness of patients to accept any new methods of administration;
- unfavorable publicity relating to our current product candidates or any future product candidates;
- the success of our physician education programs;
- the effectiveness of sales and marketing efforts;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of THB001 or any future product candidates, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications THB001 or any future product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product, if approved, is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

The market opportunities for THB001 or any of our future product candidates, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.

Our projections of both the number of people who have chronic urticaria as well as other mast cell-mediated allergic and inflammatory diseases we are targeting, and who have the potential to benefit from treatment with THB001 or any of our future product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the indications that we are targeting. The potentially addressable patient population for THB001 or any of our future product candidates may be more limited that we currently estimate or may not be amenable to treatment with such product candidates. For example, women are nearly twice as likely as men to experience urticaria, and the expected requirement of concomitant use of appropriate birth control measures may result in a lower addressable patient population than we expect. Consequently, even if THB001 or any of our future product candidates are approved, the number of patients that may be eligible for treatment, or willing to be treated, with THB001 or any future product candidates may turn out to be much lower than expected. Even if we obtain significant market share for THB001 or any future product candidates, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market THB001 or any future our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.

We currently do not have a marketing or sales team for the marketing, sales and distribution of THB001 or any future product candidates, if any of them ever obtain regulatory approval. To commercialize any product

candidates after approval, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or arrange with third parties to perform these services, and we may not be successful in doing so. If THB001 or any future product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize THB001 or any future product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of THB001 or any future product candidates if we obtain approval to market.

With respect to the commercialization of all or certain of THB001 or any future product candidates, if approved, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment any future sales force and distribution systems of our own or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of THB001 or any future product candidates if any receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing THB001 or any future product candidates, if approved, either on our own or through collaborations with one or more third parties, any future product revenue will suffer and we may incur significant additional losses.

If any of THB001 or any future our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidate, our ability to market and derive revenue from the product candidates could be compromised.

Undesirable side effects caused by THB001 or any future product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA, EMA, or other regulatory authorities. Results of future clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our future clinical trials could be suspended or terminated and the FDA, EMA, or comparable foreign regulatory authorities could order us to cease further development of or deny approval of THB001 or any future product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to initiate or complete the clinical trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, 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 THB001 or any future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any of THB001 or any future product candidates receive regulatory approval and we or others identify undesirable side effects caused by such product, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;

- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these occurrences could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Business and Operations

We expect to significantly expand our development, clinical and regulatory capabilities and operations as we grow our Company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2022, we had 16 full-time employees. We expect to increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, late-stage regulatory affairs, finance, accounting, business operations, public company compliance, communications and other corporate development functions, and, if THB001 or any of our future product candidates receive regulatory and marketing approval, sales, marketing and distribution capabilities. If we acquire additional product candidates or enter into future collaborations, we may have to further expand our employee base beyond our current projections, which may include further nonclinical research and development or later-stage regulatory operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacturing of THB001 or any future product candidates. We cannot assure you that the services of such third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our third-party contract organizations, advisors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of THB001 or any future product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing third-party contract organizations, advisors or consultants or find other competent outside third-party contract organizations, advisors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our Company, we may not be able to successfully implement the tasks necessary to further develop and commercialize, if approved, THB001 or any future product candidates and, accordingly, we may not achieve our research, development and commercialization goals.

Our future performance depends on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries largely depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on the development and management expertise of our executive officer team. We currently do not maintain key person insurance on these individuals. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel, because of the highly technical nature of THB001 or any future product candidates and technologies, and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

We primarily conduct our operations at our facility in Cambridge, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market, and nationally, is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Our future performance will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates will be limited, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our future growth may depend, in part, on our ability to operate 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 THB001, if approved, and any future product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote THB001 or any future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for THB001 or any future product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of THB001 or any future product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of THB001 or any future product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of THB001 or any future 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 materially and adversely affected. Moreover, even if we obtain approval of THB001 or any future product candidates and ultimately commercialize THB001 or any future product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business depends on the efficient and uninterrupted operation of our information technology systems and those of our third-party CROs, CDMOs, or other vendors, contractors or consultants, may fail or suffer security breaches, cyber-attacks, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

Our business success depends on the security and efficient and uninterrupted operation of our information technology systems and we may be unable to adequately protect our information technology systems from cyber- attacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and sensitive personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, CDMOs, vendors and other contractors and consultants who have access to our confidential information. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the remote work environment resulting from the COVID-19 pandemic, could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs, CDMOs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, accidents by our employees or third party service providers, natural disasters, terrorism, war, global pandemics, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, third-party CROs, CDMOs, vendors, contractors, consultants, business partners and/or other third parties, or from cyber-attacks or supply chain attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our third-party CROs, CDMOs, vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. The COVID-19 pandemic is generally increasing the attack surface available for exploitation, as more companies and individuals work online and remotely, and as such, the risk of a cybersecurity incident occurring, and our investment in risk mitigations against such an incident, are increasing. For example, there has been an increase in phishing and spam email attacks as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. We may not be able to anticipate all types of security threats, nor implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. Any breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the Health Insurance Portability and Accountability Act, or HIPAA, and other relevant state and federal privacy laws in the United States. If the information technology systems of our third-party CROs, CDMOs, vendors and other contractors and consultants become subject to disruptions or security breaches, 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.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party CROs, CDMOs, vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, CDMOs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our lead product candidate could be delayed. In addition, the loss of clinical trial data for THB001 or any other future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, CDMOs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and sensitive personal information), which could result in financial, legal, business and reputational harm to us.

A security breach could lead to claims by our counterparties that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our counterparties could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our platform, systems, networks, or physical facilities could result in litigation with our counterparties. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our solutions and/or platform capabilities in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur and the confidentiality, integrity or availability of our data or the data of our partners, patients or our counterparties was disrupted, we could incur significant liability, or our platform, systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

We may not have adequate insurance coverage with respect to security breaches or disruptions. 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 and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

When we conduct clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, if approved, such claims could result in an FDA investigation of the safety and effectiveness of our products, 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 products, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our

business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We currently maintain general liability insurance. We may, however, need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain 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 have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA regulations, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, 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 THB001 or any future product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws will likely increase. 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. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such 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 unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, EMA, or other foreign regulatory body exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.

Our research and development activities involve the use of hazardous chemicals and materials, including radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant guidelines of Middlesex County, Massachusetts. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers'

compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our CDMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Extreme weather conditions or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our CDMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time, if at all.

Our employees often conduct business outside of any facilities leased by us. These locations may be subject to additional security and other risk factors due to the limited control of our employees. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CDMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified under proposed legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act, or any other newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act, the CARES Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under the Tax Cuts and Jobs Act, as modified by the CARES

Act, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses for any year is limited to no more than 80% of the excess, if any, of current year taxable income (without regard to certain deductions) over the amount of federal net operating losses generated in tax years beginning before January 1, 2018 that are deducted in the current year. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, if we undergo an ownership change, our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Our Reliance on Third Parties

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform all of our research and nonclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our nonclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned nonclinical studies and clinical trials of our future product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with good clinical practices, or GCP, requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure, or the failure of third parties on whom we rely, to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory

requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for THB001 or any other future product candidates and will not be able to, or may be delayed in our efforts to, commercialize our products, if approved.

We may, in the future, enter into collaborations with third parties for the discovery, development and commercialization of product candidates, if approved. If those collaborations are not successful, we may not be able to capitalize on the market potential of THB001 and any future product candidates.

We may seek third-party collaborators for the development and commercialization of THB001 or any future product candidates, if approved, on a select basis, including potentially in specific foreign jurisdictions. We have not entered into any collaborations to date. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a future collaboration will depend, among other things, upon our assessment of the future collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our business.

If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of THB001 or any future product candidates. Our ability to generate revenues from these arrangements will depend on our future collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations with future collaborators involving THB001 or any future product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of THB001 or any future product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with THB001 or any future product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product, if approved, relative to other products;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or, if approved, commercialization of THB001 or any future 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, if approved, commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or, if approved, commercialization of product candidates in the most efficient manner or at all; and

- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or, if approved, commercialization program could be delayed, diminished or terminated.

If we establish one or more collaborations, all of the risks relating to product development, regulatory approval and, if approved, commercialization described above would also apply to the activities of any such future collaborators.

We rely on third-party manufacturers and suppliers to supply components of THB001 or any future product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on CDMOs, including in the United States, China and Europe, to manufacture bulk drug substances, drug products, raw materials, samples, components, or other materials and reports. Reliance on CDMOs may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our nonclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our CDMOs could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA, EMA and other foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and other foreign regulatory authorities. If our contract manufacturers are unable to maintain a compliance status acceptable to the FDA, EMA and other foreign regulatory authorities, THB001 or any future product candidates may not be approved. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of components of THB001 or any future product

candidates. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are nonetheless responsible for ensuring that THB001 or any future product candidates are manufactured in accordance with applicable laws and regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture THB001 or any future product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty transferring the manufacturing of THB001 or any future product candidates to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture THB001 or any future product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on CDMOs if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce THB001 or any future product candidates will be subject to periodic review and inspection by the FDA, EMA and other foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize THB001 or any future product candidates, if approves. Our or a third party's failure to execute on our manufacturing requirements, to comply with cGMPs or to maintain a compliance status acceptable to the FDA, EMA or other foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, if any, for product candidates;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of THB001 or any future product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter any of these difficulties, our ability to provide THB001 or any future product candidates to patients in nonclinical and clinical trials, or to provide products for treatment of patients, if approved and commercialized, would be jeopardized.

Risks Related to Intellectual Property

If we are not able to obtain, maintain and enforce patent protection for our technologies or product candidates, development and commercialization, if approved, of THB001 or any future product candidates may be adversely affected.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for THB001 and any future product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Currently, our intellectual property protection includes patent applications owned by us and patents and patent applications that we have in-licensed from Novartis Pharma AG., or Novartis, under the Novartis License Agreement. We may not be able to apply for patents on certain aspects of THB001 or any future product candidates in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

There may be circumstances where we may not have the right to control the preparation, filing and prosecution of all patent applications that we license from third parties, or to maintain and/or enforce the rights to patents licensed from third parties, in which case, we will be dependent on our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property. Our licensors may not successfully prosecute the patent applications that are licensed to us and even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents or may determine not to pursue litigation against other companies that are infringing these patents. In other words, such licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Further, we cannot be certain that such activities related to the preparation, filing, prosecution, maintenance and/or enforcement of the licensed patent rights by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patent rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the licensed patent rights, or defend certain of the licensed patent rights. It is possible that the licensor's infringement proceeding or defense activities with respect to the licensed patent rights may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for the licensed patents and patent applications they control, and to timely cede control of such prosecution and/or enforcement to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our future issued or granted patents will not later be found to be invalid or unenforceable or that any future issued or granted patents will include claims that are sufficiently broad to cover THB001 or any future product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents, or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

Our 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. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However,

prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. 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 be certain that 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.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a large number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, for a given period after allowance or grant patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation action in court or before patent offices or similar proceedings, during which time third parties can raise objections against such initial grant. Such proceedings may continue for a protracted period of time and an adverse determination in any such proceedings could reduce the scope of the allowed or granted claims thus attacked, or could result in our patents being invalidated in whole or in part, or being held unenforceable, which could allow third parties to commercialize THB001 or any future product candidates and compete directly with us without payment to us. In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell compounds that are the same as or similar to THB001 or any future product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed or that we may license in the future will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop additional proprietary technologies that are patentable;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors fail to maintain the patents and patent applications covering THB001 or any future product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

In addition to seeking patent protection for certain aspects of THB001 or any future product candidates, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we breach our license agreements it could have a material adverse effect on our commercialization efforts for THB001 or any future product candidates.

We are party to a license agreement, the Novartis Agreement, that enable us to utilize third-party intellectual property in the development of our lead product candidate, THB001, and we may in the future enter into more such license agreements with third parties under which we license the use, development and commercialization rights to THB001 or any future product candidates or technology from third parties.

These intellectual property license agreements may require us to comply with various obligations, including diligence obligations such as development and commercialization obligations, as well as potential royalty and milestone payments and other obligations. If we fail to comply with our obligations under any of these license agreements, use the licensed intellectual property in an unauthorized manner, we are subject to bankruptcy-related proceedings or otherwise materially breach any of these license agreements, the terms of the license granted may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate the applicable license agreement, in whole or in part. Generally, the loss of or termination of our rights under the Novartis Agreement, or any other licenses we may acquire in the future, could harm our business, financial condition, results of operations and prospects.

We may also, in the future, enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may result in termination of our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on

reasonable terms, or at all, which may impact our ability to continue to develop and commercialize THB001 or any future product candidates incorporating the relevant intellectual property.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of THB001 or any future product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the 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
- whether and the extent to which inventors are able to contest the assignment of their rights to our licensors.

If disputes over intellectual property that we have licensed or license in the future prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates, which could have material adverse effect on our business. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Further, certain of our future license agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions or may limit our ability to pursue certain activities (e.g., we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place).

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

Licensors often retain certain rights under license agreements, including the right to use the underlying licensed intellectual property for non-commercial academic and research use, to publish general scientific findings from research related to the licensed intellectual property, and to make customary scientific and scholarly disclosures of information relating to the licensed intellectual property. It is difficult to monitor whether licensors limit their use of the licensed intellectual property to these uses, and we could incur substantial expenses to enforce our rights to our licensed intellectual property in the event of misuse.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive,

partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. In the future, we may need to collaborate with academic institutions to accelerate our research or development with respect to THB001 or any future product candidates. While we try to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot guarantee that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license intellectual property 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 such licensed intellectual property may be adversely affected.

Our strategy of obtaining rights to key technologies through in-licenses may not be successful.

We may seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates or technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The in-licensing and acquisition of these technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business, financial condition, results of operations and prospects could suffer.

Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.

Oral KIT inhibitor therapies for the treatment of mast cell-mediated allergic and inflammatory disease are a relatively new scientific field. In addition to patent applications that we own or in-license to KIT inhibitor therapies, there are pending patent applications by others in the United States and in key markets around the world that claim many different methods, compositions and processes relating to the discovery, development and manufacture of small-molecule KIT inhibitor-based and other therapeutics.

As the field of small-molecule KIT inhibitor-based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product.

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

Filing, prosecuting, defending and enforcing patents covering our technology in the United States and in other jurisdictions worldwide would be extremely costly, and our or our licensors' or collaborators' intellectual

property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensors or collaborators have not obtained patent protection, competitors may seek to use our or our licensors' or collaborators' technology to develop competing products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our or our licensors' or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to pharmaceuticals or biopharmaceuticals. This could make it difficult for us or our licensors or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

When we elect to pursue patent protection on an invention, we generally first file a U.S. provisional patent application (a priority filing) at the USPTO. An international patent application under the Patent Cooperation Treaty, or PCT, is then usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, the European Patent Office and, depending on the individual case, also in any or all of, *inter alia*, Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Eurasia, South Africa, South Korea and other jurisdictions. We have thus far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent office is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that, depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries 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. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such a patent. If we or any of our licensors or collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

We, our licensors or collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents, if and when granted, or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of THB001 or any future product candidates, or put our patents, if and when granted, and other proprietary rights at risk.

Competitors may infringe our patents, if and when granted, or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology,

the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, lack of adequate written description, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual 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 or unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the inventorship or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring THB001 or any future product candidates to market. 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 this type of 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 have a material adverse effect on the price of our common stock. Patents and other intellectual property rights will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize THB001 or any future 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 THB001 or any future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

We, our licensors or collaborators, or any future strategic partners, may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries, including patent infringement lawsuits, interferences, derivations, post-grant reviews, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. There may be issued patents and pending patent applications that claim aspects of our targets or THB001 or any future product candidates and modifications that we may need to apply to THB001 or any future product candidates. There may be issued patents that claim KIT inhibitors which may be relevant to the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages and attorneys' fees if we or they are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if

a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by THB001 or any future product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by THB001 or any future product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon THB001 or any future product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, in certain situations, a U.S. patent application can remain confidential until the patent application issues as a U.S. patent. International patent applications and parallel patent applications in the United States and elsewhere are 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. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of THB001 or any future product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees, including our management, were previously employed at biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and ultimately commercialize, or prevent us from developing and commercializing, THB001 or any future product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Patent terms may be insufficient to protect our competitive position on THB001 or any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various patent term adjustments or extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering THB001 or any future 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 new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and/or rely on our outside counsel to pay these fees due to the USPTO and non-U.S. governmental patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and 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. However, there are situations in which non-compliance 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, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop and our technology, our U.S. patent or one or more U.S. patents that may issue in the future based on a patent application that we license or may own may be eligible for limited patent term extension under Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term 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 product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 and enforce our intellectual property rights. For example, the America Invents Act, involved significant changes in patent legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, the decision by the *U.S. Supreme Court in Association for Molecular Pathology v. Myriad Genetics, Inc.* precludes a claim to a nucleic acid having a stated

nucleotide sequence that is identical to a sequence found in nature and unmodified. Moreover, in 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to patent-ineligible subject matter. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once 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 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 existing patents and patents that we might obtain in the future.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize THB001 or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

THB001 and any future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of drugs. Rigorous nonclinical testing and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us to begin selling them.

We have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other 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 require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from nonclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We 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. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of nonclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of THB001 or any future product candidates. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any.

Further, the FDA and its foreign counterparts may respond to any NDA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of THB001 or any future product candidates.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any

regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for THB001 or any of THB001 or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, THB001 or any future 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 products.

Any regulatory approvals that we obtain for THB001 or any of our future 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 THB001 or any of our future product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping 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 and 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 after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. 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 agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our CDMOs, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on CDMOs, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote THB001 or any of our future product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Moreover, while we believe that THB001 or any future product candidates may provide better safety or effectiveness as compared to approved products, if we do not study THB001 or any future product candidates in head-to-head trials with those products, we will not be able to make comparative claims for our products, if approved. If we or our, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies 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.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our CDMOs or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of THB001 or any of our future product candidates. 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We also 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. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government such as the one that occurred from December 22, 2018 through January 25, 2019. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If any legislation, executive orders, or lapses in agency funding impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare and privacy laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute THB001 or any of our future product candidates. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the

purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program 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;

- the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent,. knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, 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 prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing information,

state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and 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, any of which could adversely affect our financial results.

These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

We are subject to stringent and changing obligations 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 process personal data and other sensitive information, including our proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws and consumer protection laws. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. At the state level, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on businesses to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA could increase compliance costs and potential liability. In addition, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. Other states have also enacted or proposed data privacy laws, which could further complicate compliance efforts.

Outside the United States, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Certain foreign jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make

it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU).

Although we endeavor to comply with all applicable data privacy and security obligations, these obligations are quickly changing, creating some uncertainty as to how to comply. Further, we may at times fail (or be perceived to have failed) to have complied and could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal 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 revision or restructuring of our operations.

We may face difficulties from healthcare legislative and regulatory reform measures.

Existing laws and regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of THB001 or any of our future product candidates. We 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 lose any marketing approval that we may have obtained, or may face penalties for any approved products, and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. Among other things, the ACA, enacted in 2010, increased manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole," which is now 70% of the negotiated price.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. For example, in July 2021, President Biden issued an executive order pertaining to drug pricing, which expressed support for legislation allowing direct negotiation in Medicare Part D and inflationary rebates and directed various executive branch agencies to take actions to lower drug prices and promote generic competition. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles.

These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which, among other things, will allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also,

beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. Thus, it is unclear how the IRA will be implemented but will likely have a significant impact on the pharmaceutical industry.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including restrictions or prohibitions on certain marketing practices, reporting of specified categories of remuneration provided to health care practitioners, and reporting and justification of price increases greater than a specified level. In some cases, states have designed programs to encourage importation from other countries and bulk purchasing, though the federal government has not yet approved any such plans. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for pharmaceuticals and other healthcare products and services, which could result in reduced demand for THB001 or any future product candidates or companion diagnostics or additional pricing pressures.

We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Even if we are able to commercialize THB001 or any of our future product candidates, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if THB001 or any of our future product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors including government authorities, such as Medicare and Medicaid, private health insurers and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors are critical to new product acceptance. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts

reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and 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 United States. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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, or FCPA, 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. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of THB001 or any future product candidates to certain governments, persons, entities, countries and territories, including those that are the target of comprehensive sanctions or an embargo. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents and contractors, 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, or other partners 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.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly member states of the European Union, or EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of THB001 or any future product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected.

Risks Related to Our Common Stock and This Offering

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 and an active trading market for our shares may never develop or be sustained following 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 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. Moreover, the initial public offering price for our common stock was determined through negotiations with the underwriters and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. 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, if at all. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

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

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of THB001, our lead product candidate or any future development programs;

- results of nonclinical and future clinical trials, or the addition or termination of future clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of THB001 or any future product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- the continuing effect of the COVID-19 pandemic on our business and operations;
- regulatory developments affecting THB001 or any future product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control, including without limitation as a result of the COVID-19 pandemic. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including the other risks described in this "Risk Factors" section and the following:

- results of nonclinical studies and future clinical trials of THB001 or any future product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States or other countries, especially changes in laws or regulations applicable to THB001 or any future product candidates;
- the success or failure of competitive products or technologies;
- introductions and announcements of new product candidates by us, any future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to THB001 or any future product candidates, clinical studies, and, if approved, manufacturing process or sales and marketing terms;

- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies or product candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners if THB001 or any future product candidates are approved;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for THB001 or any future product candidates;
- our ability or inability to raise additional capital and the terms on which we are able to raise it, if at all;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates, development timelines or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- fluctuations of trading volume of our common stock;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- expiration of market stand-off or lock-up agreements;
- changes in accounting principles;
- actions instituted by activist shareholders or others;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities, including global pandemics such as the COVID-19 pandemic; and
- general economic, industry and market conditions, including rising interest rates and inflation.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

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

You will suffer immediate and substantial dilution with respect to the common stock you purchase in this offering. If you purchase common stock in this offering, at the initial public offering price of $17.00 per share, and assuming that the underwriters do not exercise their over-allotment option to purchase additional common stock in this offering, you will incur immediate dilution of $9.91 per share, representing the difference between the initial public offering price of $17.00 per share and our pro forma net tangible book value per share as of June 30, 2022, after giving effect to this offering and the conversion of all outstanding shares of our convertible preferred stock to common stock upon the completion of this offering.

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

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Based on shares outstanding as of June 30, 2022, upon completion of this offering, we will have outstanding a total of 38,693,935 shares of common stock. Of these shares, only 10,900,000 shares of common stock sold in this offering, or 12,535,000 shares if the underwriters exercise their over-allotment option in full, will be freely tradable, without restriction, in the public market immediately after this offering. Each of our officers, directors and holders of substantially all of our outstanding equity securities have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. However, Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, the shares of common stock subject to these lock-up agreements will be eligible for sale in the public market, unless held by our officers, directors and their affiliated entities, in which case such shares will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

After this offering, the holders of an aggregate of 25,508,705 shares of our outstanding common stock as of June 30, 2022 (as a result of the 1-for-2.259 reverse stock split of our outstanding common stock), will have rights, subject to some 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 our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above and in the section titled "Underwriters."

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares of common stock or other securities convertible into shares of common stock, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares of common stock, could reduce the market price of our common stock.

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

Based on the beneficial ownership of our common stock as of August 26, 2022, prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 88.5% of our voting stock and, upon the completion of this offering, that same group will hold approximately 63.5% of our outstanding voting stock (assuming no exercise of the underwriters' over-allotment option, no exercise of our outstanding options and no purchases of shares of common stock in this offering by anyone of this group). The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our Company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus.

We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700.0 million as of the prior June 30, or if we have total annual gross revenue of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an

"emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that the market value of our common stock held by non-affiliates plus the proposed 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 common 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 common 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, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with annual report for our fiscal year ending December 31, 2023. This assessment will need to include the disclosure of any material weaknesses or significant deficiencies in our internal control over financial reporting identified by our management or our independent registered public accounting firm. When we become an "accelerated filer" or a "large accelerated filer," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated.

In connection with the preparation of our financial statements for the year ended December 31, 2021, we concluded that there was a material weakness in our internal control over financial reporting. See the section titled "—Risks Related to Our Financial Position and Need for Additional Capital—We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock." Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or

investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

Our restated certificate of incorporation and our restated bylaws that will be in effect upon completion of this offering contain provisions that could delay or prevent a change in control of our Company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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

The exclusive forum provisions in our organizational documents 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, or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation that will be in effect upon completion of this offering, to the fullest extent permitted by law, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision 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, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, results of operations and prospects.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws will provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents, which may discourage lawsuits against us and our directors, officers, other employees or agents.

Because we do not anticipate paying any dividends on our capital stock for the foreseeable future, capital appreciation, if any, will be your sole source of gain and you may never obtain a return on your investment.

We have never declared or paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any dividends for the foreseeable future, if at all. In addition, any future debt financings may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future and you may never obtain a return on your investment. As a result, investors seeking cash dividends should not purchase our common stock.

General Risk Factors

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced 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. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our nonclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

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.

As a public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations 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.

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

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or 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 party

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. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

The market price of our common stock is likely to be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" and elsewhere in this prospectus. Moreover, we operate in a 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 in this prospectus include, among other things, statements about:

- our plans to develop and commercialize THB001 for the treatment of chronic inducible urticaria and our plans to further develop THB001 for the treatment of chronic spontaneous urticaria, asthma and additional indications;
- the timing to complete our clinical trials for THB001;
- our ability to develop and obtain regulatory approval for THB001 for the treatment of chronic inducible urticaria, as well as in additional indications and any other future product candidates;
- our ability to obtain funding for our operations, including funding necessary to complete further discovery, development and commercialization of THB001 and our future product candidates;
- estimates of the addressable urticaria market and market growth;
- our expectations regarding demand for, and market acceptance of, our product candidates;
- our ability to compete effectively with existing competitors and new market entrants;
- the potential effects of extensive government regulations relating to our industry;
- our ability to obtain, maintain and protect and enforce intellectual property and proprietary rights;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to expand our pipeline of product candidates;
- our ability to attract and retain key management and technical personnel;
- the effects of the ongoing COVID-19 pandemic on any of the above or any other aspect of our business operations;
- general economic, industry and market conditions, including rising interest rates and inflation;

- our expectations regarding expenses, future revenue, capital requirements and our needs for additional financing; and
- our expected use of the net proceeds from this offering and our existing cash and cash equivalents.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in 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. 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, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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

MARKET AND INDUSTRY DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to our industry and the markets in which we operate, including our general expectations and market position, market opportunity, the incidence of certain medical conditions and other industry data. In some cases, we do not
expressly refer to the sources from which these data are derived. These data, to the extent they contain estimates or projections, involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $169.0 million, or approximately $194.9 million if the underwriters exercise their over-allotment option in full, based on the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $80.0 to $90.0 million to advance the continued clinical development of THB001 for the treatment of urticaria, including through completion of a Phase 1b clinical trial for chronic inducible urticaria and initiation of a Phase 2 clinical trial for chronic spontaneous urticaria;
- approximately $30.0 to $40.0 million to advance the continued clinical development of THB001 in additional indications, including through completion of a Phase 1b clinical trial for asthma and to fund further development or acquisition of future programs to advance nonclinical and clinical development; and
- the remainder for potential expansion of our pipeline and other research and development activities, as well as for working capital and other general corporate purposes.

However, because the length of time and activities associated with successful research and development of THB001 or any future product candidates is highly uncertain, and the regulatory approval pathway for any product candidate is inherently difficult to predict and subject to clinical results and ongoing discussions with regulators, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements for THB001, any future product candidates and our ongoing operations, both near and long-term, will depend on many factors. See "Risk Factors—Risks Related to Our Financial Position, Limited Operating History and Need for Additional Capital—Even if we complete this offering, we will need substantial additional funds to pursue our business objectives, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations."

We expect to report initial data from our Phase 1b clinical trial for chronic inducible urticaria in the second half of 2023, and to file both a CTA in Europe and an IND in the United States to support initiation of our Phase 2 clinical trial in chronic spontaneous urticaria in the first half of 2024. We also expect to report initial data from our Phase 1b clinical trial for asthma in the second half of 2024. We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient for us to fund our operations and capital expenses through 2025. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Following this offering, we will need substantial additional capital to complete clinical development of THB001 in any of its initial indications, to seek regulatory approval of THB001 and to commercialize THB001, if approved. We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, additional licensing agreements and/or collaborations, or a combination of one or more of these funding sources.

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current

intentions and will depend on a number of factors, including the success of research and development efforts, the results and timing of any future nonclinical studies and clinical trials, the product approval process with the FDA and other regulatory agencies, any new collaborations or licenses we may enter into, cash generated from future operations, actual expenses to operate our business and the other factors described under "Risk Factors" in this prospectus. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our cash resources sooner than we expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical trials is costly and the timing of progress in these clinical trials is uncertain. In addition, we might decide to postpone or not pursue nonclinical studies or clinical trials or if the net proceeds from this offering and any other sources of cash are less than expected. We may also use a portion of the net proceeds of this offering to in-license, acquire or invest in complementary businesses, products, assets, or technologies, or to obtain the right to use such complementary technologies. We have no commitments with respect to any acquisition or investment.

Pending the uses described above, we intend to invest the net proceeds from this offering in short term, investment-grade interest-bearing securities such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2022:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2022 into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering, and (ii) the filing and effectiveness of our restated certificate of incorporation in connection with the completion of this offering; and
- on a pro forma as adjusted basis giving effect to (i) the pro forma adjustments described above, and (ii) the sale and issuance by us of 10,900,000 shares of our common stock in this offering at the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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

	As of June 30, 2022		
	Actual	Pro Forma	Pro Forma As Adjusted
	(unaudited) (in thousands, except share and per share amounts)		
Cash and cash equivalents	$ 112,731	$ 112,731	$ 281,760
Convertible preferred stock, par value $0.0001 per share; 49,624,190 shares authorized, 49,624,187 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	170,184	—	—
Stockholders' equity (deficit):			
Preferred stock, par value $0.0001 per share; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, par value $0.0001 per share; 72,731,000 shares authorized, 4,416,054 shares issued and outstanding, actual; 500,000,000 shares authorized, 27,793,935 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 38,693,935 shares issued and outstanding, pro forma as adjusted	1	3	4
Additional paid-in capital	3,143	173,325	337,963
Accumulated deficit	(63,701)	(63,701)	(63,701)
Total stockholders' equity (deficit)	(60,557)	109,627	274,266
Total capitalization	$ 109,627	$ 109,627	$ 274,266

If the underwriters' over-allotment option is exercised in full, our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization as of June 30, 2022, would be $307.6 million, $363.8 million, $300.1 million, and $300.1 million, respectively.

The number of shares of our common stock to be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 27,793,935 shares of common stock outstanding as of June 30, 2022

(including (i) 1,410,565 shares of unvested restricted common stock subject to repurchase and (ii) after giving effect to the automatic conversion of all of our shares of convertible preferred stock outstanding as of June 30, 2022 into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering) and excludes:

- 1,803,079 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2022 under our 2019 Plan, with a weighted-average exercise price of $7.50 per share;
- 753,139 shares of our common stock issuable upon the exercise of options to purchase shares of our common shares of our common stock granted after June 30, 2022 under our 2019 Plan, with a weighted-average exercise price of $8.60 per share; and
- 5,079,624 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of:
  - 283,808 shares of our common stock reserved for future issuance under our 2019 Plan as of August 31, 2022,
  - 4,426,737 shares of our common stock to be reserved for future issuance under our 2022 Plan, which became effective immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part, and
  - 369,079 shares of our common stock to be reserved for future issuance under our ESPP, which became effective immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part.

Our 2022 Plan and our ESPP provide for automatic annual increases in the number of shares of our common stock reserved thereunder, and our 2022 Plan provides for increases to the number of shares that may be granted thereunder based on shares under our 2019 Plan that expire, are tendered to or withheld by us for payment of an exercise price or for satisfying tax withholding obligations or are forfeited or otherwise repurchased by us. See the section titled “Executive Compensation—Equity Compensation Plans and Other Benefit Plans” for additional information.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Net tangible book deficit per share is determined by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities and convertible preferred stock by the number of shares of our common stock outstanding. Our historical net tangible book deficit as of June 30, 2022 was $61.6 million, or $13.96 per share, based on 4,416,054 shares of our common stock outstanding as of that date.

Our pro forma net tangible book value as of June 30, 2022 was $108.5 million, or $3.91 per share of our common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets (which excludes deferred offering costs) less our total liabilities and divided by the total number of shares of our common stock outstanding as of June 30, 2022, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering.

Dilution per share to new investors in this offering represents the difference between the initial public offering price per shares of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering. After giving effect to (i) the pro forma adjustments set forth above and (ii) our sale in this offering of 10,900,000 shares of our common stock at the initial public offering price of $17.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2022 would have been approximately $274.3 million, or $7.09 per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $3.18 per share to our existing stockholders and an immediate dilution of $9.91 per share to investors in this offering, as illustrated in the following table:

Initial public offering price per share		$17.00
Historical net tangible book deficit per share as of June 30, 2022	$(13.96)	
Increase attributable to pro forma adjustments	17.87	
Pro forma net tangible book value per share as of June 30, 2022	3.91	
Increase in pro forma net tangible book value per share attributable to new investors in this offering	3.18	
Pro forma as adjusted net tangible book value per share after this offering		7.09
Dilution per share to new investors in this offering		$ 9.91

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value per share after this offering would be $7.44 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $3.53 per share and the dilution to new investors in this offering would be $9.56 per share.

The following table shows, as of June 30, 2022, on a pro forma as adjusted basis described above, the differences between the existing stockholders and the new investors purchasing shares in this offering with respect to the number of shares purchased from us, the total consideration paid, which includes net proceeds received from the issuance of common and convertible preferred stock, cash received from the exercise of stock options, and the value of any stock issued for services and the weighted-average price paid per share (in thousands, except share and per share amounts, and percentages):

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	27,793,935	71.8%	$138,355,422	42.7%	$ 4.98
New investors	10,900,000	28.2	185,300,000	57.3	$ 17.00
Total	38,693,935	100.0%	$323,655,422	100.0%	

In addition, to the extent that any outstanding options are exercised, investors in this offering will experience further dilution.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' over-allotment option. If the underwriters exercise their over-allotment option in full, our existing stockholders would own 68.9% and our new investors would own 31.1% of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of our common stock to be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 27,793,935 shares of common stock outstanding as of June 30, 2022 (including (i) 1,410,565 shares of unvested restricted common stock subject to repurchase and (ii) after giving effect to the automatic conversion of all of our shares of convertible preferred stock outstanding as of June 30, 2022 into an aggregate of 21,967,316 shares of our common stock immediately prior to the completion of this offering), and excludes:

- 1,803,079 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2022 under our 2019 Plan, with a weighted-average exercise price of $7.50 per share;
- 753,139 shares of our common stock issuable upon the exercise of options to purchase shares of our common stock granted after June 30, 2022 under our 2019 Plan, with a weighted-average exercise price of $8.60 per share; and
- 5,079,624 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of:
  - 283,808 shares of our common stock reserved for future issuance under our 2019 Plan as of August 31, 2022,
  - 4,426,737 shares of our common stock to be reserved for future issuance under our 2022 Plan, which became effective immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part, and
  - 369,079 shares of our common stock to be reserved for future issuance under our ESPP, which became effective immediately prior to the date of the effectiveness of the registration statement of which this prospectus forms a part.

Our 2022 Plan and ESPP provide for automatic annual increases in the number of shares of our common stock reserved thereunder, and our 2022 Plan provides for increases to the number of shares that may be granted

thereunder based on shares under our 2019 Plan that expire, are tendered to or withheld by us for payment of an exercise price or for satisfying tax withholding obligations or are forfeited or otherwise repurchased by us. See the section titled "Executive Compensation—Equity Compensation Plans and Other Benefit Plans" for additional information.

To the extent that these outstanding stock options are exercised, new stock options are issued or we issue additional shares of our common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that 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.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of the next wave of medicine for the treatment of allergic and inflammatory diseases. Our lead product candidate, THB001, is a highly selective, oral small molecule inhibitor of KIT, a cell surface receptor that acts as the master survival and functional regulator of mast cells. Mast cells are a part of the immune system, and dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders including urticaria, asthma and gastrointestinal disorders, among others. KIT inhibition has shown positive clinical responses in mast cell mediated diseases such as asthma and chronic urticaria. In our recently completed Phase 1a clinical trial, THB001 demonstrated dose-dependent reductions of serum tryptase, a key biomarker of mast cell activity which has been shown to correlate with clinical benefit in chronic urticaria patients. We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024. We intend to submit both a CTA in Europe and an IND in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024. We are also exploring development opportunities across a range of other indications where THB001 may provide benefit to patients suffering from mast cell driven inflammation to demonstrate the "pipeline-in-a-product" potential of THB001.

Since our inception in 2019, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, acquiring or discovering product candidates, research and development activities for THB001 and other compounds, establishing arrangements with third parties for the manufacture of our product candidates and component materials, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from sales of shares of our preferred stock. From inception, we have raised aggregate gross proceeds of approximately $155.0 million through the sale and issuance of our preferred stock. Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses, and general overhead costs.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of THB001 and any future product candidates. Our net losses were $12.8 million and $29.6 million for the years ended December 31, 2020 and 2021, respectively, and $6.4 million and $15.5 million for the six months ended June 30, 2021 and 2022, respectively. As of June 30, 2022, we had an accumulated deficit of $63.7 million. We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will increase substantially in connection with our ongoing activities, particularly if, and as, we:

- advance THB001 through clinical development for chronic inducible urticaria, chronic spontaneous urticaria and asthma;

- conduct additional nonclinical studies and clinical trials for THB001 in additional potential indications;
- discover and develop new product candidates;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- manufacture, or have manufactured, nonclinical, clinical and potentially commercial supplies of THB001 and any future product candidates;
- seek regulatory approvals for THB001 or any future product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize THB001 or any future product candidates, if approved;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses;
- hire additional clinical, scientific and management personnel, as well as administrative staff to support the growth of our business;
- add operational, financial and management information systems and personnel;
- incur additional legal, accounting and other costs associated with operating as a public company following the completion of this offering;
- experience delays related to the COVID-19 pandemic in the United States and in other countries in which we have planned or have active clinical trial sites and where our third-party CDMOs operate; and
- establish licenses, collaborations or strategic partnerships.

Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures related to our research and development activities.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate. 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.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or additional licensing arrangements. We may be unable to raise additional funds or enter into such arrangements when needed, on favorable terms, or at all. 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. The amount and timing of our future funding requirements will depend on many factors including the successful advancement of THB001 or any future product candidates. Our ability to raise additional funds may also be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as those resulting from the ongoing COVID-19 pandemic, the hostilities in Ukraine, and increasing interest rates and rates of inflation.

Because of the numerous risks and uncertainties associated with development of treatment of allergic 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. 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.

We oversee and manage third party Contract Development and Manufacturing Organizations, or CDMOs, to support development and manufacture of THB001 for our clinical trials. We currently use two geographically-distributed CDMOs to supply our GMP drug substance. The manufacturing process has readily-sourced available raw materials and straightforward scalability. We use three geographically-distributed CDMOs for drug product manufacturing. The THB001 drug product is a cost-effective and readily scaled solid oral dosage form in standard gelatin capsules. We expect to enter into commercial supply agreements with commercial manufacturers prior to any potential regulatory approval of THB001. We continue to develop a commercial route for THB001 manufacture in alignment with our program timeline. We believe our current manufacturers are able to supply the upcoming clinical trials and additional CDMOs may be on-boarded at later stages of clinical and commercial development.

As of June 30, 2022, we had $112.7 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenses through 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See the subsection titled "—Liquidity and Capital Resources."

License Agreement with Novartis International Pharmaceutical Ltd.

On June 28, 2019, we entered into a license agreement with Novartis International Pharmaceutical Ltd. (which subsequently merged into the company Novartis Pharma AG), or Novartis, as amended, or the Novartis Agreement. Pursuant to the Novartis Agreement, Novartis granted us an exclusive, worldwide, sublicensable (subject to certain requirements therein) license under specified patent rights and know-how related to three licensed compounds to develop, make, use and sell certain products incorporating or comprising a licensed compound, including THB001, or the Licensed Products. Under the Novartis Agreement, we are solely responsible for all research, development, regulatory and commercialization activities related to the Licensed Products. We are required to use commercially reasonable efforts to develop and seek regulatory approval for, and commercialize, at least one Licensed Product in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Pursuant to the Novartis Agreement, we made a one-time payment of $0.4 million to Novartis and agreed to issue shares of preferred stock pursuant to that certain Investment Letter dated as of June 27, 2019, or the Novartis Investment Letter. Pursuant to the Novartis Investment Letter, we have issued Novartis 5,970,000 shares of Series A-1 Preferred Stock. Further, we are obligated to pay Novartis up to an aggregate of: (i) $31.7 million upon the achievement of certain specified development milestones for the Licensed Products and (ii) $200.0 million upon the achievement of certain specified sales and commercialization milestones with respect to the Licensed Products. We are also required to pay Novartis, on a Licensed Product-by-Licensed Product and country-by-country basis, tiered royalties in the single-digit percentage range on annual net sales of Licensed Products, subject to reduction and offset upon certain specified events. The foregoing royalty payment obligations will expire on the latest to occur of: (a) expiration of the last valid claim of the licensed patent rights that covers such Licensed Product in such country; (b) the expiration of any regulatory exclusivity for such Licensed Product in such country; and (c) ten years following the first commercial sale of such Licensed Product in such country. Upon the expiration of such royalty term in a particular country for a particular Licensed Product, the license granted to us with respect to such Licensed Product in such country will become fully paid-up, royalty-free, transferable, perpetual and irrevocable.

For a more detailed description of this agreement, see the section titled "Business—Licenses, Partnerships and Collaborations" and Note 5 to our consolidated financial statements and our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus.

Impact of COVID-19 on Our Business

The COVID-19 pandemic continues to evolve, and we will continue to monitor any developments. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our CDMOs, contract research organizations, or CROs, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, though it is possible we may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. Measures we have taken in response to the COVID-19 pandemic include, where feasible, conducting remote clinical trial site activations and data monitoring. However, despite these efforts, we have experienced delays in trial site initiations, patient participation and patient enrollment in our clinical trial and we may continue to experience some delays in our clinical trials and nonclinical studies and delays in data collection and analysis. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and is subject to change. For additional details regarding the COVID-19 pandemic's impact and potential impact on our business, operations and prospects, see the section titled "Risk Factors—Risks Related to Discovery, Development and Commercialization—The COVID-19 pandemic could adversely impact our business, including the conduct of our clinical trials."

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products or from other sources in the near future, if at all. If our development efforts for our current product candidate, THB001, or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of costs incurred in connection with the discovery, nonclinical development, clinical development and manufacturing of THB001 and potential future product candidates, and include:

Direct Costs:

- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our clinical trials; CDMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Indirect Costs:

- personnel-related expenses including, salaries, benefits, stock-based compensation and other related costs for individuals involved in research and development activities; and
- facilities and other expenses not directly tied to a program.

We expense research and development costs as incurred. We recognize direct development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors or our estimate of the level of service that has been performed at each reporting date. Payments for these development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued expenses.

A significant portion of our research and development costs to date have been third-party costs, which we track on an individual product candidate basis after a clinical product candidate has been identified. Currently, our sole clinical product candidate is THB001. Our indirect research and development costs are primarily personnel-related costs and facilities and other costs. Employees and infrastructure are not directly tied to any one program and are deployed across our programs. As such, we do not track these costs on a specific program basis. We utilize third party contractors for our research and development activities and CDMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we advance THB001 into multiple Phase 1b clinical trials, continue to discover and develop additional product candidates, expand our headcount and maintain, expand and enforce our intellectual property portfolio. If THB001 or any future product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. There are numerous factors associated with the successful development and commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

Our research and development expenses may vary significantly in the future based on factors, such as:

- the number and scope of nonclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;

- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional collaboration or license agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

Any changes in the outcome of any of these variables with respect to the development of THB001 or any future product candidates in nonclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA, EMA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any clinical trials following the applicable regulatory authority's acceptance and clearance, we could be required to expend significant additional financial resources and time to complete clinical development than we currently expect. We may never obtain regulatory approval for any product candidates that we develop.

The successful development of THB001, or any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of THB001 and any other product candidates we may develop. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of THB001 or any future product candidate, if approved. This is due to the numerous risks and uncertainties associated with product development.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, benefits and stock-based compensation expenses for personnel in executive and other administrative functions. Other significant general and administrative expenses include legal fees relating to patent, intellectual property and corporate matters, and fees paid for accounting, consulting and other professional services, and expenses for rent, insurance and other operating costs.

We expect that our general and administrative expenses will continue to increase in the foreseeable future as our business expands to support our continued research and development activities, including any future clinical trials. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums and investor relations costs. In addition, if we obtain regulatory approval for our current product candidate or any product candidates we may develop in the future and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Total Other (Income) Expense, Net

Change in Fair Value of Anti-Dilution Right Liability

We classified the anti-dilution right liability under the Novartis Agreement, as a liability on our consolidated balance sheets as the anti-dilution right liability represented a freestanding financial instrument that required us to transfer equity instruments upon future equity closings. The anti-dilution right liability was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. The issuance date fair value of the derivative liability was recognized as a research and development expense upon entering into the agreement with Novartis. Changes in the fair value of the anti-dilution right liability were recognized as a component of other expense in our consolidated statements of operations. Changes in the fair value of the anti-dilution right liability were recognized until the anti-dilution rights liability was satisfied in the first quarter of 2021.

In February 2021, in connection with our issuance and sale of the second tranche of Series A-2 Preferred Stock, we satisfied our anti-dilution right liability under the Novartis Agreement by issuing 5,970,000 total shares of Series A-1 Preferred Stock to Novartis for a total value of $6.0 million. We remeasured the fair value of the anti-dilution right liability on the date of settlement, and recorded a charge of $0.7 million, in other (income) expense, net.

Change in Fair Value of Preferred Stock Tranche Liability

In connection with the issuance of our Series A Preferred Stock, we granted investors future tranche rights to purchase the Preferred Stock. We classified the preferred stock tranche liability for the future purchase and option to purchase Series A Preferred Stock as a liability on our consolidated balance sheets as the preferred stock tranche liability is a freestanding financial instrument that will require us to transfer equity instruments upon future closings of the Series A Preferred Stock. The preferred stock tranche liability was initially recorded at fair value upon the date of issuance and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock tranche liability are recognized as a component in other (income) expense, net in the consolidated statements of operations. Changes in the fair value of the preferred stock tranche liability were recognized until the tranche liability were fulfilled or otherwise extinguished in the fourth quarter of 2021.

In November 2021, in connection with our issuance and sale of Series A-3 Tranche 2, we satisfied our liability to issue additional shares under the second tranche closing and accordingly reclassified the carrying value of the preferred stock tranche liability associated with the future purchase obligation, equal to the then current value of $16.3 million, to the carrying value of the Series A-3 Preferred Stock.

Other Income

Other income primarily consists of interest income generated from interest bearing money market accounts.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each period or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2021, we had U.S. federal and state net operating loss carryforwards of $29.8 million and $26.7 million, respectively, which may be available to offset future income tax liabilities and expire at various dates beginning in 2039. As of the six months ended June 30, 2021 and 2022, and the years ended December 31, 2020 and 2021, we have recorded a full valuation allowance against our deferred tax assets.

Results of Operations

Comparison of the Six Months Ended June 30, 2021 and 2022

The following table summarizes our results of operations for each of the periods presented (in thousands, except percentages):

	Six Months Ended June 30,		$ Change	% Change
	2021	2022		
	(unaudited)			
Operating expenses:				
Research and development	$ 6,546	$ 10,393	$ 3,847	59%
General and administrative	1,010	5,177	4,167	413
Total operating expenses	7,556	15,570	8,014	106
Loss from operations	7,556	15,570	8,014	106
Other (income) expense, net:				
Change in fair value of anti-dilution right liability	682	—	(682)	(100)
Change in fair value of preferred stock tranche liability	(1,790)	—	1,790	(100)
Other income	(2)	(110)	(108)	5,400
Total other (income) expense, net	(1,110)	(110)	1,000	(90)
Net loss	$ 6,446	$ 15,460	$ 9,014	140%

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands, except percentages):

	Six Months Ended June 30,		$ Change	% Change
	2021	2022		
	(unaudited)			
Direct costs:				
THB001	$ 4,629	$ 6,169	$ 1,540	33%
Other discovery and development	1,074	1,975	901	84
Indirect costs:				
Personnel-related	843	2,248	1,405	167
Facilities and other	—	1	1	—
Total research and development expenses	$ 6,546	$ 10,393	$ 3,847	59%

Research and development expenses increased by $3.8 million from $6.5 million for the six months ended June 30, 2021 to $10.4 million for the six months ended June 30, 2022. This increase was primarily attributable to the following:

- a $1.5 million increase in costs related to the clinical development of THB001 as part of the Phase 1a clinical trial phase;
- a $0.9 million increase in other discovery and development costs, primarily relating to the research and nonclinical development of discovery compounds and other programs; and
- a $1.4 million increase in personnel-related costs, including $0.3 million in stock-based compensation expense, primarily due to an increase in headcount in 2022 to support the advancement of our development efforts.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands, except percentages):

	Six Months Ended June 30,			
	2021	2022	$ Change	% Change
	(unaudited)			
Personnel-related expenses	$ 681	$ 2,851	$ 2,170	319%
Professional fees	233	1,772	1.539	660
Other expenses	96	554	458	476
Total general and administrative expenses	$ 1,010	$ 5,177	$ 4,167	412%

General and administrative expenses increased by $4.2 million from $1.0 million for the six months ended June 30, 2021 to $5.2 million for the six months ended June 30, 2022. This increase was primarily attributable to the following:

- a $2.2 million increase in personnel-related costs, including $1.2 million in stock-based compensation expense, primarily due to an increase in headcount in 2022 to support the advancement of our development efforts;
- a $1.5 million increase in professional fees, driven by a $1.0 million increase to accounting and audit fees related to the preparation of this offering, $0.3 million increase in legal fees related to intellectual property-related matters, and $0.2 million increase in website and graphic fees; and
- a $0.5 million increase in other expenses primarily driven by an increased investment in professional development and education and computer and software-related expenses in preparation of this offering and operating as a public company.

We anticipate that our general and administrative expenses will increase in the future as we incur increased accounting, audit, legal, tax, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with maintaining compliance with Nasdaq-exchange listing and SEC requirements.

Total Other (Income) Expense, Net

Total other (income) expense, net decreased by approximately $1.0 million from $1.1 million of income for the six months ended June 30, 2021 to $0.1 million of income for the six months ended June 30, 2022. This decrease was primarily attributable to $1.8 million in other income due to the remeasurement of the fair value of the preferred stock tranche liability that was recognized in the six months ended June 30, 2021.

Comparison of the Years Ended December 31, 2020 and 2021

The following table summarizes our results of operations for each of the periods presented (in thousands, except percentages):

	Year Ended December 31, 2020	2021	$ Change	% Change
Operating expenses:				
Research and development	$ 9,953	$ 15,748	$ 5,795	58%
General and administrative	1,166	3,256	2,090	179
Total operating expenses	11,119	19,004	7,885	71
Loss from operations	11,119	19,004	7,885	71
Other (income) expense, net:				
Change in fair value of anti-dilution right liability	607	682	75	12
Change in fair value of preferred stock tranche liability	1,081	9,928	8,847	818
Other income	—	(5)	(5)	100
Total other (income) expense, net	1,688	10,605	8,917	528
Net loss	$ 12,807	$ 29,609	$ 16,802	131%

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands, except percentages):

	Year Ended December 31, 2020	2021	$ Change	% Change
Direct costs:				
THB001	$ 7,212	$ 11,062	$ 3,850	53%
Other discovery and development	979	2,105	1,127	115
Indirect costs:				
Personnel-related	1,763	2,569	806	46
Facilities and other	—	12	12	—
Total research and development expenses	$ 9,953	$ 15,748	$ 5,795	58%

Research and development expenses increased by $5.8 million from $9.9 million for the year ended December 31, 2020 to $15.8 million for the year ended December 31, 2021. This increase was primarily attributable to the following:

- a $3.9 million increase in costs related to the nonclinical development of THB001 as it progressed into the Phase 1a clinical trial phase;
- a $1.1 million increase in other discovery and development costs, primarily relating to the research and nonclinical development of discovery compounds and other programs; and
- a $0.8 million increase in personnel-related expenses, relating to the increase in headcount in 2021 to support the advancement of our development efforts.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands, except percentages):

	Year Ended December 31,			
	2020	2021	$ Change	% Change
Personnel-related expenses	$ 468	$ 2,045	$ 1,577	337%
Professional fees	582	893	311	53
Other expenses	117	318	202	173
Total general and administrative expenses	$ 1,166	$ 3,256	$ 2,090	179%

General and administrative expenses increased by $2.1 million from $1.2 million for the year ended December 31, 2020 to $3.3 million for the year ended December 31, 2021. This increase was primarily attributable to the following:

- a $1.6 million increase in costs related to personnel-related expenses;
- a $0.3 million increase in professional fees related to legal, accounting and IT consulting costs; and
- a $0.2 million increase in other expenses primarily driven by rent and business insurance costs.

Total Other (Income) Expense, Net

Total other (income) expense, net increased by approximately $8.9 million from $1.7 million of expense for the year ended December 31, 2020 to $10.6 million of expense for the year ended December 31, 2021. This increase is primarily attributable to a $8.8 million increase in the expense due to the remeasurement of the fair value of the preferred stock tranche liability.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates or from other sources for several years, if at all. As of June 30, 2022, we had $112.7 million in cash and cash equivalents, and we had an accumulated deficit of $63.7 million. We have funded our operations primarily with gross proceeds of $155.0 million from sales of our preferred stock.

Cash Flows

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

	Year Ended December 31,		Six Months Ended June 30,	
	2020	2021	2021	2022
			(unaudited)	
Net cash used in operating activities	$ (9,187)	$ (15,746)	$ (7,251)	$ (14,852)
Net cash used in investing activities	—	—	—	—
Net cash provided by (used in) financing activities	10,825	135,749	15,921	(697)
Net increase (decrease) in cash and cash equivalents	$ 1,638	$ 120,003	$ 8,670	$ (15,549)

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $9.2 million, and was primarily due to our net loss of $12.8 million, which included a non-cash charge of $1.7 million related to the changes in fair value of the preferred stock tranche liability and anti-dilution right liability, and changes of working capital consisting of a $1.9 million increase in accrued expenses and other current liabilities and accounts payable.

Net cash used in operating activities for the year ended December 31, 2021 was $15.7 million, and was primarily due to our net loss of $29.6 million, which included a non-cash charge of $10.6 million related to the changes in fair value of the preferred stock tranche liability and anti-dilution right liability, and changes of working capital consisting of a $3.5 million increase in accrued expenses and other liabilities, and $0.5 million in stock-based compensation expense, partially offset by $0.7 million decrease in prepaid expenses and other current assets.

Net cash used in operating activities for the six months ended June 30, 2021 was $7.3 million, and was primarily due to our net loss of $6.4 million, which included a non-cash gain of $1.8 million related to the change in fair value of the preferred stock tranche liability and a non-cash charge of $0.7 million related to the change in fair value of the anti-dilution right liability, and changes of working capital consisting of a $0.4 million increase in accrued expenses and other current liabilities and accounts payable.

Net cash used in operating activities for the six months ended June 30, 2022 was $14.8 million, and was primarily due to our net loss of $15.5 million, and changes in working capital consisting of an increase of $0.3 million in prepaid expenses, a $1.6 million stock-based compensation expense, and an increase of $0.4 million in accounts payable, partially offset by a $1.6 million decrease in accrued expenses and other current liabilities.

Net Cash Provided by (Used in) Investing Activities

We had no investing activities for the years ended December 31, 2020 and 2021 and the six months ended June 30, 2021 and 2022.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was $10.8 million, resulting entirely from proceeds received from the issuance and sale of shares of our Series A Preferred Stock, net of issuance costs.

Net cash provided by financing activities for the year ended December 31, 2021 was $135.7 million, resulting from proceeds of $30.9 million received from the issuance and sale of shares of our Series A Preferred Stock, net of issuance costs, and $104.8 million received from the issuance and sale of shares of our Series B Preferred Stock, net of issuance costs.

Net cash provided by financing activities for the six months ended June 30, 2021 was $15.9 million, resulting entirely from proceeds received from the issuance and sale of shares of our Series A Preferred Stock, net of issuance costs.

Net cash used in financing activities for the six months ended June 30, 2022 was $0.7 million, resulting from costs incurred in preparation of this offering.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase significantly in connection with our ongoing activities.

Based on our current operating plan, we believe that our existing cash and cash equivalents, without taking into consideration the net proceeds from this offering, will be sufficient to fund our operations and capital expenses through at least the next 12 months from the date of this prospectus. In addition, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenses through 2025. However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties 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 will depend on, and could increase significantly as a result of, many factors, including:

- the timing, cost and progress of nonclinical and clinical development activities;
- the cost of regulatory submissions and timing of regulatory approvals;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we are obligated to make under our Novartis Agreement or any future license agreements;
- the cash requirements of any future acquisitions or discovery of product candidates;
- 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;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of commercialization activities if THB001 or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to satisfy our obligations as a public company.

A change in the outcome of any of these or other variables with respect to the development of our THB001 or any product or development candidate we may develop in the future could significantly change the costs and timing associated with our development plans. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or licensing arrangements. We currently have no credit facility or committed sources of capital. Adequate additional funds may not be available to us on acceptable terms, or at all. To the

extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or 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 when needed, we may be required to delay, limit, reduce or terminate our 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. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. Because of the numerous risks and uncertainties associated with product development, there is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Other Commitments

Novartis Agreement

We may incur contingent royalty payments that we are required to make under the Novartis Agreement. Due to the uncertainty of the achievement and timing of the events requiring payment under our license agreement with Novartis, the amounts to be paid by us are not fixed or determinable at this time. We are required to pay Novartis royalties on all sales of licensed products, with such royalty percentages in the mid-single digits of sales. We have not paid any royalties to date as we have no products commercially approved for sale. For additional information regarding the license agreement and royalties payable to Novartis, see the subsection titled "—License Agreement with Novartis International Pharmaceutical Ltd.," the section titled "Business—Licenses, Partnerships and Collaborations" and Note 5 to our audited consolidated financial statements and our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus.

Lease Obligations

Our leases are comprised of month-to-month office space leases entered into with Atlas for various office suites located at 300 Technology Square in Cambridge, Massachusetts, with us acting as a subtenant.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, CDMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service provided up to one year after the date of cancellation.

Critical Accounting Policies

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

assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates.

While our accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this prospectus, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Accrued and Prepaid Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued and prepaid third-party research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued and prepaid expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued and prepaid research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Preferred Stock Tranche Liability

The fair value of the preferred stock tranche liability recognized in connection with our Series A-1 Preferred Stock financing in July 2019, Series A-2 Preferred Stock financing in July 2020, and Series A-3 Preferred Stock financing in February 2021, was determined based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The fair value of the preferred stock tranche liabilities were estimated based on results of a third party valuation performed in connection with each redeemable convertible preferred stock issuance.

A change in the assumptions related to the valuation of the tranche liability could have a significant impact on the value of the liability. The tranche liability was valued as a forward contract. The value was determined using an option pricing model, in which fair value was determined using the Black-Scholes option pricing model. In determining the fair value of the tranche liability, estimates and assumptions impacting the fair value included

the estimated future values of the Company's Preferred Stock, discount rates, estimated time to tranche closing, and probability of each tranche closing. We remeasured the preferred stock tranche liabilities at each reporting period and prior to settlement.

Anti-Dilution Right Liability

The initial fair value of the anti-dilution right liability issued to Novartis in June 2019 was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value was estimated using a Monte Carlo analysis to simulate the fair value of the preferred stock to be issued to maintain the fully diluted ownership percentages based on the expected financing dates. Changes in the estimated fair value and the probability of achieving different financing scenarios can have a significant impact on the fair value of the anti-dilution right liability. We remeasured the anti-dilution right at each reporting period and prior to settlement.

Stock-Based Compensation

We measure stock-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value, based on the date of the grant, and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Our stock-based payments include stock options and grants of restricted stock awards. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the straight-line method. For awards with both performance and service-based vesting conditions, we record expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using our best estimates.

At inception of the 2019 Stock Incentive Plan, we adopted the guidance of Accounting Standards Update, or ASU, No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU No. 2018-07, prior to the issuance of any stock option grants. The measurement date for non-employee awards is the date of grant without changes in the fair value of the award. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis.

We classify stock-based compensation expense in our statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

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

- *Fair Value of Common Stock*—See the subsection titled "—Common Stock Valuations" below.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the options.
- *Expected Volatility*—Because we have been privately held and do not have any trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *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 awards.

- *Expected Dividend Yield*—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.

The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of our common stock on that same date. See Note 8 to our consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2020 and 2021.

We recorded stock-based compensation expense of $0.1 million and $1.6 million for the six months ended June 30, 2021 and 2022, respectively. As of June 30, 2022, there was $9.1 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 0.38 years. In future periods, we expect our stock-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain our employees.

Based on the initial public offering price of $17.00 per share, the aggregate intrinsic value of vested and unvested stock options outstanding as of June 30, 2022 was $2.3 million and $16.5 million, respectively.

Common Stock Valuations

Historically, for all periods prior to this offering, as there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors, with input from management, as of the date of each award grant, considering our most recently available independent third-party valuations of common stock and any additional objective and subjective factors that we believed were relevant and which may have changed from the date of the most recent valuation through the date of each award grant. The independent third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. We determined that based on our stage of development and other relevant factors, it was most appropriate to prepare our common stock valuations using the option-pricing method, or OPM, which used a market approach to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. In the course of preparing for this offering, we performed retrospective fair value assessments of all options granted during the years ended December 31, 2021 and 2022 and the six months ended June 30, 2022 solely for accounting purposes. We applied the fair values of our common stock from our retrospective fair value assessments to determine the fair value of these awards and calculate stock-based compensation expense solely for accounting purposes. These reassessed values were based, in part, upon third-party valuations of our common stock prepared as of each grant date on a retrospective basis. The third-party valuations were prepared using the hybrid method and used market approaches to determine our enterprise value. The hybrid method also uses a market approach to estimate our enterprise value. It is a probability-weighted expected return method, or PWERM, where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of our common stock based upon an analysis of our future values, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

The assumptions underlying these valuations were highly complex and subjective and 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 be materially different.

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

- contemporaneous valuations performed by an independent third-party valuation firm;
- our stage of development and material risks related to our business;
- the progress of our research and development programs, including the status and results of nonclinical studies and clinical trials;
- our business conditions and projections;
- sales of our preferred stock;
- the rights, preferences and privileges of our preferred stock relative to those of our common stock;
- lack of marketability of our common and preferred stock as a private company;
- our operating results and financial performance;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, in light of prevailing market conditions;
- the trends, developments and conditions in the life sciences and biopharmaceutical industry sectors;
- analysis of initial public offerings and the market performance and stock price volatility of similar public companies in the life sciences and biopharmaceutical sectors; and
- the economy in general.

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.

Internal Controls Over Financial Reporting

A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

In preparing our financial statements as of and for the year ended December 31, 2021, management identified a material weakness in our internal control over financial reporting. The material weakness we identified related to the lack of segregation of duties, certain system limitations in our accounting software and the overall control environment as we had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process.

We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel and engaging financial consultants to enable the implementation of internal control over financial reporting and segregating duties amongst accounting and finance personnel. In addition, we are in the process of selecting and implementing an accounting software system with the design and functionality to segregate incompatible accounting duties, which we currently expect will be fully implemented in our 2023 fiscal year.

While we are implementing these measures, we cannot assure you that these efforts will remediate our material weakness and significant deficiencies in a timely manner, or at all, or prevent restatements of our financial statements in the future. In particular, we do not currently expect that our material weakness related to our accounting software will be fully remediated for the fiscal year ended December 31, 2022 as we expect to implement new software in 2023. If we are unable to successfully remediate our material weakness, or identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our common stock may decline as a result.

Emerging Growth Company and Smaller Reporting Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable we have early adopted certain standards as described in Note 2 of our consolidated financial statements included elsewhere in this prospectus. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will continue to remain an "emerging growth company" until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.07 billion; (iii) the date on which we have issued more than $1 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 are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed 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.

Recent Accounting Pronouncements

We have reviewed all recently issued accounting pronouncements and have determined that, other than as disclosed in Note 2 to our condensed consolidated financial statements included elsewhere in this prospectus, such standards do not have a material impact on our financial statements or do not otherwise apply to our operations.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in the form of standard checking accounts and amounts held in money market funds that are invested in U.S. Treasury securities. Interest income is sensitive to changes in the general level of interest rates. However, due to the short-term maturities of our cash equivalents, we believe a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements included elsewhere in this prospectus.

As of June 30, 2022, we had no debt outstanding and therefore were not exposed to related interest rate risk.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in local currency. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 100 basis point increase or decrease in exchange rates during any of the periods presented would not have a material effect on our consolidated financial statements included elsewhere in this prospectus.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the development of the next wave of medicine for the treatment of allergic and inflammatory diseases. Our lead product candidate, THB001, is a highly selective, oral small molecule inhibitor of KIT, a cell surface receptor that acts as the master survival and functional regulator of mast cells. Mast cells are a part of the immune system, and dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders including urticaria, asthma and gastrointestinal disorders, among others. KIT inhibition has shown positive clinical responses in mast cell mediated diseases such as asthma and chronic urticaria. In our recently completed Phase 1a clinical trial, THB001 demonstrated dose-dependent reductions of serum tryptase, a key biomarker of mast cell activity which has been shown to correlate with clinical benefit in chronic urticaria patients. We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024. We intend to submit both a CTA in Europe and an IND in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024. We are also exploring development opportunities across a range of other indications where THB001 may provide benefit to patients suffering from mast cell driven inflammation to demonstrate the "pipeline-in-a-product" potential of THB001. There is no guarantee that any CTA that we submit will be approved, and even if a CTA were to be approved, there is no guarantee that our trials will begin within our anticipated timeframe.

Mast cells are a main driver of allergic inflammatory responses. They are present throughout the body in connective and vascularized tissues, most prominently along surface boundaries with exposure to the external environment: in the skin, the respiratory tract and the gastrointestinal tract. For many patients suffering from allergic conditions, inhibition of mast cell derived mediators, including histamines, leukotrienes and prostaglandins, has demonstrated insufficient therapeutic value to date given that many mast cell-driven disorders involve multiple pro-inflammatory mediators. As a result, we believe that targeting mast cells directly through highly selective inhibition of KIT is key to achieving the clinical efficacy needed for broad symptomatic relief across a range of allergic and other inflammatory disorders.

Since KIT is a cell surface receptor that acts as the master regulator of mast cell function and survival, our approach impacts mast cells directly and provides what we believe to be a favorable point of intervention. Furthermore, significant clinical and nonclinical data has been generated internally and by third parties that demonstrate that KIT is a potential target for broad and potentially clinically differentiated inhibition of mast cells. For example, an anti-KIT antibody demonstrated positive clinical responses in chronic inducible urticaria patients in a third-party Phase 1 trial.

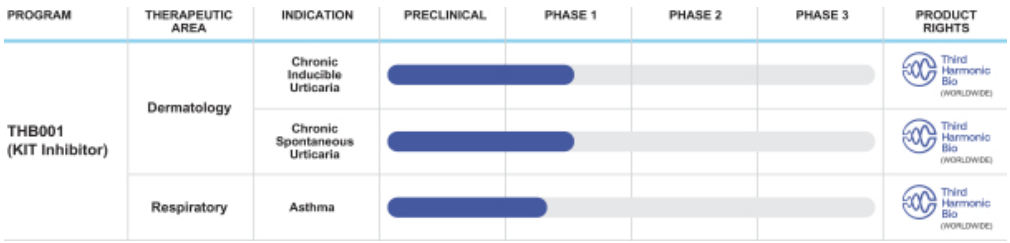
Our lead product candidate THB001 is a potent and highly selective, oral small molecule wild-type KIT inhibitor in development for the treatment of mast cell mediated inflammatory diseases. In nonclinical studies, THB001 demonstrated what we believe to be evidence of highly selective KIT inhibition and mast cell depletion in skin, respiratory and gastrointestinal tissues with a potent therapeutic profile. We believe that chronic inducible urticaria represents an attractive initial clinical indication for THB001 as a precursor for chronic spontaneous urticaria, given the ability to efficiently evaluate clinical activity outcomes through provocation testing, in concert with biomarker measures of mast cell activity and safety data. Our goal is to be a leader in the oral KIT inhibitor space, and we continue to invest in formulation and discovery for next generation molecules. In addition to initially developing THB001 for treatment of chronic urticaria, we are exploring THB001 as a potential treatment for other indications where mast cell dysfunction plays a key role.

In our recently completed Phase 1a trial in healthy volunteers, we have observed dose dependent increases in THB001 serum concentration levels above the protein binding adjusted KIT cellular IC_{50} value. As positive signs of the potential efficacy of THB001, we observed that dose levels of 200 mg once daily, or QD, 200 mg

twice daily, or BID, and 400 mg BID resulted in dose dependent declines in serum tryptase. The twice daily dose at the 400 mg level of THB001 resulted in mean serum tryptase that was at the lower limit of quantification. Reductions in serum tryptase have been associated with a robust clinical response in a clinical trial of an anti-KIT antibody in chronic inducible urticaria patients conducted by a third party. Furthermore, THB001 was well-tolerated, with no serious adverse events, or SAEs, one moderate adverse event that led to discontinuation and one mild adverse event that led to discontinuation, but was deemed not related to the drug, in the trial to date.

We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, which has been cleared in the Netherlands and Germany. We initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024. We intend to submit both a CTA in Europe and an IND in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024.

There remains a large unmet need in chronic urticaria. Epidemiological studies indicate that up to 25% of the population suffers from urticaria at some point in their lifetime, with 0.5-1% of the population suffering from the disease at any point in time, suggesting a point prevalence of over 1.5 million patients in the United States. Approximately 70% to 80% of patients with urticaria are women. Many patients are first provided H1 antihistamine therapy when diagnosed with urticaria; however, there remains a large unmet need. Approximately 50% of chronic spontaneous urticaria patients continue to experience itch and hives despite H1 antihistamine treatment at FDA-approved doses. There have been no new approved therapies to treat chronic urticaria in eight years, and the most recently approved treatment, the injectable biologic Xolair, provided complete hive and itch symptom relief to approximately 36% of patients in clinical trials. We believe Xolair is currently addressing less than 20% of eligible patients whose symptoms have failed to be controlled by H1 antihistamine therapy. There is a clear unmet need for chronic urticaria treatments that provide higher levels of complete hive and itch symptom relief, while also providing improved patient comfort and convenience via an oral route of administration. We believe an oral therapy offers clear advantages over an injectable therapy, and an oral therapy with the potential to improve upon the results of the existing standard of care offers a significant opportunity to address a large unmet need. While the potential market opportunity within urticaria alone is vast, dysfunctional mast cell activity has also been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders, including respiratory and gastrointestinal disorders. Furthermore, in nonclinical studies, THB001 has demonstrated the ability to deplete mast cells across different tissue types, which we believe supports its ability to potentially treat a range of mast cell mediated skin, respiratory and gastrointestinal conditions supporting our ultimate goal of THB001 achieving its potential as a "pipeline-in-a-product." The table below reflects our initial targeted indications for THB001.



Our Team and Investors

Founded by Atlas Venture in 2019, we are led by a strong management team with diverse backgrounds and significant experience in drug discovery, development and company building, as well as a demonstrated track record of delivering breakthrough therapeutic approaches for patients. Our management team are industry veterans with extensive experience at biopharmaceutical companies such as Audentes, Cadent Therapeutics,

Genentech/Roche, Gilead Sciences, Morphic Therapeutic and Pfizer. Together, our team has a proven track record in the discovery, development and commercialization of numerous approved therapeutics.

Since our inception, we are supported by and have raised approximately $155 million of capital from a group of premier life science investors including Atlas Venture, OrbiMed, BVF Partners L.P., General Atlantic, RA Capital, RTW Investments, Boxer Capital, Deep Track Capital, Commodore Capital and Ajax Health|Zeus.

Our Strategy

Our goal is to develop the next wave of medicine for the treatment of allergic and inflammatory diseases. The key components of our strategy are to:

- **Continue to advance THB001 through clinical development in chronic urticaria.** Chronic urticaria represents a significant unmet need as there is a large patient population who remain poorly controlled or elect not to take the standard of care injectable biologic therapy prescribed for antihistamine refractory patients. We believe that a highly selective, convenient, oral small molecule KIT inhibitor that targets mast cells directly provides a potentially new compelling treatment option. We believe THB001's potency, selectivity, tolerability profile and oral bioavailability offers a promising therapeutic profile for the substantial chronic urticaria market. We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023.

- **Continue to advance THB001 into our second indication in asthma.** Given the prior clinical validation of small molecule KIT inhibition for the treatment of asthma, we believe asthma is a potential second indication for THB001. In clinical results by a third party published in *The New England Journal of Medicine*, imatinib, a multi-tyrosine kinase inhibitor that has demonstrated KIT inhibitory activity, achieved a 43% reduction in plasma levels of serum tryptase, a biomarker used to assess mast cell activation, for patients with severe refractory asthma, which resulted in a statistically significant decrease in airway hyperresponsiveness at 24 weeks. We believe these results provide compelling clinical proof-of-concept that mast cell reduction may drive meaningful symptomatic relief. In addition, in nonclinical studies, THB001 produced statistically significant airway improvements in a rat model of allergic asthma. We intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024.

- **Develop THB001 in a broad range of indications across therapeutic areas where mast cell driven inflammation can benefit from THB001's product profile, including in the skin, respiratory and gastrointestinal tracts.** We believe that KIT inhibition may find wide therapeutic utility across a range of inflammatory indications as mast cells are present in numerous tissue types. There are multiple skin, respiratory and gastrointestinal conditions such as atopic dermatitis, prurigo nodularis, chronic rhinusitis, allergic conjunctivitis, eosinophilic esophagitis and irritable bowel syndrome, where we believe mast cells maintain a vital role in driving the pathophysiology of the disease. We believe these potential extension opportunities represent attractive markets with clinical unmet need and established development and regulatory pathways. In our nonclinical studies, THB001 has demonstrated the ability to potently deplete mast cells across a variety of tissue types tested in rats and dogs.

- **Continue to innovate and potentially expand the pipeline through our internal discovery efforts and selectively evaluate strategic collaborations.** Our team brings invaluable experience from all aspects of drug discovery, clinical development, business development and commercialization. We will continue to invest in research and development and evaluate potential selective collaboration opportunities to build upon our deep know-how around oral small molecule KIT inhibition to potentially advance next-generation compounds and expand our pipeline in allergic and inflammatory diseases.

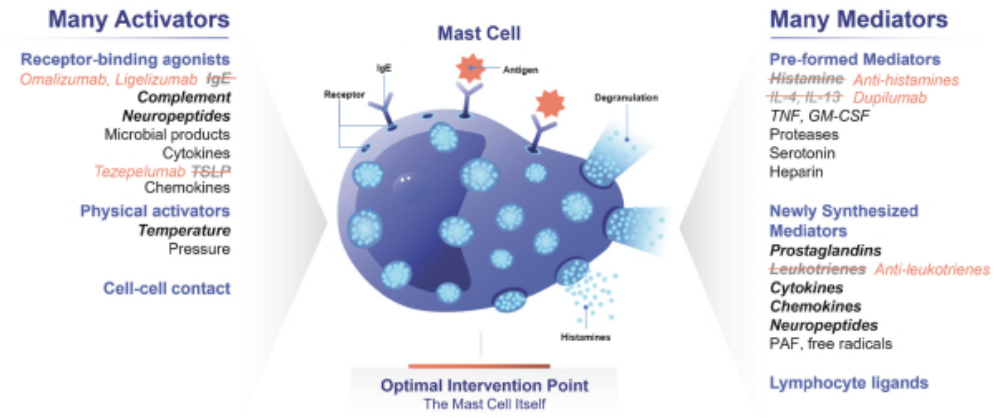
Overview of Mast Cells and KIT

Mast Cells and Their Role in Immunity

Mast cells derive from KIT-positive hematopoietic progenitors in the bone marrow and are present throughout the body in connective and vascularized tissues, most prominently along surface boundaries with exposure to the external environment such as the skin, the respiratory tract and the gastrointestinal tract. Their numerous physiological functions include regulation of inflammation, vasodilation, vascular homeostasis and angiogenesis as well as involvement in the control of other elements of the immune response. Dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders, including urticaria, asthma and gastrointestinal disorders, among others.

The cytoplasm of mast cells stores inflammatory mediators including histamine, the proteolytic enzyme tryptase, and various cytokines including interleukins IL-4, IL-5 and IL-13, and Tumor Necrosis Factor-a, or TNF-a. Mast cells express multiple cell-surface receptors, one of which is FceR that has particularly high affinity for immunoglobin E, or IgE, antibodies. As shown in the figure below, upon the stimulation of IgE, change of temperature, or pressure, a signaling cascade leads to activation of the mast cell and its degranulation resulting in the release of tryptase, histamine and other inflammatory mediators. In addition to IgE dependent activation, other IgE independent stimuli can also trigger mast cell activation. The release of inflammatory mediators can manifest into a broad range of allergic or inflammatory diseases. Moreover, mast cell activation and degranulation lead to the recruitment of other progenitor cells to the specific tissue site and the propagation of the inflammatory response.

Mast cells mediate multiple pro-inflammatory activities



In the skin, antigens activate mast cells in the deep layers of connective tissue triggering the release of histamine and other vasoactive molecules, and causing allergic reactions, including urticaria. In chronic urticaria, patients will develop wheals, together with the sensations of pain and itch. If antigens activate mast cells deeper in the tissue this can lead to angioedema. Another chronic skin disorder involving mast cells is atopic dermatitis, or eczema.

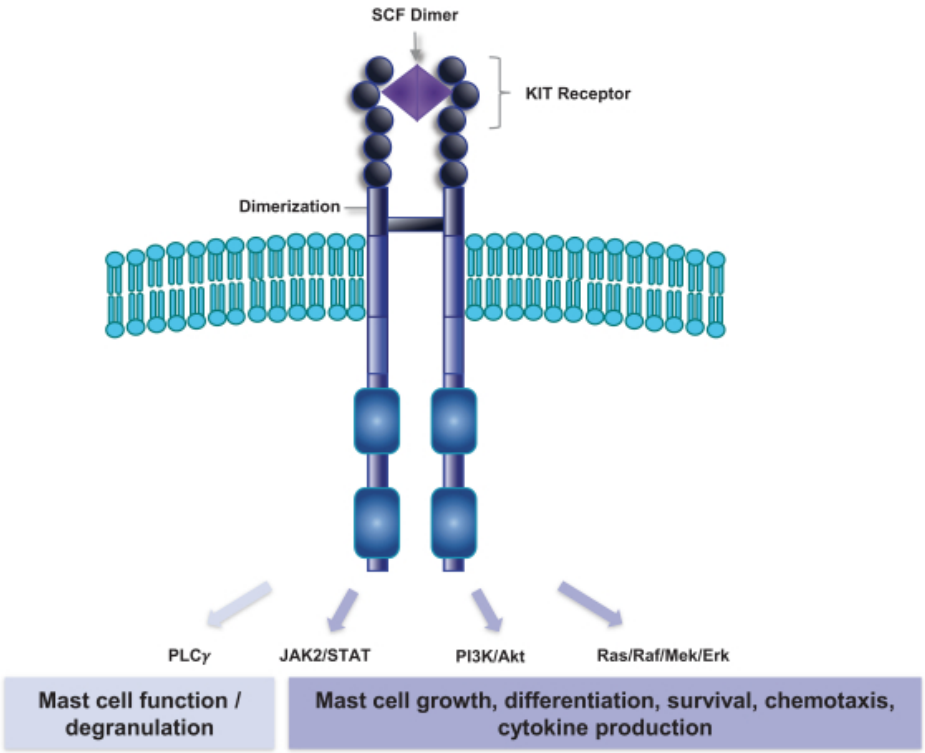
In the respiratory tract, mucosal mast cells in the nasal epithelium are activated by inhaled antigens, eliciting an immune response and resulting in airway constriction, increased mucous production and cough. Mast cells also play a role in the pathophysiology of asthma which is caused by an inflammatory response in the airways due to inhaled antigens that get into the lower respiratory tract and cause mast cell degranulation and local inflammation. This leads to symptoms characteristic of asthma including increased vascular permeability, fluid accumulation, edema, bronchial constriction and obstruction of airways.

In the gastrointestinal tract, dietary proteins can act as antigens and activate the immune system in affected individuals. Antigens permeate the epithelial layer of the mucosa of the gut and bind to IgE antibodies on mucosal mast cells. Elevated numbers of activated mast cells have been observed in allergic eosinophilic gastrointestinal disorders, including eosinophilic esophagitis, gastritis and duodenitis. Mast cells are also involved in the pathophysiology of irritable bowel syndrome and, inflammatory bowel disease, including driving symptomology via their close interaction with nerves.

KIT Signaling in Mast Cells is a Central Node for Therapeutic Intervention

The receptor tyrosine kinase KIT, also known as CD117, is recognized as a master regulator of mast cell activity. Under normal physiological conditions, mast cell progenitors circulate in an immature form and only fully develop into mature mast cells upon migration to a specific tissue type. Mature mast cells remain localized to a designated destination. The figure below shows the KIT structure on the mast cell membrane. As shown below, stem cell factor, or SCF, which is also referred as the c-kit ligand, binds to KIT on the surface of the mast cell, enables signal transduction into the mast cell and activates the KIT-mediated signaling cascade critical to mast cell survival, propagation and differentiation via pathways such as PLCg, JAK2/STAT, PI3K/AKT and RAS/RAF/MEK/ERK.

KIT (CD117) is the master regulator of mast cell function and survival



As the master regulator of mast cell function and survival, we believe that the KIT-SCF signaling axis is the optimal intervention point to treat many mast cell mediated diseases. Inhibition of KIT drives both mast cell inactivation and depletion, independent of mast cell activation status.

In a rat model of allergic asthma, THB001 achieved statistically significant reduction in early airway response, correlating with the depletion of mast cells. Consistent with our nonclinical findings, significant clinical and nonclinical data that have been generated by us and by third-party organizations support KIT as an attractive therapeutic target for mast cell regulation. The multi-tyrosine kinase inhibitor imatinib, which is sold under the brand name Gleevec, has been approved by the FDA to treat chronic myelogenous leukemia, acute lymphoblastic leukemia and myelodysplastic syndrome, among other indications. In clinical results by a third party published in *The New England Journal of Medicine*, daily imatinib, which has demonstrated KIT inhibitory activity, achieved a 43% reduction in plasma levels of serum tryptase, a biomarker used to assess mast cell activation, for patients with severe refractory asthma, which resulted in statistically significant improvement in airway hyperresponsiveness at 24 weeks. We believe these results provide compelling clinical proof-of-concept that mast cell reduction may drive meaningful symptomatic relief. Furthermore, an anti-KIT antibody demonstrated compelling clinical responses in patients with chronic inducible urticaria in a Phase 1 clinical trial conducted by a third party.

Therapeutic Modulation of the Allergic Response

There are several approved therapeutics used to treat allergy and related inflammatory conditions by targeting specific mediators released by mast cells upon degranulation, including histamines, leukotrienes, cytokines, such as IL-4, IL-5, IL-13, and TNF-a. However, we believe targeting the mast cell directly provides a broader approach to addressing mast cell mediated diseases over only targeting an individual mediator. Due to the involvement of multiple pro-inflammatory mediators, mast cell mediator inhibitors often require use in combination with another treatment modality. As a result, single agent inhibition of individual mast cell mediators, such as the H1 antihistamine, do not provide adequate symptomatic relief to a large proportion of the patient population.

Under current standard of care, patients whose disease does not respond to mediator inhibition, are often candidates for anti-IgE monoclonal antibodies, or mAbs, designed to inhibit IgE-driven mast cell activation. While IgE blockade has demonstrated some clinical benefit in the treatment of a range of mast cell mediated inflammatory disorders, anti-IgE therapy does not fully remedy symptoms for most patients, potentially in part because it does not address IgE-independent pathways of mast cell activation. Omalizumab, the anti-IgE mAb sold under the brand name Xolair, is approved for the treatment of persistent allergic asthma, nasal polyps and chronic spontaneous urticaria. Omalizumab generated an estimated $3.5 billion in 2021 sales worldwide.

Despite current treatment options, there remains a significant unmet need. The targeting of the mast cell directly represents a novel therapeutic approach to address inflammatory diseases. While this approach benefits from clinical validation, advancing the development of therapeutics designed to directly reduce mast cell activity has been thwarted by the potential risk of off-target adverse effects. We believe THB001 has the potential to address this unmet need and enable us to exploit the advantages of mast cell inhibition.

Overview of Urticaria

Urticaria, which is also referred to as “hives”, is a common inflammatory disorder that has a lifetime prevalence of up to 25% with females twice as likely to experience the condition as men. Onset peaks between the ages of 20 and 40 years old. It is not a single disease but a reaction pattern that represents cutaneous mast cell degranulation. Mast cell degranulation and the release of vasoactive mediators, primarily histamine, results in extravasation of plasma into the dermis, forming the characteristic hives and edematous pruritic pink wheals of various shape and size.

While the majority of urticaria cases involve acute episodes which are self-limiting and of a short duration, patients with chronic urticaria experience constant or frequently recurring lesions for six or more weeks regularly over months if not years. Chronic urticaria has a negative impact on patients’ quality of life, particularly as the occurrence of angioedema often leads to significant discomfort. Patients have reported an impact on facets of

everyday life that include lack of quality sleep, recreation and social interaction, mobility, rest and work. As such, patients with chronic urticaria frequently exhibit psychiatric comorbidities such as anxiety and depression. At any time, 0.5-1% of the population suffers from chronic urticaria, suggesting a point prevalence of over 1.5 million patients in the United States. Approximately 70% to 80% of patients with urticaria are women. The duration of the disease is generally 1-5 years but is likely to be longer in more severe cases.

Chronic urticaria is comprised of two distinct disease types, inducible urticaria and spontaneous urticaria, which was previously referred to as idiopathic urticaria. Chronic inducible urticaria is caused by exposure to specific triggers, which include excessive cold or heat, the application of pressure and exercise. No underlying cause or underlying disease process has been identified in the majority of patients with chronic spontaneous urticaria. In patients with no identified trigger, the rate of spontaneous remission at 1 year is approximately 20% to 50%, while 30% of moderate to severe patients suffer from chronic urticaria for more than 5 years.

Current Treatments for Chronic Urticaria

Current chronic urticaria treatment guidelines recommend first line treatment with second generation H1 antihistamines to provide hive and itch symptom control. For those patients whose symptoms remain uncontrolled following first line therapy, second line treatment is initiated with either elevated doses (up to fourfold) of second generation H1 antihistamines or the addition of another class of agent including first generation H1 antihistamines. For the approximately 50% of chronic spontaneous urticaria patients who remain uncontrolled following second line therapy, Xolair is approved as third line therapy. In clinical trials, Xolair reported complete response rates of approximately 36% in chronic spontaneous urticaria and is estimated to address less than 20% of eligible patients whose symptoms have failed to be controlled by H1 antihistamine therapy. As such, there remains a large population of patients that have unmet need.

Our Solution: The KIT Inhibitor THB001

Summary

THB001 is a highly potent and selective, small molecule wild-type KIT inhibitor in development for the treatment of mast cell mediated inflammatory diseases. THB001 is designed to offer attractive drug-like properties, including high potency and oral bioavailability, and high selectivity for the wild-type KIT receptor. Based on nonclinical and available clinical data to date, we believe THB001 differentiates from other KIT-targeting therapeutics in the following designed aspects:

- The small molecule modality is anticipated to provide more refined dose titration capabilities than anti-KIT mAbs.
- Oral administration offers improved patient convenience while avoiding mAb-related injection events.
- Higher selectivity for wild-type KIT relative to other small molecule inhibitors. The most potent THB001 off-target effect was against the tyrosine kinase receptor colony stimulating factor 1 with approximately 48-fold selectivity versus KIT when evaluated in a cell-based Ba/F3 assay. Selectivity against platelet-derived growth factor receptor (PDGFR)-a and PDGFR-b was 198- and 106-fold, respectively, in cell-based assays.
- THB001 binds intracellularly to an inactive conformation of KIT, avoiding the risk of paradoxical mast cell activation that can result from a KIT mAb binding to the extracellular portion of the KIT receptor.

In our recently completed Phase 1a clinical trial, THB001 demonstrated dose-dependent reductions of serum tryptase, a key biomarker of mast cell activity which has been shown to correlate with clinical benefit in chronic urticaria patients. We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic

inducible urticaria in May 2022, which has been cleared in the Netherlands and Germany. We initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit a CTA to support initiation of a Phase 1b trial in asthma in the first half of 2023 and expect to report initial data from this trial in the second half of 2024. We intend to submit both a CTA in Europe and an IND in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024. We are also exploring development opportunities across a range of other indications where THB001 may provide benefit to patients suffering from mast cell driven inflammation to demonstrate the "pipeline-in-a-product" potential of THB001.

In addition, we are continuing to optimize the formulation of THB001 from our free base formulation for clinical entry toward a commercial formulation which achieves our target product profile. We have identified a micronized THB001·HCl salt formulation that has demonstrated more favorable solubility, dissolution, manufacturability, and dog pharmacokinetics, or PK, performance over the free base formulation in nonclinical studies. Interim PK data of our THB001·HCl salt formulation in normal healthy volunteers indicates improved exposure per unit dose. We anticipate this improved THB001·HCl salt formulation will enable a QD dosing regimen in future clinical trials.

Phase 1a Healthy Volunteer Trial Design

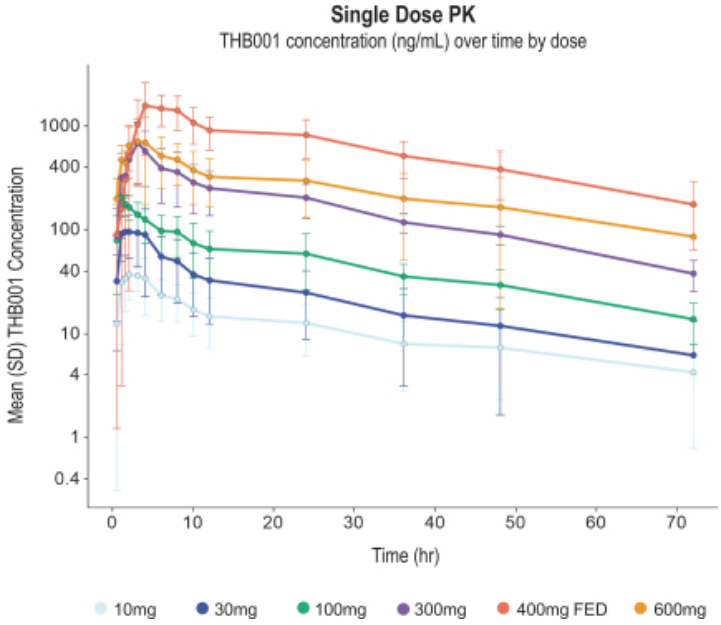
We recently conducted a three-part, 84 subject, Phase 1a clinical trial of THB001 in healthy adult volunteers between the ages of 18 and 65. The primary objective is to evaluate safety and tolerability. Secondary objectives include characterizing pharmacokinetics, including in the presence or absence of food to inform further clinical and drug product formulation development and to measure the pharmacodynamic effect by serum tryptase. The first part of this trial was a single-ascending dose, or SAD, involving five cohorts of up to ten participants assigned to receive a single dose of THB001 or placebo in a 3:1 ratio. Doses ranged from 10 mg to 600 mg across the five cohorts. The second part of the trial was designed to evaluate the effect of food on the pharmacokinetics, or PK, profile of 200 mg THB001. A single 200 mg dose was administered to one cohort of ten participants, half of which received THB001 along with a standardized high-fat breakfast, while the other half received THB001 in a fasted state. Following a washout period of at least 7 days, each participant crossed over to receive THB001 in the alternate fed or fasted state. Safety and tolerability of THB001, together with its PK profile was evaluated during this portion of the trial. Upon completion of this second part of the Phase 1a trial, a sixth SAD cohort was added enabling the evaluation of a 400 mg THB001 dose when administered together with food. The third part of the Phase 1a trial was a multiple ascending dose, or MAD, format of four eight-subject cohorts, administered THB001 over 14 consecutive days. The first cohort received 200 mg of THB001 QD, the second cohort received 200 mg of THB001 BID, the third cohort received 400 mg THB001 BID, and the fourth cohort received 500 mg QD administered with a standardized non-high fat breakfast to further characterize the effect of food on the PK of THB001. A schema of our Phase 1a trial is presented below.

Schema of our Phase 1a trial in healthy volunteers.

Phase 1a Pharmacokinetics, Pharmacodynamics, and Biomarker Data in Healthy Volunteers

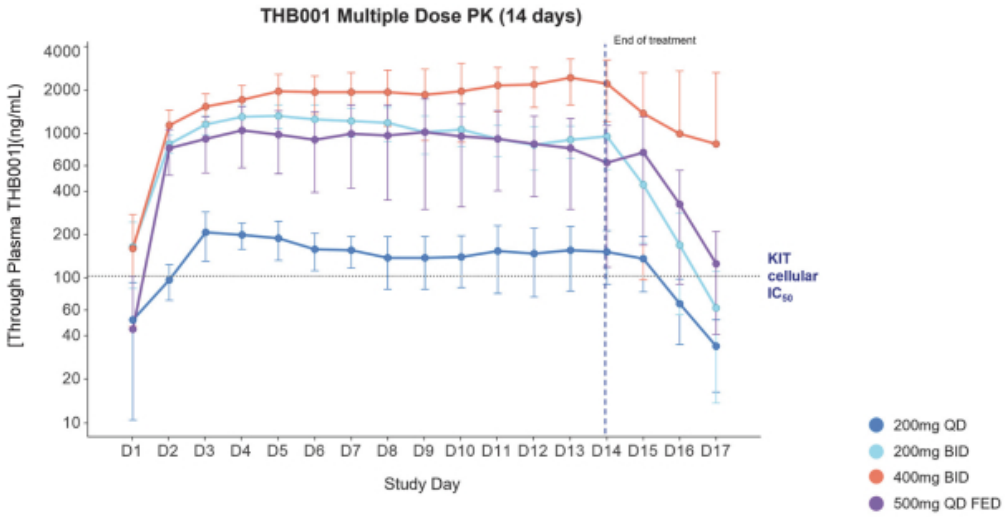
In the SAD portion of the Phase 1a trial, we observed approximately dose proportional increases in serum concentration of THB001 between the 10 mg and 300 mg doses. As reflected in the chart below at 300 mg and higher dosing levels, THB001 concentration exceeded 100 ng/ml through 24 hours, which is the level needed to achieve a KIT half-maximal inhibitory concentration, or IC_{50}, between daily doses. This is consistent with the observed mean half-life of THB001 of approximately 24 hours. Administration of THB001 in combination with food was also noted to enhance exposure approximately three-fold.

SAD pharmacokinetics in doses up to 600 mg



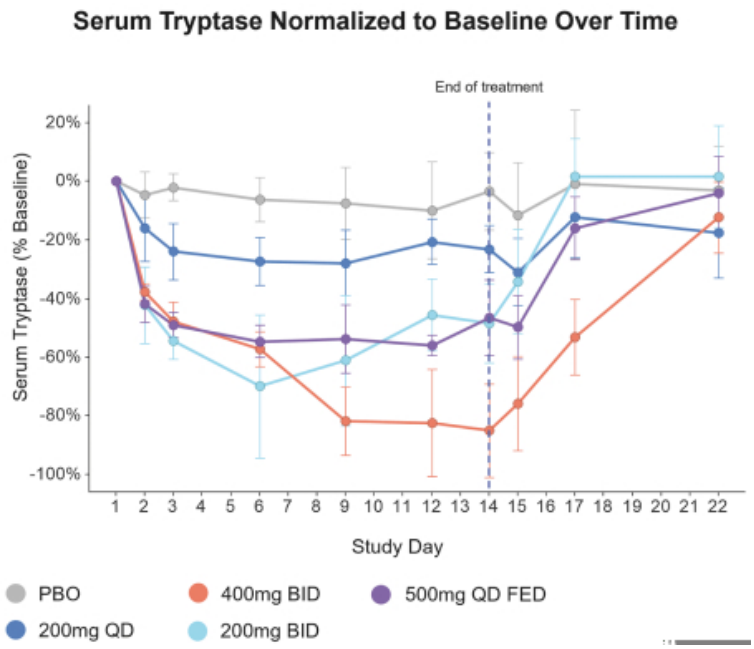
In the MAD portion of the trial, the increase in THB001 dosage from 200 mg BID to 400 mg BID was observed to generate approximately dose proportional increases in THB001 serum concentration levels which provided a trough value difference between THB001 and the protein binding adjusted KIT IC_{50} of approximately 20-fold, which provides evidence of attractive therapeutic exposure. Administration of 500 mg QD with a standardized non-high fat breakfast produced a PK profile that was similar to the 200 mg BID dose administered in the fasted state, confirming the positive effect of food on THB001 exposure.

200/400 mg BID and 500 mg QD dosing of THB001 generated through serum concentrations which exceeded the IC_{50}



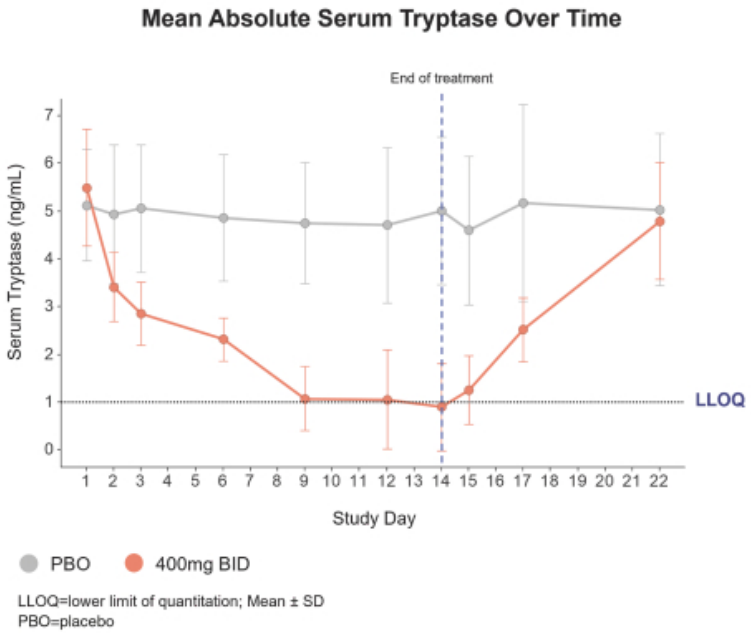
Dose levels of 200 mg per day or greater, given QD or BID, were observed to result in dose dependent declines in serum tryptase concentrations, a key biomarker of mast cell activity which has been demonstrated to correlate with clinical benefit in chronic urticaria, as compared to placebo, or PBO, as reflected in the graph below.

Twice-daily administration of THB001 resulted in a dose-dependent decrease in serum tryptase levels.



As reflected in the chart presented below, which shows absolute serum tryptase levels in patients over time, twice daily dosing of the higher 400 mg level of THB001 resulted in mean serum tryptase which was at the lower limit of quantification.

The higher 400 mg BID dose resulted in a serum tryptase level at the lower limit of quantitation.



Phase 1a Safety Data in Healthy Volunteers

THB001 was well-tolerated at all dose levels administered in the SAD and MAD cohorts in this Phase 1a trial.

In the SAD cohort, no SAEs were observed. Among the AEs recorded, one was categorized as moderate due to a rash and the remaining were characterized as mild in intensity and included headache, fatigue, myalgia and dizziness. Adverse events did not result in any early terminations or subject discontinuation from participation in this portion of the trial. No trial stopping criteria were met and no significant changes or trends in hematology, blood chemistries, vital signs or electrocardiogram, or ECG, measurements were noted. The following table shows all treatment emergent adverse events that were reported by more than two patients.

SAD/FE Treatment Emergent Adverse Events

Adverse Events Reported by >2 Subject by Treatment Assignment

	THB001															
	10mg		30mg		100mg		200mg FED/FAST		300mg		600mg		400mg FED		PBO	
Preferred Term, n %	6	% (n)	6	% (n)	5	% (n)	10	% (n)	4	% (n)	5	% (n)	6	% (n)	10	% (n)
Headache	—	—	—	—	—	—	5	50.0%	—	—	2	40.0%	—	—	—	—
Fatigue			—	—	1	20.0%	2	20.0%	—	—	—	—	—	—	1	10.0%
Myalgia	1	16.7%	—	—	—	—	1	10.0%	—	—	1	20.0%	—	—	—	—
Dizziness	1	16.7%	—	—	—	—	—	—	—	—	2	40.0%	—	—	—	—

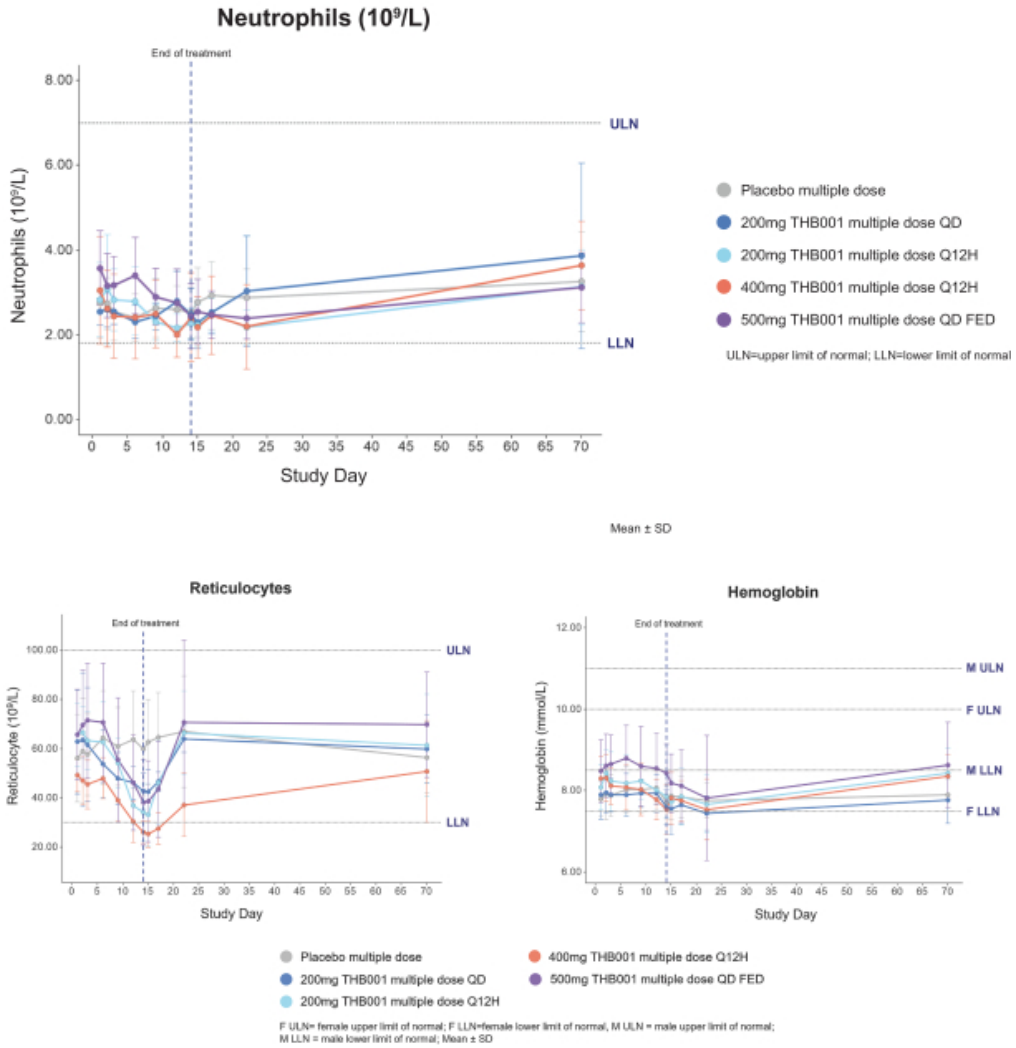
In the MAD portion of the Phase 1a trial, no SAEs were observed. Among the AEs recorded, three were categorized as moderate and the remaining categorized as mild. Among the three AEs characterized as moderate, two AEs were determined to have been unlikely to be related to or unrelated to THB001. The treatment related moderate AE was low neutrophil levels, which resolved after discontinuation in the trial. This subject was subsequently determined to have a neutrophil count below the lower range limit prior to entering the trial. AEs reported as mild included change in hair color, headache, nausea, diarrhea, dizziness, COVID-19, gastric reflux, nasopharyngitis and skin irritation, and one subject experiencing a mild AE discontinued the Phase 1a trial on day twelve due to anxiety. As in the SAD portion of the trial, no trial stop criteria were encountered and no clinically relevant changes or trends in hematology, blood chemistries, vital signs or ECG measurements were observed. The following table shows all treatment emergent adverse events that were reported by more than two patients.

MAD Treatment Emergent Adverse Events

Adverse Events Reported by Treatment Assignment in >2 Subjects

	THB001									
	200mg QD		200mg BID		400mg BID		500mg QD FED		PBO	
Preferred Term, n %	6	% of (n)	6	% of (n)	6	% of (n)	6	% of (n)	8	% of (n)
Hair Color Changes	2	33.3%	6	100.0%	5	83.3%	4	66.7%	—	—
Headache	2	33.3%	2	33.3%	2	33.3%	4	66.7%	3	37.5%
Nausea	1	16.7%	2	33.3%	—	—	2	33.3%	2	25.0%
Diarrhea	1	16.7%	1	16.7%	—	—	1	16.7%	2	25.0%
Dizziness	—	—	1	16.7%	—	—	4	66.7%	1	12.5%
COVID-19	1	16.7%	—	—	—	—	2	33.3%	—	—
Gastric reflux	—	—	1	16.7%	1	16.7%	—	—	1	12.5%
Nasopharyngitis	1	16.7%	—	—	2	33.3%	—	—	—	—
Skin Irritation	—	—	—	—	1	16.7%	1	16.7%	1	12.5%

As reflected in the charts below, neutrophil declines were initially observed, but stabilized, and the average values remained above the lower limit of normal through day 14. In addition, declines in reticulocytes were observed, a pre-cursor cell to red blood cells; however, these declines did not manifest into any clinically meaningful adverse events and did not translate into hemoglobin levels below the lower limit of normal, which is a key clinical measure given hemoglobin is a protein in red blood cells that carries oxygen to tissues throughout the body. We believe compensatory mechanisms, such as erythropoietin signaling, mitigate the effects of KIT inhibition.



Nonclinical Safety Pharmacology and Toxicology

A standard battery of nonclinical central nervous system, cardiovascular and respiratory safety pharmacology studies have been completed with THB001 with no findings anticipated to be of clinical relevance. Genotoxicity assessments conducted according to International Conference on Harmonization, or ICH, guidance were negative as were tests for photoirradiation potential.

The nonclinical toxicology profile of THB001 has been demonstrated to be on-target with evidence of reversibility. Repeat dose GLP toxicology studies of up to 13 weeks of continuous dosing or 14 weeks of episodic dosing have been completed with THB001 in both rats and dogs. As expected and consistent with KIT function, dose related on-target histopathologic observations were noted in spermatogenesis, hematology and hair pigmentation. Either partial or complete reversibility was established during the recovery periods for these findings consistent with the growth kinetics of affected cells. We believe these effects will be completely reversible with sufficient recovery periods.

Species difference in the hematologic effects of inhibition or genetic loss of function of KIT have been reported with rodents and dogs being relatively more sensitive than monkeys and humans. For example, the disproportionate sensitivity of mice relative to humans has been mechanistically attributed to the lack the compensatory expression of the receptor tyrosine kinase FLT3 in mice during different stages of hematopoietic stem cell differentiation.

In nonclinical animal models of allergic disease, THB001 showed dose-dependent reductions in tissue mast cells correlating with efficacy in rat models of dermal anaphylaxis (28 day passive cutaneous anaphylaxis) and asthma (9 day ovalbumin induced early airway response). Trough levels of THB001 in these studies were consistent with levels achieved during our Phase 1a healthy volunteer trial.

As expected based on the role of KIT in fetal development, an initial embryo fetal development study of THB001 in rats has shown evidence for teratogenicity. We have initiated a development and reproductive toxicology, or DART, program and intend to conduct genotoxicity assessments in accordance with ICH guidelines. We believe that the administration of THB001 in women of childbearing potential will require the concomitant use of appropriate birth control measures.

We believe these studies support the planned Phase 1b trial in CIndU, regulatory filing for asthma and further clinical development of THB001. We have initiated the chronic toxicology of 26 weeks in rats and 39 weeks in dogs required to continue dosing beyond 13 weeks in Phase 2.

Our Planned Phase 1b Trial in Chronic Inducible Urticaria

We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, which has been cleared in the Netherlands and Germany. We initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. Chronic inducible urticaria is caused by exposure to excessive cold or heat, the application of pressure and exercise, among other triggers. Accordingly, there is an inherent ability to induce the disease state in the clinical setting, similar to real world triggering situations, in a predictable and controlled manner through provocation testing. We believe that chronic inducible urticaria represents an attractive initial clinical indication for THB001 as a precursor for chronic spontaneous urticaria, given the ability to efficiently evaluate clinical activity outcomes through provocation testing, in concert with biomarker measures of mast activity and safety data.

The planned Phase 1b trial is expected to enroll 30 patients to evaluate three dose levels over twelve weeks of treatment. The primary objective is to evaluate safety and tolerability, primarily by mean reduction in critical temperature threshold. Secondary objectives include characterizing pharmacokinetics, measuring the pharmacodynamic effect by serum tryptase as well as clinical outcome measures.

We plan to seek regulatory approval to commercialize THB001 or any future product candidates in the United States, the European Union and in selected foreign countries, including the United Kingdom and Japan.

"Pipeline-in-a-Product" Potential of THB001

Dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of allergic and other inflammatory disorders that impact the skin, eye, respiratory tract and gastrointestinal tract. Given KIT is

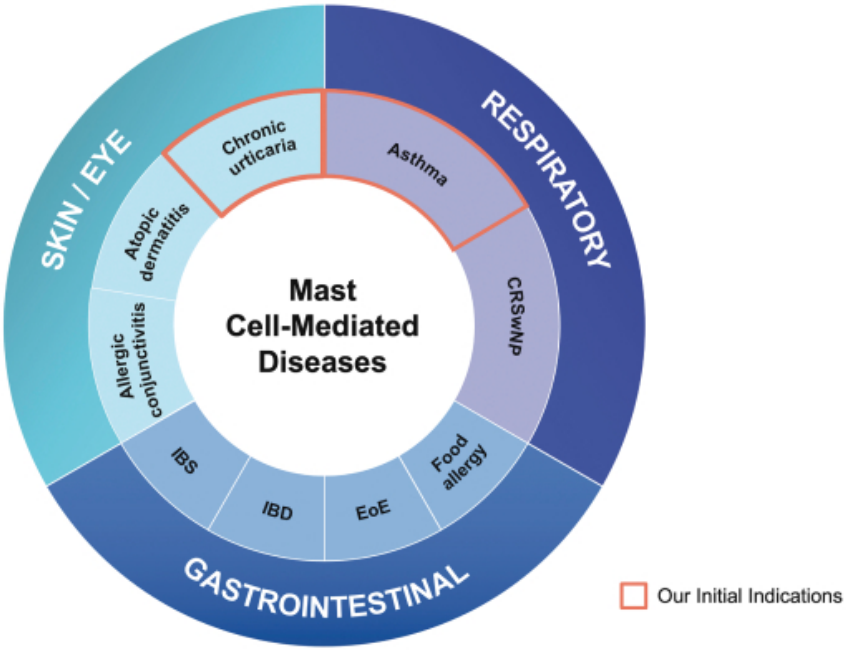
the master regulator of mast cell function and survival, we believe that KIT inhibition is the optimal approach to treat many of these mast cell mediated diseases. As such, we believe THB001 represents a "pipeline-in-a-product" opportunity.

Related to the skin and eye, potential indications addressable with KIT inhibition include chronic urticaria, systemic sclerosis, atopic dermatitis and allergic conjunctivitis. We submitted a CTA in Europe for our dose escalation Phase 1b proof-of-concept trial in chronic inducible urticaria in May 2022, which has been cleared in the Netherlands and Germany. We initiated the trial in September 2022, and expect to report initial data from this trial in the second half of 2023. We also intend to submit both a CTA in Europe and an IND in the United States to support initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of 2024.

In the respiratory tract, potential indications addressable with KIT inhibition include asthma and chronic rhinosinusitis with nasal polyposis, or CRSwNP. We intend to submit for regulatory clearance to initiate a Phase 1b trial for asthma in the first half of 2023, and expect to report initial data from this trial in the second half of 2024. We intend to conduct the planned Phase 1b trial as a parallel, placebo-controlled dose-escalation trial involving mild, stable, allergic asthmatic subjects who are not on regular anti-inflammatory treatment. The primary objective is to evaluate the change from baseline in forced expiratory volume during late asthmatic response by measuring forced expiratory volume, with additional secondary biomarker and clinical measurements as secondary endpoints.

In the gastrointestinal tract, potential indications addressable with KIT inhibition include irritable bowel syndrome, or IBS, inflammatory bowel disease, or IBD, eosinophilic esophagitis and food allergy.

Examples of selected mast cell mediated diseases potentially addressable with KIT inhibition

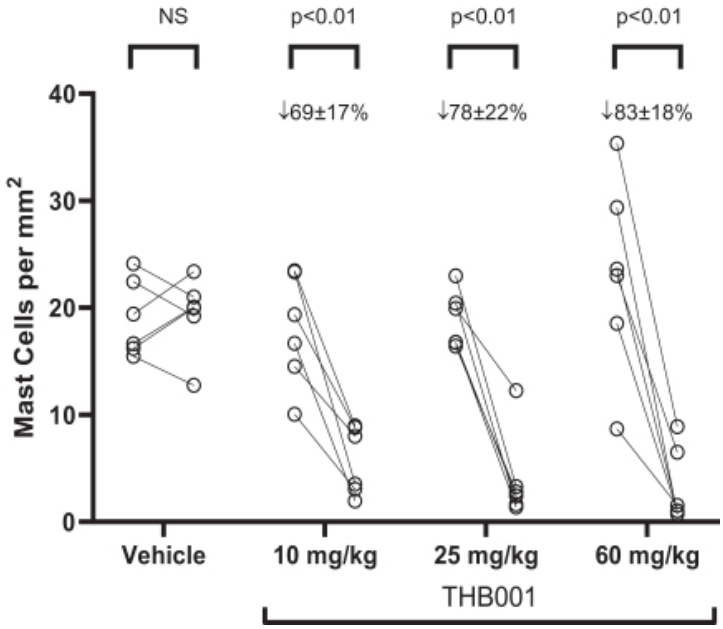


THB001's Therapeutic Potential in Other Mast Cell Driven Inflammatory and Allergic Diseases

Nonclinical studies of THB001 provide evidence of its ability to deplete and inhibit mast cell activity in multiple species and tissue types. Significant therapeutic improvement has also been observed in animal disease models.

In a 14-day repeat dose study of THB001 conducted in dogs, samples were collected from the skin both before and after administration of the drug candidate and evaluated for mast cell counts. As is reflected in the results presented below, we observed a dose-dependent decline in mean skin mast cell count in every treated animal. Statistical significance is important and when used herein is denoted by p-values. The p-value is the probability that the reported result was achieved purely by chance (for example, a p-value < 0.001 means that there is a less than 0.1% chance that the observed change was purely due to chance). Generally, a p-value less than 0.05 is considered to be statistically significant.

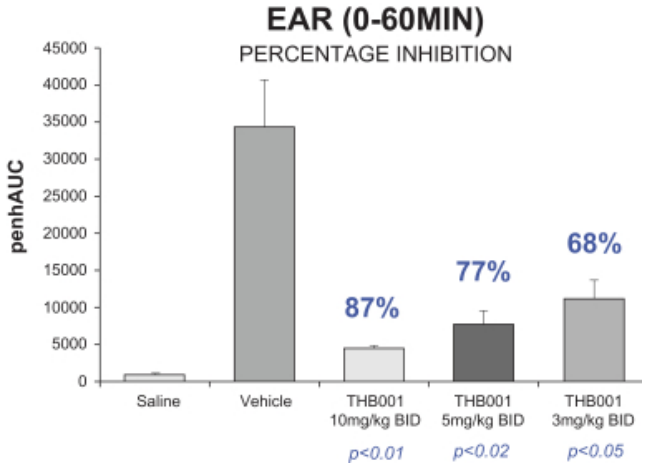
THB001 generated dose-dependent mast cell depletion in a 14-day repeat dose study in dogs.



In a rat model of allergic asthma conducted by Novartis, THB001 also demonstrated robust *in vivo* activity, with improvements in early airway response, or EAR, and reduction in the lung mast cell specific gene signature by approximately 50% or greater. The degranulation of mast cells is the main contributor in the early phase allergic response upon antigen exposure and accordingly, inhibition of mast cell survival and function by prevention of KIT activation is expected to result in the improvement of allergic symptoms.

In this study, animals received OVA antigen to stimulate allergic reaction in the lung with the exception of one cohort receiving saline. The OVA antigen treated animals were administered either a 3 mg/kg, or mpk, 5 mpk or 10 mpk dose of THB001 twice daily for seven days and compared to animals administered vehicle alone. As is reflected in the experimental results presented in the chart below, THB001 produced a dose dependent, statistically significant therapeutic response, with measures of lung function enhanced pause, or Penh, used to assess changes in the shape of airflow pattern entering and leaving the animal, displaying notable improvement with increased KIT inhibition. Moreover, at the lowest level administered to the animals, 3 mg/kg BID, the serum concentration of THB001 exceeded the *in vitro* protein binding adjusted KIT IC_{50} over the dosing period, providing evidence of adequate sustained suppression of KIT-mediated signaling activity.

The use of THB001 produced statistically significant airway improvements in a rat model of allergic asthma.



Gene expression profiles provided further support of THB001's inhibition of mast cell activity. Expression patterns for mast cell associated genes were evaluated after administration of the various dose levels of THB001 relative to expression levels observed after dosing with vehicle. These expression profiles revealed that at approximately one-half the expression levels seen after administration of vehicle, which was achieved at the lower dosing level of 3 mpk, the animals began to benefit from significant airway improvement. These results suggest that modulation to some intermediate inhibitory level that is less than complete inhibition of mast cell activity may provide meaningful clinical benefit. The analysis of the gene expression profiles is outlined in the chart below.

Mast cell-associated gene expression is suppressed in the presence of THB001.

Percentage of Vehicle Response

Treatment	Challenge	Cpa3	FceR1a	Mcpt2	Mcpt9
None	Saline	68	80	55	76
Vehicle	OVA	100	100	100	100
3 mg/kg THB001 (BID)	OVA	44	38	46	50
5 mg/kg THB001 (BID)	OVA	41	38	47	54
10 mg/kg THB001 (BID)	OVA	24	21	28	29

Abbreviations: BID=twice daily; Cpa3=carboxypeptidase 3; FceR1a=Fc epsilon receptor 1 alpha chain; Mcpt2=Mast cell tryptase 2; Mcpt9=Mast cell tryptase 9; OVA=ovalbumin.

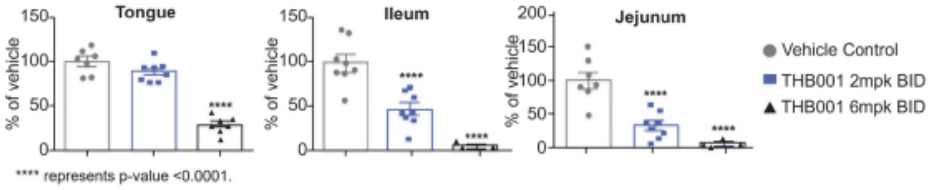
The Therapeutic Benefit of THB001 May Extend to a Range of Tissues

We are also exploring development opportunities across a range of other indications where THB001 may provide benefit to patients suffering from mast cell driven inflammation. We believe that KIT inhibition may provide wide therapeutic utility across other indications as mast cells are present in numerous tissue types with external exposures. In addition to skin, where chronic urticaria represents our initial clinical indication, there are multiple respiratory and gastrointestinal conditions including eosinophilic esophagitis and asthma, where we believe mast cells maintain a vital role in driving the pathophysiology of the disease. We believe these potential additional opportunities represent attractive markets with established development and regulatory pathways, for which there remains a large unmet need.

For example, approximately five to ten percent of asthma patients suffer from severe asthma, or an estimated 750,000 to one million patients in the United States alone.

In a nine-day repeat dose rat pharmacology study, THB001 demonstrated the ability to potently deplete mast cells across all tissues tested. As is noted in the chart below, in tissue taken from the oral cavity (tongue tissue) and the small intestine (ileum and jejunum tissue), there was statistically significant mast cell suppression following administration of THB001.

THB001 demonstrated mass cell depletion across a range of tissue types.



Licenses, Partnerships and Collaborations

License Agreement with Novartis International Pharmaceutical Ltd.

On June 28, 2019, we entered into a license agreement with Novartis International Pharmaceutical Ltd. (which subsequently merged into the company Novartis Pharma AG), or Novartis, as amended, or the Novartis Agreement. Pursuant to the Novartis Agreement, Novartis granted us an exclusive, worldwide, sublicensable (subject to certain requirements therein) license under specified patent rights and know-how related to three licensed compounds to develop, make, use and sell certain products incorporating or comprising a licensed compound, including THB001, or the Licensed Products. Under the Novartis Agreement, we are solely responsible for all research, development, regulatory and commercialization activities related to the Licensed Products. We are required to use commercially reasonable efforts to develop and seek regulatory approval for, and commercialize, at least one Licensed Product in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

Pursuant to the Novartis Agreement, we made a one-time payment of $350,000 to Novartis and agreed to issue shares of preferred stock pursuant to that certain Investment Letter dated as of June 27, 2019, or the Novartis Investment Letter. Pursuant to the Novartis Investment Letter, we have issued Novartis 5,970,000 shares of Series A-1 Preferred Stock, consisting of shares issued as part of entering into the agreement and shares issued subsequently under the anti-dilution right included within the license agreement. As of June 30, 2022 all of the Company's obligations under the anti-dilution right have been fulfilled. Further, we are obligated to pay Novartis up to an aggregate of (a) $31.7 million upon the achievement of certain specified development milestones for the Licensed Products and (b) $200.0 million upon the achievement of certain specified sales and commercialization milestones with respect to the Licensed Products. We are also required to pay Novartis, on a Licensed Product-by-Licensed Product and country-by-country basis, tiered royalties in the single-digit percentage range on annual net sales of Licensed Products, subject to reduction and offset upon certain specified events. The foregoing royalty payment obligations will expire on the latest to occur of: (i) expiration of the last valid claim of the licensed patent rights that covers such Licensed Product in such country; (ii) the expiration of any regulatory exclusivity for such Licensed Product in such country; and (iii) ten years following the first commercial sale of such Licensed Product in such country. Upon the expiration of such royalty term in a particular country for a particular Licensed Product, the license granted to us with respect to such Licensed Product in such country will become fully paid-up, royalty-free, transferable, perpetual and irrevocable.

The Novartis Agreement will expire (a) on a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of the royalty term for such Licensed Product in such country and (b) in its entirety upon

the expiration of the royalty term with respect to the last Licensed Product being developed, manufactured or commercialized worldwide. Each party may terminate the Novartis Agreement for uncured material breach by the other party or in the case of the other party's insolvency. Additionally, we have the right to terminate the Novartis Agreement for convenience upon 90 days' prior written notice to Novartis. Upon termination of the Novartis Agreement by us for convenience or by Novartis for our uncured material breach or insolvency, the license granted to us by Novartis will terminate and we will be obligated to, (i) grant to Novartis an exclusive, worldwide, reversion license under certain patent rights and know-how with respect to the terminated Licensed Products, (ii) transfer to Novartis certain know-how and regulatory documentation with respect to the terminated Licensed Products and (iii) to the extent applicable, use commercially reasonable efforts to transfer agreements between us and third parties that are solely related to the terminated licensed compounds and Licensed Products.

Manufacturing

We oversee and manage third party Contract Development and Manufacturing Organizations, or CDMOs, to support development and manufacture of THB001 for our clinical trials.

We currently use two geographically-distributed CDMOs to supply our GMP drug substance. The manufacturing process is robust with readily-sourced commercially available raw materials and straightforward scalability. The drug substance demonstrates excellent room temperature stability, and all batch releases have met all phase-appropriate specifications.

We use three geographically-distributed CDMOs for drug product manufacturing. The THB001 drug product is a cost-effective and readily scaled solid oral dosage form in standard gelatin capsules. More than 100,000 capsules have been produced to date, which meet all release specifications. Excellent room temperature stability has been established for the THB001 drug product.

We expect to enter into commercial supply agreements with commercial manufacturers prior to any potential approval of THB001. We continue to develop a commercial route for THB001 manufacture in alignment with our program timeline. We believe our current manufacturers are able to supply the upcoming clinical trials and additional CDMOs may be on-boarded at later stages of clinical and commercial development.

Competition

We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunology and, furthermore, within the treatment of allergic and inflammatory conditions.

In addition to the current standard of care treatments for patients with allergic and inflammatory diseases, numerous commercial and academic nonclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates. There are numerous other competitive approaches, including inhibitors of activators of mast cells such as IgE antibodies like omalizumab, inhibitors of mediators such as anti-histamines and anti-IL-4 /IL-13 therapies, other small molecule approaches such as Bruton's tyrosine kinase inhibitors, and other small molecule and biologic KIT inhibitors, including Celldex's CDX-0159, a monoclonal antibody KIT inhibitor, among others.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain 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 commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

As with other biotechnology and pharmaceutical companies, our commercial success will depend in part on obtaining and maintaining patent protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending any such patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

The terms of individual patents depend upon the legal term of the 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, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug 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 provisions to extend the term of a

patent that covers an approved drug are available in Europe and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

In some instances, we have submitted and expect to submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

The ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our

employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see the section titled "Risk Factors—Risks Related to Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see the section titled "Risk Factors—Risks Related to Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

As of June 30, 2022, our overall patent portfolio contained eight patent families that collectively contain issued patents, pending provisional and non-provisional U.S. patent applications, PCT international patent applications, and pending patent applications in foreign jurisdictions. The patents and patent applications have claims relating to our current product candidate THB001, pharmaceutical compositions, methods of use, as well as claims directed to other KIT inhibitor compounds.

THB001

As of June 30, 2022, we exclusively licensed from Novartis a first patent family to THB001 containing patents and patent applications directed to compositions of matter and methods of use. This first patent family contains one patent in the United States, 67 patents, collectively, in Europe, Japan, Australia, Canada, China, Mexico and other foreign countries, as well as over six patent applications pending, collectively, in India, Thailand and other foreign countries. These U.S. and foreign patents, and any further foreign patents that may issue from these pending foreign patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in 2032, not including any patent term adjustment, patent term extension, or SPC.

As of June 30, 2022, we exclusively licensed from Novartis one patent family and solely own another patent family, each directed to certain physical forms of THB001 and having patent applications to compositions of matter and methods of use. The patent family that we exclusively license to certain physical forms of THB001 contains 16 patent applications, collectively, in the United States, Europe, Japan, Australia, Canada, China, Mexico and other foreign countries. Any U.S. or foreign patents that issue from these exclusively licensed patent

applications, if granted and all appropriate maintenance fees paid, are expected to expire in year 2040, not including any patent term adjustment, patent term extension, or SPC. Our solely owned patent family directed to certain physical forms of THB001 contains one pending international patent application and one pending U.S. patent application. Any U.S. or foreign patents that issue from these solely owned patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in year 2041, not including any patent term adjustment, patent term extension, or SPC.

As of June 30, 2022, we exclusively licensed from Novartis one patent family and solely own another patent family, each directed to certain pharmaceutical compositions containing THB001 and having patent applications to compositions of matter and methods of use. The patent family that we exclusively license to certain pharmaceutical compositions containing THB001 contains one pending international patent application, one pending U.S. patent application, and one pending patent application in Taiwan, whereby any U.S. or foreign patents that issue based on these exclusively licensed patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in year 2041, not including any patent term adjustment, patent term extension, or SPC. Our solely owned patent family directed to pharmaceutical compositions containing THB001 contains one pending international patent application, one pending U.S. patent application, and one pending patent application in Taiwan, whereby any U.S. or foreign patents that issue based on these solely owned patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in year 2041, not including any patent term adjustment, patent term extension, or SPC.

As of June 30, 2022, we solely owned one pending international patent application directed to methods of treatment using THB001 according to particular dosing protocols. Any U.S. or foreign patents that issue from a national phase patent application filed based on this international application, if granted and all appropriate maintenance fees paid, are expected to expire in year 2042, not including any patent term adjustment, patent term extension, or SPC. Additionally, as of June 30, 2022, we solely owned one pending U.S. provisional application directed to methods of treating certain indications using THB001. Any U.S. or foreign patents that issue from an application claiming priority to this provisional application, if granted and all appropriate maintenance fees paid, are expected to expire in the year 2043, not including any patent term adjustment, patent term extension, or SPC.

Additional KIT Inhibitor Compounds

As of June 30, 2022, we exclusively licensed one patent family from Novartis to additional KIT inhibitor compounds containing patents and patent applications directed to compositions of matter and methods of use. This patent family contains three patents in the United States, 21 patents, collectively, in Europe, Japan, Canada, China, Mexico and other foreign countries, as well as one patent application pending in India and two patent applications pending in Brazil. These U.S. and foreign patents, and any further foreign patents that may issue from these pending foreign patent applications, if granted and all appropriate maintenance fees paid, are expected to expire in 2032, not including any patent term adjustment, patent term extension, or SPC.

Government Regulation

Regulation Within the United States

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or FDC Act, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Nonclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, and ethics committee for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1a, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two

adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including: (i) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible; or (ii) when in conjunction with other confirmatory evidence.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fees for each prescription product. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. Most applications for standard review drug products are reviewed within ten to twelve months of the date of submission of the NDA to the FDA; most applications for priority review drugs are reviewed in six to eight months of the date of submission of the NDA to the FDA. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices, or cGMPs, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or

certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. FDA may grant full or partial waivers, or deferrals, for submission of data. With certain exceptions, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the FDA inspects

manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year period of exclusivity if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were

essential to the approval of the application. The FDA cannot approve an ANDA for a generic drug that includes the change during the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

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 clinical trials, commercial sales, and distribution of our products. Most countries outside of the United States require that clinical trial applications be submitted to and approved by the local regulatory authority for each clinical study. In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence clinical trials or marketing of the product in those countries. The approval process and requirements vary from country to country, so the number and type of nonclinical, clinical, and manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

Non-Clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the ICH guidelines on GCP as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries member states, the sponsor is liable to provide "no fault" compensation to any study subject injured in the clinical trial.

Marketing Authorization

To obtain marketing approval of a product under the EU regulatory system, we are mandated to submit a Marketing Authorization Application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. The centralized procedure, which came into operation in 1995, allows applicants

to obtain a marketing authorization that is valid throughout the EU. It is compulsory for medicinal products derived from biotechnological processes, designated orphan medicinal products, ATMPs such as gene therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance which was not authorized in the EU before May 20, 2004 (date of entry into force of Regulation (EC) No. 726/2004) and which are intended for the treatment of AIDS, cancer, neurodegenerative disorder, diabetes, auto immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for any other products containing new active substances not authorized in the EU before May 20, 2004 or for products which constitute a significant therapeutic, scientific, or technical innovation or for which the granting of authorization is in the interests of patients at the EU level. The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the Committee for Medicinal Products for Human Use, or CHMP, for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

When a company wishes to place on the market a medicinal product that is eligible for the centralized procedure, it sends an application directly to the EMA to be assessed by the CHMP. The CHMP is responsible for conducting the assessment of whether a medicine meets the required quality, safety, and efficacy requirements, and whether the product has a positive risk/benefit profile. The centralized procedure, as described below, culminates with a decision by the European Commission, which is valid in all EU member states. Centrally authorized products may be marketed in all member states.

Full copies of the MAAs are sent to a rapporteur and a co-rapporteur designated by the competent EMA scientific committee. They coordinate the EMA's scientific assessment of the medicinal product and prepare draft reports. Once the draft reports are prepared (other experts might be called upon for this purpose), they are sent to the CHMP, whose comments or objections are communicated to the applicant. The rapporteur is therefore the privileged interlocutor of the applicant and continues to play this role, even after the MAA has been granted.

The rapporteur and co-rapporteur then assess the applicant's replies, submit them for discussion to the CHMP, and taking into account the conclusions of this debate, prepare a final assessment report. Once the evaluation is completed, the CHMP gives a favorable or unfavorable opinion as to whether to grant the authorization. When the opinion is favorable, it will include the draft summary of the product's characteristics, the package leaflet, and the texts proposed for the various packaging materials. The time limit for the evaluation of a MAA by the EMA is 210 days (excluding clock stops). The EMA has fifteen days to forward its opinion to the European Commission. This is the start of the second phase of the procedure: the decision-making process. The EMA sends to the European Commission its opinion and assessment report, together with annexes containing: the SmPC (Annex 1); the particulars of the MAH responsible for batch release, the particulars of the manufacturer of the active substance, and the conditions of the marketing authorization (Annex 2); and the labelling and the package leaflet (Annex 3). The annexes are translated into the 22 other official languages of the EU. During the decision-making process, the European Commission services verify that the marketing authorization complies with EU law. The European Commission has fifteen days to prepare a draft decision. The medicinal product is assigned an EU registration number, which will be placed on its packaging if the marketing authorization is granted. During this period, various European Commission directorates-general are consulted on the draft marketing authorization decision.

The draft decision is then sent to the Standing Committee on Medicinal Products for Human Use, (member states have one representative in the Standing Committees on Medicinal Products for Human Use) for its opinions. The Centralized Procedure provides for the grant of a single marketing authorization that is valid for all EU member states. The Decentralized Procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one-member state, known as the reference member state. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to the public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

MAAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Under the Centralized Procedure and in exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops).

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving a MAA, reference product candidates generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MAA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MAA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MAA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Pediatric Development

A Pediatric Investigation Plan, or PIP, in the EU is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All MAAs for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorization holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines are available in the EU. Medicines authorized across the EU with the results of studies from a PIP included in the

product information are eligible for an extension of their supplementary protection certificate by six months (if any is in effect at the time of authorization). This is the case even when the studies' results are negative. For orphan medicines, the incentive is an additional two years of market exclusivity. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use marketing authorization, or PUMA. If a PUMA is granted, the product will benefit from ten years of market protection as an incentive.

In March 2016, the EMA launched an initiative, The Priority Medicines (PRIME) scheme, to facilitate development of product candidates that target an unmet medical need and are expected to be of major public health interest. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product 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, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Post-Approval Requirements

Similar to the United States, both MAA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MAA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

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. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each Member State and can differ from one country to another.

Brexit and the Regulatory Framework in the United Kingdom

The UK left the EU on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the UK during the transition period under the terms of the EU-UK Withdrawal Agreement. The transition period, which ended on December 31, 2020, maintained access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement, or TCA, and became effective on the January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation such as the EU CTR will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an "appropriate authority" to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain, or GB. Broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. The MHRA has published a guidance on how various aspects of the UK regulatory regime for medicines will operate in GB and in Northern Ireland following the expiry of the Brexit transition period on December 31, 2020. The guidance includes clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK. The new guidance was given effect via the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019, or the Exit Regulations. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MAA holder chooses to opt-out. In order to use the centralized procedure to obtain a MAA that will be valid throughout the EEA, companies must be established in the EEA. Therefore after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAAs. In order to obtain a UK MAA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a MAA to commercialize products in the UK. The MHRA may rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MAA when determining an application for a GB authorization or use the MHRA's decentralized or mutual recognition procedures which enable MAAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in GB.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, transparency and health information privacy laws and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or ACA, amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the Civil Monetary Penalties Law statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates and their subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates, their covered subcontractors and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not pre-empted by HIPAA.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule that requires certain manufacturers of prescription drugs to collect and annually report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data are made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, or that apply regardless of payor. In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Further, certain states

require the posting of information relating to clinical trials and their outcomes. Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Additionally, we may also be subject to state and foreign laws governing the privacy and security of health information in some circumstances, such as California's CCPA or Europe's General Data Protection Regulation, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that business arrangements with third parties comply with applicable state, federal and foreign healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also, beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

Coverage and Reimbursement

Patients in the U.S. and elsewhere generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Accordingly, market acceptance of THB001 or any future product candidates, if approved, will be dependent on the extent to which third-party coverage and reimbursement is available from third-party payors, including government health program administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid), private healthcare insurers and other healthcare funding organizations. Coverage and reimbursement policies for products can differ

significantly from payor to payor, as there is no uniform policy of coverage and reimbursement for products among commercial third-party payors in the United States. There also may be significant delays in obtaining coverage and reimbursement, as the process of determining coverage and reimbursement is often time consuming and can require health care providers to provide clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. In addition, the increased emphasis by such third-party payors and government authorities in the United States on managed care and cost containment measures will continue to place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for THB001 or any future product candidates, if approved, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees and Human Capital Resources

As of June 30, 2022, we had 16 employees, all of whom were full-time and nine of whom were engaged in research and development activities. Six of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

We are currently a remote-based company, and substantially all of our employees work remotely. We currently lease office space in Cambridge, Massachusetts from Atlas Venture Life Science Advisors, LLC on a monthly basis, but do not otherwise maintain a corporate headquarters. As we expand, we believe suitable additional or substitute space will be available as and when needed.

Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table provides information, including ages as of August 31, 2022, regarding our executive officers and directors:

Name	Age	Position
Executive Officers and Employee Directors:		
Natalie Holles	50	Chief Executive Officer and Director
Edward R. Conner, M.D.	49	Chief Medical Officer
Robert Ho	47	Chief Financial Officer
Julie Person	49	Chief Administrative Officer
Adrian S. Ray, Ph.D.	47	Chief Scientific Officer
Non-Employee Directors:		
Mark Iwicki(1)	55	Chairman of the Board, Director
David P. Bonita, M.D.(1)	47	Director
Michael Gladstone(1)	35	Director
Shao-Lee Lin, M.D., Ph.D.(3)	56	Director
Rob Perez(2)	58	Director
Jason Rhodes(4)	53	Director
H. Martin Seidel, Ph.D.(2)(3)	58	Director
Thomas M. Soloway(2)(3)	55	Director

(1) Member of the Compensation Committee.
(2) Member of the Audit Committee.
(3) Member of the Nominating and Governance Committee.
(4) Mr. Rhodes resigned from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Executive Officers and Employee Directors

Natalie Holles has served as our Chief Executive Officer and a member of our board of directors since August 2021. Prior to joining us, Ms. Holles worked at Audentes Therapeutics, Inc., or Audentes, serving as President and Chief Executive Officer from January 2020 through March 2021, President and Chief Operating Officer from May 2018 to January 2020 and Senior Vice President, Chief Operating Officer from August 2015 to May 2018. Previously, Ms. Holles served as Senior Vice President, Corporate and Business Development at Hyperion Therapeutics, Inc., from June 2013 through its acquisition by Horizon Pharma, plc in May 2015. From December 2010 to June 2013, Ms. Holles served as an independent life sciences corporate development consultant. Earlier in her career, Ms. Holles served as the Vice President, Business Development at KAI Pharmaceuticals, Inc., which was acquired by Amgen, Inc. in 2012, and previously held business development and commercial roles at InterMune, Inc. and Genentech, Inc. In addition to serving on our board of directors, Ms. Holles also currently serves on the board of Day One Biopharmaceuticals, Inc. since January 2021. Formerly, Ms. Holles served on the board of directors of Rubius Therapeutics, Inc. from March 2019 to August 2022 and Allakos Inc. from December 2020 to August 2021. Ms. Holles holds a B.A. in human biology from Stanford University and an M.A. in molecular, cellular and developmental biology from the University of Colorado, Boulder. We believe Ms. Holles is qualified to serve on our board of directors because of her operational leadership and business development experience.

Edward R. Conner, M.D. has served as our Chief Medical Officer since June 2022. Dr. Conner previously served as Chief Medical Officer of Locanabio, Inc., or Locanabio, from July 2021 until June 2022. Prior to joining Locanabio, Dr. Conner was the Site Lead and Division Head of Gene Therapy Medical & Development at Astellas Gene Therapies, or Astellas, from January 2020 to July 2021. Before Astellas, Dr. Conner served as the Chief Medical Officer and Senior Vice President of Audentes (now Astellas Gene Therapies) from July 2019 to January 2020. Dr. Conner previously served as Chief Medical Officer and Senior Vice President at Sangamo

Therapeutics, Inc. from November 2016 until May 2019, and as Vice President, Clinical Development of Ultragenyx Pharmaceutical Inc. from January 2015 until October 2016. Earlier in his career, Dr. Conner also served as the Senior Medical Director at BioMarin Pharmaceutical Inc. from November 2013 to December 2014 and as Medical Director at Genentech, Inc. (now a member of the Roche Group) from June 2008 to October 2013. In these roles, Dr. Conner led functions including clinical development and operations, medical affairs, regulatory, drug safety and patient advocacy. Dr. Conner has been a member of the board of directors of Imara Inc. since April of 2020. Dr. Conner holds a B.S. in biology from Duke University and an M.D. from the University of California, San Francisco.

Robert Ho has served as our Chief Financial Officer since March 2022. Prior to joining us, Mr. Ho worked at Neoleukin Therapeutics, Inc. serving as Chief Financial Officer from March 2020 to March 2022. Mr. Ho served in various positions at Davita Inc., including most recently as Senior Finance Director from January 2016 to March 2020. Prior to that, and a one-year break in service, Mr. Ho served as Strategic Financial Advisor to a privately owned company from February 2007 to December 2014. Mr. Ho also served in various positions at Morgan Stanley from March 2004 to February 2007, including most recently as a Vice President in the Healthcare Investment Banking Division. Mr. Ho holds a B.B.A. in accountancy and computer applications from the University of Notre Dame and an M.B.A. from the University of Virginia Darden School of Business.

Julie Person has served as our Chief Administrative Officer since June 2022. Ms. Person served as the Chief People Officer of Neumora Therapeutics, Inc., or Neumora, from January 2021 until June 2022. Prior to joining Neumora, Ms. Person was the Senior Vice-President of Human Resources at Audentes from April 2020 to January 2021 and the Vice-President of Human Resources at Sangamo Therapeutics, Inc. from March 2019 to April 2020. Ms. Person also served as Vice President Talent and Organization Development at Shire plc (now Takeda Pharmaceutical Co Ltd) from February 2017 until March 2019, and as its Vice President of Global Head of Talent Management from June 2016 until February 2017. Ms. Person earned a B.A. in Communications from the Saint Mary's College of California and attended the University of Michigan Ross School of Business Executive Leadership Program.

Adrian S. Ray, Ph.D. has served as our Chief Scientific Officer since April 2022. Prior to joining us, Dr. Ray worked at Morphic Therapeutic Inc. serving as the Senior Vice President of Biology and Translation from February 2020 through March 2022, and Vice President and Head of Translational Sciences from November 2018 through February 2020. Dr. Ray served as Senior Vice President of Discovery Biology at Nimbus Therapeutics from May 2018 to October 2018. Prior to that, Dr. Ray held positions of increasing responsibility in research and development at Gilead Sciences, Inc. from June 2002 to May 2018, serving most recently as Senior Director Clinical Research from October 2016 to May 2018. Dr. Ray holds a B.A. in molecular, cellular and developmental biology from the University of California, Santa Cruz and a Ph.D. in molecular, cellular, and developmental biology from Yale University.

Non-Employee Directors

Mark Iwicki has served as Chairman of our board of directors since May 2020. Mr. Iwicki also currently serves as Chief Executive Officer and Executive Chairman of the board of directors of Kala Pharmaceuticals, Inc., since March 2015. Prior to joining Kala Pharmaceuticals, Mr. Iwicki served as President and Chief Executive Officer of Civitas Therapeutics, Inc. from January 2014 to November 2014. Prior to Civitas, Mr. Iwicki served as President and Chief Executive Officer at Tarveda Therapeutics, Inc. (formerly known as Blend Therapeutics, Inc.) from December 2012 to January 2014. Prior to Blend, Mr. Iwicki was President and Chief Executive Officer of Sunovion Pharmaceuticals Inc. (formerly known as Sepracor Inc.) from October 2007 to June 2012. Prior to joining Sunovion, Mr. Iwicki was Vice President and Business Unit Head at Novartis Pharmaceuticals Corporation from March 1998 to October 2007. Prior to that, Mr. Iwicki held sales positions at Astra Merck Inc. and Merck & Co., Inc. In addition to serving on our board of directors, Mr. Iwicki also currently serves on the boards of Merus N.V., Pulmatrix Inc., Akero Therapeutics, Inc., Aerovate Therapeutics, Inc., and Kala Pharmaceuticals, Inc. In the past five years, Mr. Iwicki also served on the Aimmune Therapeutics,

Inc. board of directors. Mr. Iwicki holds a B.S. in marketing from Ball State University and an M.B.A. from Loyola University Maryland. We believe that Mr. Iwicki is qualified to serve on our board of directors because of his extensive experience as a pharmaceutical industry leader managing all stages of drug development and commercialization in multiple therapeutic areas.

David P. Bonita, M.D. has served as a member of our board of directors since July 2020. Dr. Bonita is currently a member at OrbiMed Advisors LLC, an investment firm, where he has served in various roles of increasing responsibility since 2004. Dr. Bonita currently serves on the boards of directors of Acutus Medical, Inc., Ikena Oncology, Inc., IMARA Inc., Prelude Therapeutics, Inc., Repare Therapeutics Inc., and Tricida, Inc., as well as several private companies. Dr. Bonita previously served on the boards of directors of several companies, including Clementia Pharmaceuticals Inc., Loxo Oncology, Inc., SI-BONE Inc., and ViewRay Inc. Dr. Bonita has also worked as a corporate finance analyst in the healthcare investment banking groups of Morgan Stanley and UBS. He has published scientific articles in peer-reviewed journals based on signal transduction research performed at the Harvard Medical School. He received his A.B. in Biological Sciences from Harvard University and his joint M.D./M.B.A. from Columbia University. We believe Dr. Bonita is qualified to serve on our board of directors because of his operational and business development experience.

Michael Gladstone has served as a member of our board of directors since April 2019. Mr. Gladstone previously served as our Chief Executive Officer from June 2019 through August 2021. He is a partner at Atlas Venture. Prior to joining Atlas in March 2012, Mr. Gladstone worked at L.E.K. Consulting from December 2009 through March 2012, and previously, he conducted HIV vaccine research in the Viral Pathogenesis department of Beth Israel Deaconess Medical Center. Mr. Gladstone is a member of the Corporate Advisory Committee for National Tay Sachs and Allied Diseases and serves as an advisor to several other organizations. Since December 2019, Mr. Gladstone has served as a member of the board of directors of Day One Biopharmaceuticals, Inc. Gladstone holds an B.S. in biochemical sciences from Harvard University. We believe Mr. Gladstone is qualified to serve on our board of directors because of his extensive experience in the field of biotechnology.

Shao-Lee Lin, M.D., Ph.D. has served as a member of our board of directors since September 2020. Dr. Lin co-founded and currently serves as the Chief Executive Officer of ACELYRIN, Inc. since its formation in July 2020. From January 2018 to January 2020, Dr. Lin served as Executive Vice President, Research and Development and Chief Scientific Officer at Horizon Pharma plc. From March 2015 to December 2017, Dr. Lin served as a corporate officer and Vice President of Therapeutic Areas, Development Excellence and International Development at Abbvie Inc. Prior to Abbvie, Dr. Lin served as Vice President, Inflammation and Respiratory Development at Gilead Sciences from August 2012 to February 2015 and served in various roles of increasing responsibility at Amgen, Inc. from April 2004 to August 2012. In addition to serving on our board of directors, Dr. Lin has served on the Surrozen, Inc. board of directors since January 2021, and formerly served on the board of directors of Principia Biopharma Inc., from April 2019 until it was acquired in September 2020. Dr. Lin also serves as a Clinical Scholar at The Rockefeller University and adjunct faculty at the medical schools of Cornell University, The University of California, Los Angeles, Stanford University and Northwestern University. Dr. Lin received her B.A. in biochemistry and chemical engineering from Rice University and holds a joint M.D./Ph.D in medicine and biochemistry from Johns Hopkins University. We believe that Dr. Lin's scientific training, work experience, and experience as a director of other publicly traded biopharmaceutical companies provide her with the qualifications and skills to serve on our board of directors.

Rob Perez has served as a member of our board of directors since December 2021. He has served as an Operating Partner at General Atlantic Service Company, L.P. since January 2019. Prior to that, Mr. Perez served as a Managing Director of Vineyard Sound Advisors, LLC from March 2015 through January 2019. Previously, Mr. Perez worked at Cubist Pharmaceuticals, Inc, from October 2003 to January 2015, where he served as Chief Commercial Officer, Chief Operations Officer, President and Chief Executive Officer at the time of its sale to Merck & Co., Inc. in January 2015. Before joining Cubist, he worked at Biogen Inc. from June 1995 until October 2003, where he served in various commercial roles, including as Vice President of Biogen's CNS Business Unit. Mr. Perez has served as a board member for Unum Therapeutics, Inc. since March 2018, Spark

Therapeutics, Inc. since January 2018 and AMAG Pharmaceuticals, Inc. since February 2009. Mr. Perez holds a joint B.S./B.A. in business from California State University, Los Angeles and an M.B.A. from the Anderson Graduate School of Management at the University of California, Los Angeles. We believe Mr. Perez is qualified to serve on our board of directors because of his operational and business development experience.

Jason Rhodes has served as a member of our board of directors since June 2019. Mr. Rhodes has been a partner at Atlas Venture since 2014. He was the chairman and founding Chief Executive Officer of Disarm Therapeutics, which was acquired by Eli Lilly in 2020. Mr. Rhodes has served as the chairman and the founding Chief Executive Officer of Generation Bio since 2016, and Dyne Therapeutics since 2018. He has served as a board member for Replimune Group Inc. since 2015, and Gemini Therapeutics, Inc. since 2016. Mr. Rhodes received his B.A. from Yale University and his M.B.A. from the Wharton School of the University of Pennsylvania. We believe Mr. Rhodes is qualified to serve on our board of directors because of his extensive experience in the field of biotechnology and as a director of other publicly traded biopharmaceutical companies.

H. Martin Seidel, Ph.D. has served as a member of our board of directors since July 2019. Dr. Seidel has served as Chief Executive Officer of IFM Therapeutics since December 2019, after serving as Executive Vice President of Research and Development since June 2017. Prior to IFM Therapeutics, Dr. Seidel served as Global Head Global Head of Strategic Alliances for the Novartis Institutes for Biomedical Research from March 2014 through June 2017. Prior to that, Dr. Seidel held positions of increasing responsibility at of NIBR's Genomics Institute of the Novartis Research Foundation from 2003 through 2014, ultimately serving as Institute Director and Site Head from 2010 to 2014. Dr. Seidel received his B.A. in chemistry from Princeton University and his Ph.D. from Harvard University. We believe Dr. Seidel is qualified to serve on our board of directors because of his extensive research and operational experience.

Thomas M. Soloway has served as a member of our board of directors since July 2022. Since December 2020, Mr. Soloway has served as the Chief Executive Officer and a member of the board of directors of T-Knife Therapeutics, Inc. From September 2015 to September 2020, he held positions of increasing responsibility at Audentes, ultimately serving as Executive Vice President, Chief Financial Officer. Previously, Mr. Soloway served as Senior Vice President, Chief Financial Officer of Ascendis Pharma A/S, or Ascendis, a biopharmaceutical company, from January 2014 until September 2015. Prior to Ascendis, Mr. Soloway co-founded Transcept Pharmaceuticals, Inc., or Transcept, in 2002, where he held positions of increasing responsibility, serving initially as Senior Vice President, Operations and Chief Financial Officer and subsequently as Executive Vice President, Chief Operating Officer until December 2013. Prior to Transcept, Mr. Soloway was a Principal at Montreux Equity Partners, a venture capital firm focused on providing growth capital for early-stage healthcare and life sciences companies. Since July 2020, Mr. Soloway has also served on the board of Satsuma Pharmaceuticals, Inc., a biopharmaceutical company. He holds a B.S. in Entrepreneurial Studies from the University of Southern California and an M.B.A. from Georgetown University. We believe that Mr. Soloway is qualified to serve on our board of directors based on his over 25 years of experience in the life sciences industry, with senior roles in strategy, operations, corporate finance and venture capital.

Election of Executive Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Board Composition

Our board of directors currently consists of eight members. Seven of our directors are independent within the meaning of the independent director guidelines of Nasdaq. Pursuant to our current certificate and our amended and restated voting agreement, as amended, Natalie Holles, Mark Iwicki, David P. Bonita, M.D., Michael Gladstone, Shao-Lee Lin, Rob Perez, H. Martin Seidel and Thomas M. Soloway have been designated to

serve as members of our board of directors. The amended and restated voting agreement, as amended, and the provisions of our current certificate that govern the election and designation of our directors will terminate in connection with this offering, after which no contractual obligations will concern the election of our directors.

Classified Board of Directors

In accordance with the terms of our restated certificate of incorporation and restated bylaws that will become effective upon the completion of this offering, our board of directors will be divided into three staggered classes of directors. At each annual meeting of our stockholders, a class of directors will be subject to re-election for a three-year term. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

Our directors will be divided among the three classes as follows:

- the Class I directors will be Mark Iwicki, Natalie Holles and Rob Perez, and their terms will expire at the first annual meeting of our stockholders held following the completion of the offering;
- the Class II directors will be Michael Gladstone, Shao-Lee Lin and H. Martin Seidel, and their terms will expire at the second annual meeting of our stockholders held following the completion of the offering; and
- the Class III directors will be David Bonita and Thomas M. Soloway and their terms will expire at the third annual meeting of our stockholders held following the completion of the offering.

Each director's term continues until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Our restated certificate of incorporation and restated bylaws that will be in effect upon the completion of this offering authorize only our board of directors to fill vacancies on our board of directors. 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. See the section titled "Description of Capital Stock—Anti-Takeover Provisions—Restated Certificate of Incorporation and Restated Bylaw Provisions" for additional information.

Director Independence

In connection with this offering, we have been approved to list our common stock on Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within a specified period following the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (ii) be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 as of the completion of this offering. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Ms. Holles, are "independent directors" as defined under the current Nasdaq listing standards and SEC rules and regulations. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them as described in the section titled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and governance committee, each of which will have the composition and responsibilities described below as of the completion of this offering. Each of the below committees has a written charter approved by our board of directors. Upon completion of this offering, copies of each charter will be posted on the investor relations page of our website. Members that serve on these committees will serve until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee is comprised of Rob Perez, H. Martin Seidel, Ph.D. and Thomas M. Soloway, with Mr. Soloway serving as the chairperson of our audit committee. Our board of directors has determined that the composition of our audit committee meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations, and that each member of our audit committee is financially literate. In addition, our board of directors has determined that Mr. Soloway is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on him or her any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors.

Our audit committee is directly responsible for, among other things:

- selecting and hiring our independent registered public accounting firm;
- the qualifications, independence and performance of our independent registered public accounting firm;
- the preparation of the audit committee report to be included in our annual proxy statement;
- our compliance with legal and regulatory requirements;
- assisting our board of directors with risk assessment and management, including cybersecurity risk management;
- our accounting and financial reporting processes, including our financial statement audits and the integrity of our consolidated financial statements; and
- reviewing and approving related-person transactions.

Compensation Committee

Our compensation committee is comprised of Mark Iwicki, David P. Bonita, M.D. and Michael Gladstone, with Mr. Iwicki serving as the chairperson of our compensation committee. Our board of directors has determined that each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations.

Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and
- overseeing our compliance with regulatory requirements associated with the compensation of directors, executive officers and employees.

Nominating and Governance Committee

Our nominating and governance committee is comprised of Shao-Lee Lin, M.D., Ph.D., H. Martin Seidel, Ph.D. and Thomas M. Soloway, with Dr. Lin, M.D., Ph.D. serving as the chairperson of our nominating and governance committee. Our board of directors has determined that each member of our nominating and governance committee meets the requirements for independence under the current Nasdaq listing standards.

Our nominating and governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on environmental, social and other corporate governance matters.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has been an officer or employee of our Company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions) of any entity that has one or more of its executive officers serving on our board of directors or compensation committee. See the section titled “Certain Relationships and Related Party Transactions” for additional information. Prior to establishing the compensation committee, our full board of directors made decisions relating to the compensation of our officers.

Code of Business Conduct and Ethics

Prior to the completion of this offering, our board of directors will adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including our President and Chief Executive Officer and other executive and senior officers. The full text of our code of business conduct and ethics will be

posted on the investor relations page of our website. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules.

Non-Employee Director Compensation

Our employee directors have not received any compensation or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) for their services as directors for the year ended December 31, 2021.

The following table sets forth information concerning the compensation paid to certain of our non-employee directors for the year ended December 31, 2021:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1] [2]	All Other Compensation ($)	Total ($)
Mark Iwicki	25,000	6,027	—	31,027
David P. Bonita, M.D.	—	—	—	—
Michael Gladstone	—	—	—	—
Shao-Lee Lin, M.D., Ph.D.	25,000	4,018	—	29,018
Rob Perez	—	—	—	—
Jason Rhodes	—	—	—	—
H. Martin Seidel, Ph.D.	25,000	4,018	—	29,018

(1) Amounts reflect the full grant date fair value of awards of stock or options granted for the year ended December 31, 2021 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual.
(2) As of December 31, 2021, Mr. Iwicki held an aggregate of 4,299 options to purchase common stock, Dr. Lin held an aggregate of 88,619 options to purchase common stock and Dr. Seidel held an aggregate of 2,866 options to purchase common stock. None of our other non-employee directors held equity as of December 31, 2021.

Non-Employee Director Compensation Policy

Prior to this offering, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service as directors.

In connection with this offering, our board of directors approved the following non-employee director compensation policy.

Following the completion of this offering, each non-employee director will be entitled to receive cash and options under our 2022 Plan.

Cash Retainer. Cash compensation payable to each non-employee director shall consist of the following annual fees, which shall be paid quarterly in arrears and shall be pro-rated for partial quarters served, including for the initial quarter in which this policy is adopted: (i) an annual cash retainer of $40,000; (ii) $15,000, $10,000 or $8,000 if the individual is the chair of the Audit Committee, the Compensation Committee or the Nominating and Governance Committee, respectively; (iii) $7,500, $5,000 or $4,000 if the individual is a member (but not chair) of the Audit Committee, the Compensation Committee or the Nominating and Governance Committee, respectively; (iii) $30,000 if the individual is a chair of our board of directors; and (iv) between $15,000 and $30,000 if the individual is a lead independent director on our board of directors.

Initial Award Option Grant. Following the completion of this offering, each non-employee director newly appointed to our board of directors following this offering will be granted options to purchase shares of our

common stock, or Initial Award Options, on the date of his or her appointment to our board of directors with an aggregate value of $440,000. The Initial Award Options will vest in equal monthly installments over a period of three years from the grant date, so long as the non-employee director continues to provide services to us through each such date. The Initial Award Options will fully vest upon the consummation of a corporate transaction (as defined in the 2022 Plan).

If an individual is appointed as a non-employee director at an annual meeting of stockholders, he or she will be granted an Initial Award Option in lieu of the Annual Option Grant, as described below.

Annual Option Grant. Each non-employee director who is serving on our board of directors and who continues to serve on our board of directors following an annual meeting of our stockholders will automatically be granted, on an annual basis, options to purchase shares of common stock, or Annual Options, under our 2022 Plan with an aggregate value of $220,000. The Annual Options will vest on the earlier of (i) the date of the next annual meeting of our stockholders and (ii) the date that is one year following the Annual Option grant date, in each case so long as the non-employee director continues to provide services to us through such date. In addition, the Annual Options will fully vest upon the consummation of a corporate transaction (as defined in the 2022 Plan).

Employee directors will receive no additional compensation for their service as a director.

Non-Employee Director Compensation Limits. No non-employee director may receive equity awards under our 2022 Plan with an aggregate grant date fair value (determined as set forth in the 2022 Plan) that, when combined with cash compensation received for service as a non-employee director, exceeds $1,000,000 in any calendar year, or in the case of the first year of such individual's service with the Company as a non-employee director, $1,500,000.

EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure set forth information about the compensation earned by our named executive officers during the year ended December 31, 2021. Our named executive officers, who are our principal executive officer, former principal executive officer, and the two most highly compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2021, were:

- Natalie Holles, Chief Executive Officer;
- Howard E. Davis, Jr., Ph.D., Former Chief Operating Officer;
- Stephen Yoo, M.D., Former Chief Medical Officer; and
- Michael Gladstone, Former Chief Executive Officer.

Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to, earned by or paid to our named executive officers for the year ended December 31, 2021.

Name and Principal Position	Salary($)	Bonuses ($)	Non-Equity Incentive Plan Compensation ($)[1]	Option Awards ($)[2]	All Other Compensation ($)	Total($)
Natalie Holles[3] *Chief Executive Officer*	197,115	—	109,247	1,743,965	—	2,025,920
Howard E. Davis, Jr., Ph.D. [4] *Former Chief Operating Officer*	336,734	—	129,310	13,244	—	479,101
Stephen Yoo, M.D. [5] *Former Chief Medical Officer*	398,438	—	152,899	16,810	—	567,911
Michael Gladstone[6] *Former President and Chief Executive Officer*	—	—	—	—	—	—

(1) For additional information regarding the non-equity incentive plan compensation, see the section titled "Annual Performance-Based Bonuses."
(2) Represents the grant date fair value of options awarded during the year ended December 31, 2021 as computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option award column are set forth in Note 8 to our consolidated financial statements included elsewhere in this prospectus. Note that the amounts reported in this column reflect the aggregate accounting cost for these awards, and do not necessarily correspond to the actual economic value that may be received by each named executive officer from the options.
(3) Ms. Holles was appointed as the Chief Executive Officer on August 9, 2021. The salary reported reflects the pro rata portion of Ms. Holles' annual salary of $500,000 earned from commencement of her employment through December 31, 2021.
(4) Dr. Davis served as our Chief Operating Officer until May 2022.
(5) Dr. Yoo served as our Chief Medical Officer until May 2022.
(6) Mr. Michael Gladstone previously served as our President and Chief Executive Officer from June 4, 2019 to August 9, 2021. Mr. Gladstone did not receive any compensation for his service as our Chief Executive Officer.

Annual Performance-Based Bonuses

Annual bonuses for our executive officers are based on the achievement of corporate and individual performance objectives. For the 2021 bonuses, the corporate performance objectives included certain development goals and milestones. The 2021 target bonus amounts, expressed as a percentage of annual base salary, for Ms. Holles, Dr. Davis and Dr. Yoo were 50%, 35% and 35%, respectively. In February, our board of directors met to review performance against the 2021 bonus goals and approved cash bonuses for the named executive officers in the amounts set forth in the "Non-Equity Incentive Plan Compensation" column of the "Summary Compensation Table" above.

Outstanding Equity Awards at 2021 Fiscal Year-End Table

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each of our named executive officers as of December 31, 2021.

		Option Awards				Stock Awards	
Name	Grant Date[1]	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested(#)	Market Value of Shares of Units of Stock That Have Not Vested($)[2]
Natalie Holles	08/09/2021[3]	—	—	—	—	1,076,178	9,918,835
Chief Executive Officer	08/09/2021[4]	—	—	—	—	142,658	1,314,841
Howard E. Davis, Jr., Ph.D.	06/01/2020[5]	—	—	—	—	174,189	1,605,443
Former Chief Operating Officer	04/02/2021[6]	—	9,316	1.44	04/01/2031	—	—
Stephen Yoo, M.D.	09/26/2019[7]	—	—	—	—	135,988	1,253,339
Former Chief Medical Officer	06/07/2020[8]	—	—	—	—	28,753	264,996
	04/02/2021[9]	—	11,824	1.44	04/01/2031	—	—
Michael Gladstone	—	—	—	—	—	—	—
Former President and Chief Executive Officer							

(1) All outstanding equity awards were granted under the 2019 Plan.
(2) There was no public market for our common stock as of December 31, 2021. The fair market value of our common stock as of December 31, 2021, as determined by an independent valuation, was $9.21 per share.
(3) Represents a restricted stock award subject to our right of repurchase. The repurchase right lapses pursuant to the stock award's vesting schedule, which is as follows: 25% of the shares underlying the stock award shall vest on August 9, 2022 and the remaining 75% of the shares underlying the stock award vest in equal quarterly installments over 36 months thereafter, subject to Ms. Holles' continued service to us.
(4) Represents a restricted stock award subject to our right of repurchase. The repurchase right lapses pursuant to the stock award's vesting schedule, which is as follow: following the date of our Series A-2 Preferred Stock Financing, (i) 35,664 of the shares underlying the stock award shall vest on August 9, 2021, and (ii) 106,994 of the shares underlying the stock award vest in equal quarterly installments over 36 months thereafter, subject to Ms. Holles' continued service to us.
(5) Represents a restricted stock award subject to our right of repurchase as to the unvested portion. The repurchase right lapses pursuant to the stock award's vesting schedule, which is as follows: 25% of the shares underlying the stock award vested on June 1, 2021 and the remaining 75% of the shares underlying the stock award vest in equal quarterly installments over 36 months thereafter, subject to Dr. Davis' continued service to us.
(6) The vesting schedule for the option is as follows: the option shall vest in equal quarterly installments of 6.25% until the fourth anniversary of the Second Tranche Closing (as defined in the Series A-3 Preferred Stock Purchase Agreement dated as of February 24, 2021), with the first quarterly installment vesting on the date three months after the Second Tranche Closing, subject to Dr. Davis' continued service to us.
(7) Represents a restricted stock award subject to our right of repurchase as to the unvested portion. The repurchase right lapses pursuant to the stock award's vesting schedule, which is as follows: 25% of the shares underlying the stock award vested on September 30, 2020 and the remaining 75% of the shares underlying the stock award vest in equal quarterly installments over 36 months thereafter, subject to Dr. Yoo's continued service to us.
(8) Represents a restricted stock award subject to our right of repurchase as to the unvested portion. The repurchase right lapses pursuant to the stock award's vesting schedule, which is as follows: 6% of the shares underlying the stock award vested on September 30, 2020 and the remaining 92% of the shares underlying the stock award vest in equal quarterly installments over 44 months thereafter, subject to Dr. Yoo's continued service to us.
(9) The vesting schedule for the option is as follows: the option shall vest in equal quarterly installments of 6.25% until the fourth anniversary of the Second Tranche Closing (as defined in the Series A-3 Preferred Stock Purchase Agreement dated as of February 24, 2021), with the first quarterly installment vesting on the date three months after the Second Tranche Closing, subject to Dr. Yoo's continued service to us.

Employment Agreements

Natalie Holles Employment Offer Letter Agreement

We are party to an offer letter agreement with Natalie Holles, dated August 24, 2022 (the "Holles Offer Letter"), which amends and restates her employment agreement with us dated July 2, 2021. Pursuant to the Holles Offer Letter, Ms. Holles is an "at-will" employee without a set term and entitled to an annualized initial base salary of $500,000, and eligible for an annual incentive bonus of up to 50% of her annualized base salary. Additionally, we have paid Ms. Holles a one-time special bonus of $1,867,102 (the "Special Bonus"). The Special Bonus is subject to a three-year vesting schedule with six-month cliffs, as well as her continued

employment with us on the relevant vesting dates, and was paid to offset Ms. Holles' tax liability as a result of the forgiveness of the promissory note from Ms. Holles prior to the filing of this registration statement. See the section titled "Certain Relationships and Related Party Transactions—Loans to Executive Officers" for additional information.

Potential Payments upon Termination and Change of Control

In connection with this offering, in July 2022, our board of directors approved the terms of an Executive Officer Severance Policy, to be effective upon the completion of this offering. Under this policy, each of our officers, including our named executive officers, has entered or will enter into a participation agreement pursuant to which he or she will become a beneficiary of our Executive Officer Severance Policy, or the COC Policy.

Pursuant to the COC Policy and her participation agreement, in the event that our Chief Executive Officer is terminated without "cause" or resigns for "good reason" (A) within three months before or (B) 12 months following a "change of control" of the Company, but as to part (A) only if the "separation" occurs after a "potential change in control" (as such terms are defined in the COC Policy), Natalie Holles will be entitled to: (i) an amount equal to 18 months of her base salary at the rate in effect immediately prior to such termination; (ii) an amount equal to 150% of her target bonus in effect immediately prior to such termination; (iii) a pro-rata portion of her annual bonus for the fiscal year in which her termination occurs; (iv) the Special Bonus will accelerate and become fully vested, with the payments mentioned in (i) to (iii) to be paid in a cash lump sum; and (v) to the extent she timely elects to receive continued coverage under our group healthcare plans, we will pay the full cost of such continued coverage for a period ending on the earlier of (x) 18 months following the termination date and (y) the date that she becomes eligible for coverage under another employer's plans. In addition, each of the Chief Executive Officer's outstanding equity awards, excluding awards that would otherwise vest upon satisfaction of performance criteria (including, for the avoidance of doubt, any awards subject to both performance-based and time-based vesting criteria), will become vested and exercisable, as applicable, with respect to 100% of the underlying shares subject to time-based vesting. For the avoidance of doubt, any outstanding equity awards subject to performance-based vesting will continue to be subject to the applicable performance-based vesting condition set forth in such equity award. All such severance payments, benefits and vesting acceleration are subject to each named executive officer's execution of a general release of claims against us.

Additionally, in the event that our Chief Executive Officer is terminated without "cause" or resigns for "good reason" outside of the period three months before or 12 months after a "change of control" (as such terms are defined in the COC Policy), Ms. Holles will be entitled to (i) an amount equal to 12 months of her base salary at the rate in effect immediately prior to such termination to be received in equal installments over 12 months; (ii) a pro-rata portion of her annual bonus for the fiscal year in which her termination occurs to be paid in a cash lump sum; and (iii) to the extent she timely elects to receive continued coverage under our group healthcare plans, we will pay the full cost of such continued coverage for a period ending on the earlier of (x) 12 months following the termination date and (y) the date that she becomes eligible for coverage under another employer's plans. In addition, each of the Chief Executive Officer's outstanding equity awards, excluding awards that would otherwise vest upon satisfaction of performance criteria (including, for the avoidance of doubt, any awards subject to both performance-based and time-based vesting criteria) will become vested and exercisable, as applicable, with respect to 12 additional months of vesting credit of the underlying shares subject to time-based vesting. For the avoidance of doubt, any outstanding equity awards subject to performance-based vesting will continue to be subject to the applicable performance-based vesting condition set forth in such equity award. All such severance payments, benefits and vesting acceleration are subject to the chief executive officer's execution of a general release of claims against us.

In the event that an executive officer of the Company (other than the Chief Executive Officer) is terminated without "cause" or resigns for "good reason" (A) within three months before or (B) 12 months following a "change of control" of the Company, but as to part (A) only if the "separation" occurs after a "potential change in

control" (as such terms are defined in the COC Policy), such executive officer will be entitled to: (i) an amount equal to 12 months of his or her base salary at the rate in effect immediately prior to such termination; (ii) an amount equal to 100% of his or her target bonus in effect immediately prior to such termination with the payments mentioned in (i) and (ii) to be paid in a cash lump sum; and (iii) to the extent he or she timely elects to receive continued coverage under our group healthcare plans, we will pay the full cost of such continued coverage for a period ending on the earlier of (x) 12 months following the termination date and (y) the date that he or she becomes eligible for coverage under another employer's plans. In addition, each of the executive officer's outstanding equity awards, excluding awards that would otherwise vest upon satisfaction of performance criteria (including, for the avoidance of doubt, any awards subject to both performance-based and time-based vesting criteria) will become vested and exercisable, as applicable, with respect to 100% of the underlying shares subject to time-based vesting. For the avoidance of doubt, any outstanding equity awards subject to performance-based vesting will continue to be subject to the applicable performance-based vesting condition set forth in such equity award. All such severance payments, benefits and vesting acceleration are subject to such executive officer's execution of a general release of claims against us.

Additionally, in the event that an executive officer (other than the Chief Executive Officer) is terminated without "cause" or resigns for "good reason" outside of the period three months before or 12 months after a "change of control" (as such terms are defined in the COC Policy), he or she will be entitled to (i) an amount equal to 9 months of his or her base salary at the rate in effect immediately prior to such termination, to be received in equal installments over 9 months and (ii) to the extent he or she timely elects to receive continued coverage under our group healthcare plans, we will pay the full cost of such continued coverage for a period ending on the earlier of (x) 9 months following the termination date and (y) the date that he or she becomes eligible for coverage under another employer's plans. All such severance payments and benefits are subject to such named executive officer's execution of a general release of claims against us.

Equity Compensation Plans and Other Benefit Plans

We believe that our ability to grant equity-based awards is a valuable compensation tool that enables us to attract, retain and motivate our employees, consultants and directors by aligning their financial interests with those of our stockholders. The principal features of our equity plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2019 Stock Incentive Plan

Our 2019 Plan was initially adopted by our board of directors and approved by our stockholders in June 2019. The 2019 Plan was amended most recently on August 9, 2022.

Share Reserve. As of August 26, 2022, we had 5,317,559 shares of our common stock reserved for issuance pursuant to grants under our 2019 Plan, of which 1,036,951 remained available for grant. As of August 26, 2022, no options to purchase shares of common stock had been exercised and options to purchase 1,884,197 shares remained outstanding, with a weighted-average exercise price of $7.55 per share. As of August 26, 2022, 2,396,410 shares of restricted stock granted under our 2019 Plan were outstanding, of which 1,286,653 shares remain subject to repurchase. No other types of awards have been granted under the 2019 Plan. The 2019 Plan terminated on the date that the 2022 Plan became effective (as described below) and no additional grants will be made pursuant to the 2019 Plan following its termination. However, any outstanding options and shares of restricted stock will remain outstanding until they are exercised, as applicable, or are terminated in accordance with the terms of the 2019 Plan and the applicable award agreements evidencing such awards.

Administration. Our board of directors, or a committee thereof appointed by our board of directors, referred to as the Committee, administers the 2019 Plan and the awards granted thereunder. Subject to the terms of the

2019 Plan, the Committee has the authority to, among other things, select the persons to whom awards will be granted, construe and interpret our 2019 Plan as well as to amend, modify, suspend or terminate rules and regulations relating to the 2019 Plan.

Eligibility. The 2019 Plan provides for the grant of both Incentive Stock Options (ISOs), within the meaning of Section 422 of the Code, which qualify for favorable tax treatment to their recipients under the Code, and Nonqualified Stock Option (NQSOs), as well as for the issuance of Restricted Stock Units (RSUs), Stock Appreciation Rights (SARs), Restricted Stock and other stock-based awards (as defined in the 2019 Plan). We may grant ISOs only to our employees. We may grant NQSOs, RSUs, SARs, Restricted Stock and other stock-based awards to our employees, officers, directors, advisors and consultants (as such terms consultants and advisors are defined and interpreted for purposes of Rule 701 under the Securities Act of 1933, as amended (or any successor rule)). Only stock options and Restricted Stock have been granted under the 2019 Plan. We refer to employees, officers, directors, advisors or consultants who receive an award under our 2019 Plan as participants.

Options. The 2019 Plan provides for the grant of both (1) ISOs, intended to qualify for tax treatment under Section 422 of the Code which may be granted only to employees and (2) NQSOs, which may be granted to our employees, officers, directors, advisors and consultants, each at a stated exercise price and subject to certain vesting and other terms and conditions as set forth in the 2019 Plan. The 2019 Plan provides that the exercise price of each stock option must be at least equal to the fair market value of our common stock on the date of grant. In addition, the exercise price of any ISO granted to a participant who owns more than ten percent of the total combined voting power of all classes of our capital stock, directly or by attribution, must be at least equal to 110% of the fair market value of our common stock on the date of grant. The maximum permitted term of options granted under our 2019 Plan is ten years from the date of grant, except that the maximum permitted term of ISOs granted to a participant who owns more than ten percent of the total combined voting power of all classes of our capital stock, directly or by attribution, is five years from the date of grant.

Restricted Stocks and RSUs. The 2019 Plan provides for the grant of Restricted Stocks and RSUs, with terms as generally determined by the Committee (in accordance with the 2019 Plan) and to be set forth in an award agreement. Among other terms and conditions, we may retain an option to repurchase the unvested restricted stock at any time following the holder's termination of service. A Restricted Stock is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of a Restricted Stock will be determined by the Committee. Holders of Restricted Stocks, unlike holders of options, will have the right to vote and any dividends or stock distributions paid pursuant to Restricted Stocks will be accrued and paid when the restrictions on such shares lapse. RSUs represent the right to receive shares of our common stock at a specified date in the future and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both.

Stock Appreciation Rights. The 2019 Plan provides for the grant of SARs at a stated exercise price. The exercise value of a SAR is based upon the difference between the fair market value of our common stock on the date of exercise and a pre-determined exercise price, multiplied by the number of shares with respect to which the SAR is being exercised. The exercise price of each SAR must be at least equal to the fair market value of our common stock on the date of grant and may either be settled in cash or shares of our common stock or a combination thereof, as determined by the Committee. The Committee will determine the vesting schedule applicable to each SAR. The maximum permitted term of SARs granted under the 2019 Plan is ten years from the date of grant.

Other Stock-Based Awards. Our board of directors may grant other awards of shares of common stock, and other awards that are valued in whole or in part by reference to, or are otherwise based on, shares of common stock or other property. Such other stock-based awards will also be available as a form of payment in the

settlement of other awards granted under the 2019 Plan or as payment in lieu of compensation to which a participant is otherwise entitled. Other stock-based awards may be paid in shares of common stock or cash, as our board of directors will determine. Subject to the provisions of the 2019 Plan, our board of directors will determine the terms and conditions of each other stock-based award, including any applicable purchase price.

Limited Transferability. Awards (or any interest in an award, including, prior to exercise, any interest in shares of common stock issuable upon exercise of an option or SAR) will not be sold, assigned, transferred, pledged, hypothecated or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, and, during the life of the participant, will be exercisable only by the participant; except that awards, other than awards subject to Section 409A of the Code, may be transferred to family members (as defined in Rule 701(c)(3) under the Securities Act) through gifts or (other than ISOs) domestic relations orders or to an executor or guardian upon the death or disability of the participant.

Change in Control.

– *Consequences on Awards Other Than Restricted Stock.* In connection with a "Reorganization Event" (as defined below), our board of directors may take any one or more of the following actions: (i) provide that such awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) provide that all of the participant's unexercised and/or unvested awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the participant, (iii) provide that outstanding awards will become exercisable, or restrictions applicable to an award will lapse, prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of common stock will receive upon closing a cash payment for each share surrendered in the Reorganization Event, make or provide for a cash payment with respect to each award held by a participant, (v) provide that, in connection with a liquidation or dissolution of the Company, awards will convert into the right to receive liquidation proceeds, and (vi) any combination of the foregoing. Our board of directors will not be obligated by the 2019 Plan to treat all awards held by a participant, or all awards of the same type, identically.

– *Consequences on Restricted Stock.* Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the common stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

A "Reorganization Event" is defined in the 2019 Plan as (a) any merger or consolidation of the Company with or into another entity as a result of which all of the common stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the common stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

Adjustments. In the event of any stock dividend, recapitalization, stock split, reverse stock split, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of common stock other than an ordinary cash dividend, (i) the number and class of securities available under the 2019 Plan, (ii) the number and class of securities and exercise price per share of each outstanding option, (iii) the share and per-share provisions and the measurement price of each outstanding

SAR, (iv) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Stock and (v) the share and per-share-related provisions and the purchase price, if any, of each outstanding award of RSU and each outstanding other stock-based award, will be equitably adjusted by the Company (or substituted awards may be made, if applicable) in the manner determined by our board of directors, in each case to prevent diminution or enlargement of the benefits or potential benefits intended to be made under the 2019 Plan.

Amendment; Termination. Our board of directors may amend, suspend or terminate the 2019 Plan or any portion thereof at any time; *provided that* if at any time the approval of our stockholders is required as to any modification or amendment under Section 422 of the Code or any successor provision with respect to ISOs, our board of directors may not effect such modification or amendment without such approval.

2022 Equity Incentive Plan

We have adopted our 2022 Plan, which became effective on the date of the effectiveness of the registration statement, or 2022 Plan Effective Date, for which this prospectus form a part and will serve as the successor to our 2019 Plan. Our 2022 Plan authorizes the award of incentive stock options (ISOs), which are intended to qualify for tax treatment under Section 422 of the Code, and non-qualified stock options (NQSOs), Restricted Stock Awards (RSAs), Stock Appreciation Rights (SARs), Restricted Stock Units (RSUs), performance awards and stock bonus awards. We have initially reserved 4,426,737 shares of our common stock (subject to adjustment as provided in the 2022 Plan), plus such number of shares equal to (i) any reserved shares not issued or subject to outstanding grants under the 2019 Plan on the 2022 Plan Effective Date, (ii) shares of our common stock that are subject to outstanding awards granted under the 2019 Plan that cease to be subject to such awards by forfeiture or otherwise after the 2022 Plan Effective Date, (iii) shares of our common stock issued under the 2019 Plan that are repurchased by the us at the original issue price, (iv) shares of our common stock issued under the 2019 Plan, before or after the 2022 Plan Effective Date pursuant to the exercise of stock-options that are, after the 2022 Plan Effective Date, forfeited and (v) shares of our common stock that are subject to outstanding awards granted under the 2019 Plan that are used to pay the exercise price of an option or withheld to satisfy any tax withholding obligations related to any award. The number of shares reserved for issuance under our 2022 Plan will increase automatically on January 1 of each of 2023 through 2032 by the number of shares equal to the lesser of 5% of the aggregate number of shares of all classes of our common stock, plus the total number of shares of our common stock issuable upon conversion of any preferred stock (if any) or exercise of any pre-funded warrants, as issued and outstanding as of the immediately preceding December 31, or a number as may be determined by our board of directors. Pursuant to the 2022 Plan, ISOs may be granted only to our employees. We may grant all other types of awards to our employees, directors and consultants.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2022 Plan:

- shares subject to options or SARs granted under our 2022 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under our 2022 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2022 Plan that otherwise terminate without such shares being issued;
- shares subject to awards granted under our 2022 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof);
- shares subject to awards granted under our 2022 Plan that are surrendered pursuant to an “exchange program” (as defined in our 2022 Plan);

- shares issuable upon the exercise of options or subject to other awards granted under our 2019 Plan that cease to be subject to such options or other awards, by forfeiture or otherwise, after, in the case of awards under the 2019 Plan, the termination of the 2019 Plan;
- shares issued under the 2019 Plan before or after the effective date of the 2022 Plan pursuant to the exercise of stock options that are, after the effective date, forfeited;
- shares subject to awards granted under our 2019 Plan that are forfeited or repurchased by us at the original price after, in the case of awards under the 2019 Plan, the termination of the 2019 Plan; and
- shares subject to awards under our 2019 Plan or our 2022 Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

Administration. Our 2022 Plan is expected to be administered by our compensation committee, all of the members of which are outside directors as defined under applicable federal tax laws, or by our board of directors acting in place of our compensation committee. Subject to the terms and conditions of the 2022 Plan, the compensation committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2022 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the 2022 Plan or any award granted thereunder. The 2022 Plan provides that our board of directors or compensation committee may delegate its authority, including the authority to grant awards, to one or more executive officers to the extent permitted by applicable law, *provided that* awards granted to non-employee directors may only be determined by our board of directors.

Eligibility. Our 2022 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors.

Options. Our 2022 Plan provides for the grant of both ISOs intended to qualify under Section 422 of the Code, and NQSOs to purchase shares of our common stock at a stated exercise price. ISOs may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2022 Plan must be at least equal to the fair market value of our common stock on the date of grant. In addition, ISOs granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations or similar events, no more than 22,133,687 shares (subject to adjustment as provided in the 2022 Plan and as a result of the 1-for-2.259 reverse stock split of our outstanding common stock, which was effected on September 7, 2022) may be issued pursuant to the exercise of incentive stock options granted under the 2022 Plan.

Options may vest based on service or achievement of performance conditions. Our compensation committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. In the event of a participant's termination of service, an option is generally exercisable, to the extent vested, for a period of three months in the case of termination other than due to "cause" or the participant's death or "disability" (as such terms are defined in our 2022 Plan), or 12 months in the case of termination due to the participant's death or disability, or such longer or shorter period as the compensation committee may provide, but in any event no later than the expiration date of the stock option. Stock options generally terminate upon a participant's termination of employment for cause. The maximum term of options granted under our 2022 Plan is ten years from the date of grant, except that the maximum permitted term of ISOs granted to an individual who holds, directly or by attribution, more than ten percent of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Upon exercise of options, the option exercise price must be paid in full either in cash or cash equivalents or in other manners approved by the compensation committee, including by surrender of shares of our common

stock that are beneficially owned by the optionee free of restrictions. Subject to applicable law, the exercise price may also be paid by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or check sufficient to pay the exercise price and any required tax withholding.

Restricted Stock Awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the compensation committee. Holders of RSAs will have the right to vote and any dividends or stock distributions paid pursuant to unvested RSAs will be accrued and paid when the restrictions on such shares lapse. If any such dividends or distributions are paid in shares of our common stock, the shares will be subject to the same restrictions on transferability and forfeiture as the shares of restricted stock with respect to which they were paid. Unless otherwise determined by the compensation committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested RSAs may be forfeited to or repurchased by us.

Stock Appreciation Rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our compensation committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions and may not have a term that is longer than ten years from the date of grant.

Restricted Stock Units. RSUs represent the right to receive shares of our common stock at a specified date in the future and may be subject to vesting based on service or achievement of performance conditions. Payment of earned RSUs will be made as soon as practicable on a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than ten years from the date of grant.

Performance Awards. Performance awards granted to pursuant to the 2022 Plan maybe in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock Bonus Awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject such award as determined by our compensation committee. The awards may be granted as consideration for services already rendered, or at the discretion of the compensation committee, may be subject to vesting restrictions based on continued service or performance conditions.

Dividend Equivalents Rights. Dividend equivalent rights maybe granted at the discretion of our compensation committee and represent the right to receive the value of dividends, if any, paid by us in respect of the number of shares of our common stock underlying an award. Dividend equivalent rights will be subject to the same vesting or performance conditions as the underlying award, subject to the discretion of the compensation committee, and may be paid only at such time as the underlying award has become fully vested. Dividend equivalent rights may be settled in cash, shares or other property, or a combination of thereof as determined by our compensation committee. No dividend equivalent rights will be paid in respect of options or SARs.

Change of Control. Our 2022 Plan provides that, in the event of a “corporate transaction” (as defined in the 2022 Plan), outstanding awards under the 2022 Plan shall be subject to the agreement evidencing the corporate

transaction, which need not treat all outstanding awards in an identical manner, and may include one or more of the following actions: (i) the continuation of outstanding awards; (ii) the assumption of outstanding awards by the successor or acquiring entity or its parent; (iii) the substitution of outstanding awards by the successor or acquiring entity or its parent with equivalent awards with substantially the same terms; (iv) the full or partial acceleration of exercisability, vesting, or lapse of forfeiture conditions, including our right to repurchase shares and accelerated expiration of the award; (v) the settlement of the full value of the outstanding awards (whether or not then vested or exercisable) in cash, cash equivalents, or securities of the successor entity with a fair market value equal to the required amount, as determined in accordance with the 2022 Plan, which may be deferred until the date or dates the award would have become exercisable or vested; or (vi) the cancellation of the outstanding awards for no consideration. Notwithstanding the foregoing, upon a corporate transaction, the vesting of all awards granted to our non-employee directors will accelerate and such awards will become exercisable (to the extent applicable) in full prior to the consummation of a corporate transaction at such times and on such conditions as the compensation committee determines.

Adjustment. In the event of a change in the number of outstanding shares of our common stock without consideration by reason of a stock dividend, extraordinary dividend or distribution (whether in cash, shares, or other property, other than a regular cash dividend), recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, without consideration, appropriate proportional adjustments will be made to the number of shares reserved for issuance under our 2022 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Exchange, Repricing and Buyout of Awards. Our compensation committee may, without prior stockholder approval, (i) reduce the exercise price of outstanding options or SARs without the consent of any participant and (ii) pay cash or issue new awards in exchange for the surrender and cancellation of any, or all, outstanding awards, subject to the consent of any affected participant to the extent required by the terms of the 2022 Plan.

Director Compensation Limits. No non-employee director may receive awards under our 2022 Plan with a grant date value that when combined with cash compensation received for his or her service as a director after the effective date of the 2022 Plan, exceeds $1,000,000 in any calendar year or $1,500,000 in his or her initial year of service as a non-employee director with us.

Clawback; Transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our board of directors (or a committee thereof) or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2022 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Sub-Plans. Subject to the terms of the 2022 Plan, the compensation committee may establish one or more sub-plans under the 2022 Plan and/or modify the terms of awards granted to participants outside of the United States to comply with any laws or regulations applicable to any such jurisdiction.

Amendment and Termination. Our board of directors may amend our 2022 Plan at any time, subject to stockholder approval as may be required. Our 2022 Plan will terminate ten years from the date our board of directors adopts the plan, unless it is terminated earlier by our board of directors. No termination or amendment of the 2022 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws or as otherwise provided by the terms of the 2022 Plan.

2022 Employee Stock Purchase Plan

We have adopted our ESPP, which became effective on the date of the effectiveness of the registration statement of which this prospectus forms a part, or ESPP Effective Date, in order to enable eligible employees to

purchase shares of our common stock with accumulated payroll deductions at a discount beginning on a date to be determined by our board of directors or our compensation committee. Our ESPP is intended to qualify under Section 423 of the Code *provided that* the compensation committee may adopt sub-plans under our ESPP designed to be outside of the scope of Section 423 of the Code for participants who are non-U.S. residents.

Shares Available. We have initially reserved 369,079 shares of our common stock for sale under our ESPP (subject to adjustment as provided in the 2022 Plan). The aggregate number of shares reserved for sale under our ESPP will increase automatically on January 1st of each of 2023 through 2032 by the number of shares equal to the lesser of 1% of the aggregate number of shares of all classes of our common stock, plus the total number of shares of our common stock issuable upon conversion of any preferred stock (if any) or exercise of any pre-funded warrants, as issued and outstanding as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by our board of directors in any particular year. The aggregate number of shares issued over the term of our ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 7,381,584 shares of our common stock (subject to adjustment as provided in the 2022 Plan).

Administration. Our ESPP is expected to be administered by our compensation committee, or by our board of directors acting in place of our compensation committee. Among other things, the administrator will have the authority to determine eligibility for participation in the ESPP, designate separate offerings under the plan, and construe, interpret and apply the terms of the plan.

Eligibility. Employees eligible to participate in any offering pursuant to the ESPP generally include any employee that is employed by us or certain of our designated subsidiaries at the beginning of the offering period. However, our compensation committee may determine that employees who have been employed for less than such time period as specified by the administrator, are customarily employed for 20 hours or less per week, or for five months or less in a calendar year, or certain highly-compensated employees as determined in accordance with applicable tax laws, may not be eligible to participate in the ESPP. In addition, any employee who owns (or is deemed to own as a result of attribution) 5% or more of the total combined voting power or value of all classes of our capital stock, or the capital stock of one of our qualifying subsidiaries, or who will own such amount as a result of participation in the ESPP, will not be eligible to participate in the ESPP. Our compensation committee may impose additional restrictions on eligibility from time to time.

Offerings. Under our ESPP, eligible employees will be offered the option to purchase shares of our common stock at a discount over a series of offering periods, which may be consecutive or overlapping, through accumulated payroll deductions over the period. Each offering period may itself consist of one or more purchase periods. No offering period may be longer than 27 months. The administrator may determine to permit participants to suspend or restart contributions during any offering period. The purchase price for shares purchased under our ESPP during any given purchase period will be 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of the purchase period.

Participation. Participating employees will be able to purchase the offered shares of our common stock by accumulating funds through payroll deductions. Participants may select a rate of payroll deduction between 1% and 15% of their compensation. However, a participant may not purchase more than 3,000 shares during any one purchase period (subject to adjustment as provided in the 2022 Plan and as a result of the 1-for-2.259 reverse stock split of our outstanding common stock, which was effected on September 7, 2022), and may not subscribe for more than $25,000 in fair market value of shares of our common stock (determined as of the date the offering period commences) in any calendar year in which the offering is in effect. The administrator, in its discretion, may set a lower maximum amount of shares which may be purchased.

See the section titled “Executive Compensation—Employment Agreements” for additional information

The purchase price for shares of our common stock purchased under the ESPP will be 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of each purchase period in the applicable offering period.

Once an employee becomes a participant in an offering period, the participant will be automatically enrolled in each subsequent offering period at the same contribution level. A participant may reduce his or her contribution in accordance with procedures set forth by the compensation committee and may withdraw from participation in the ESPP at any time prior the end of an offering period, or such other time as may be specified by the compensation committee. Upon withdrawal, the accumulated payroll deductions will be returned to the participant without interest.

Adjustments Upon Recapitalization. If the number of outstanding shares of our common stock is changed by stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or similar change in our capital structure without consideration, then our compensation committee will proportionately adjust the number and class of common stock that is available under the ESPP, the purchase price and number of shares any participant has elected to purchase as well as the maximum number of shares which may be purchased by participants.

Change of Control. If we experience a change of "control transaction" (as defined in our ESPP), any offering period that commenced prior to the closing of the proposed change of control transaction will be shortened and terminated on a new purchase date. The new purchase date will occur on or prior to the closing of the proposed change of control transaction, and our ESPP will then terminate on the closing of the proposed change of control.

Transferability. A participant may not assign, transfer, pledge or otherwise dispose of payroll deductions credited to his or her account, or any rights with regard to an election to purchase shares pursuant to the ESPP other than by will or the laws of descent or distribution.

Amendment; Termination. The administrator may amend, suspend or terminate the ESPP at any time without stockholder consent, except to the extent such amendment would increase the number of shares available for issuance under our ESPP, change the class or designation of employees eligible for participation in the plan or otherwise as required by law. If our ESPP is terminated, the administrator may elect to terminate all outstanding offering periods immediately, upon next purchase date (which may be sooner than originally scheduled) or upon the last day of such offering period. If any offering period is terminated prior to its scheduled completion, all amounts credited to participants which have not been used to purchase shares will be returned to participants as soon as administratively practicable. Our ESPP will continue until the earlier to occur of (a) termination of the ESPP by our board of directors, (b) issuance of all of the shares reserved for issuance under the ESPP, or (c) the tenth anniversary of the effective date under the ESPP.

401(k) Plan

We sponsor a retirement savings plan that is intended to qualify for favorable tax treatment under Section 401(a) of the Code and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. Participants may make pre-tax and certain after-tax (Roth) salary deferral contributions to the plan from their eligible earnings up to the statutorily prescribed annual limit under the Code. Participants who are projected to reach 50 years of age or older during a calendar year may contribute additional amounts based on the statutory limits for catch-up contributions. Participant contributions are held in trust as required by law.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

Limitations on Liability and Indemnification Matters

Our restated certificate of incorporation that will become effective in connection with the completion of this offering contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves 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; or
- any transaction from which the director derived an improper personal benefit.

Our restated certificate of incorporation and our restated bylaws that will become effective in connection with the completion of this offering require us to indemnify our directors and executive officers to the maximum extent not prohibited by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors, executive officers and certain of our key employees, in addition to the indemnification provided for in our restated certificate of incorporation and restated bylaws. These agreements, among other things, require us to indemnify our directors, executive officers and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to us or any of our subsidiaries or any other company or enterprise to which these individuals provide services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We believe that these indemnification provisions and agreements are necessary to attract and retain qualified directors, executive officers and key employees. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our restated certificate of incorporation and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and executive officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including any employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled "Management" and "Executive Compensation," the following is a description of each transaction since January 1, 2019 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1.0% of our total assets; and
- any of our directors, executive officers or holders of more than 5.0% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under the section titled "Executive Compensation."

Series A-1 Preferred Stock Financing

In July 2019, we sold an aggregate of 8,000,000 shares of our Series A-1 convertible preferred stock, or Series A-1 Preferred Stock, to Atlas Venture Fund XI, L.P., at a purchase price of $1.00 per share for total gross proceeds to us of $8.0 million. Each share of our Series A-1 Preferred Stock will automatically convert into 0.4427 shares of our common stock immediately prior to the completion of this offering. Pursuant to our amended and restated investors' rights agreement, or IRA, holders of our Series A-1 Preferred Stock are entitled to certain registration rights. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

The following table summarizes the Series A-1 Preferred Stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. Please refer to the section titled "Principal Stockholders" for additional information regarding the shares held by these entities.

Name of Stockholder	Shares of Series A-1 Preferred Stock	Total Cash Purchase Price($)
Atlas Venture Fund XI, L.P.(1)	8,000,000	$ 8,000,000

(1) Consists of shares purchased by Atlas Venture Fund XI, L.P., which is affiliated with Atlas Venture Opportunity Fund I, L.P. and together hold more than 5% of our outstanding capital stock. Michael Gladstone and Jason Rhodes, a current and former member of our board of directors, respectively, are affiliated with Atlas.

Series A-2 Preferred Stock Financing

From July 2020 through February 2021, we sold an aggregate of 13,750,000 shares of our Series A-2 convertible preferred stock, or Series A-2 Preferred Stock, at a purchase price of $1.60 per share for total gross proceeds of $22.0 million. Each share of our Series A-2 Preferred Stock will automatically convert into 0.4427 shares of our common stock immediately prior to the completion of this offering. Pursuant to the IRA, holders of our Series A-2 Preferred Stock are titled to certain registration rights. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

The following table summarizes the Series A-2 Preferred Stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these

purchases were the same for all purchasers of our Series A-2 Preferred Stock. Please refer to the section titled "Principal Stockholders" for additional information regarding the shares held by these entities.

Name of Stockholder	Shares of Series A-2 Preferred Stock	Total Cash Purchase Price($)
Atlas Venture Fund XI, L.P.(1)	5,156,250	$ 8,250,000
OrbiMed Private Investments VII, LP(2)	8,593,750	$ 13,750,000

(1) Consists of shares purchased by Atlas Venture Fund XI, L.P., which is affiliated with Atlas Venture Opportunity Fund I, L.P. and together hold more than 5% of our outstanding capital stock. Michael Gladstone and Jason Rhodes, a current and former member of our board of directors, respectively, are affiliated with Atlas.
(2) Consists of shares purchased by OrbiMed Private Investments VII, LP, which holds more than 5% of our outstanding capital stock. Dr. Bonita, a member of our board of directors, is a member of OrbiMed Advisors LLC, which is the managing member of the general partner of OrbiMed Private Investments VII, L.P.

Series A-3 Preferred Stock Financing

From February 2021 through November 2021, we sold an aggregate of 7,812,501 shares of our Series A-3 convertible preferred stock, or Series A-3 Preferred Stock, at a purchase price of $2.56 per share for total gross proceeds of $20.0 million. Each share of our Series A-3 Preferred Stock will automatically convert into 0.4427 shares of our common stock immediately prior to the completion of this offering. Pursuant to the IRA, holders of our Series A-3 Preferred Stock are entitled to certain registration rights. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

The following table summarizes the Series A-3 Preferred Stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series A-3 Preferred Stock. Please refer to the section titled "Principal Stockholders" for additional information regarding the shares held by these entities.

Name of Stockholder	Shares of Series A-3 Preferred Stock	Total Cash Purchase Price($)
Atlas Venture Fund XI, L.P.(1)	1,464,844	$ 3,750,000
OrbiMed Private Investments VII, LP(2)	2,441,407	$ 6,250,000
Biotechnology Value Fund, L.P. and affiliates(3)	3,906,250	$ 10,000,000

(1) Consists of shares purchased by Atlas Venture Fund XI, L.P., which is affiliated with Atlas Venture Opportunity Fund I, L.P. and together hold more than 5% of our outstanding capital stock. Michael Gladstone and Jason Rhodes, a current and former member of our board of directors, respectively, are affiliated with Atlas.
(2) Consists of shares purchased by OrbiMed Private Investments VII, LP, which holds more than 5% of our outstanding capital stock. Dr. Bonita, a member of our board of directors, is a member of OrbiMed Advisors LLC, which is the managing member of the general partner of OrbiMed Private Investments VII, L.P.
(3) Consists of shares purchased by Biotechnology Value Fund, L.P. and affiliates, which holds more than 5% of our outstanding capital stock.

Series B Preferred Stock Financing

In December 2021, we sold an aggregate of 14,091,686 shares of our Series B convertible preferred stock, or Series B Preferred Stock, at a price per share of $7.4512 for total gross proceeds of approximately $105.0 million. Each share of our Series B Preferred Stock will automatically convert into 0.4427 shares of our common stock immediately prior to the completion of this offering. Pursuant to the IRA, holders of our Series B Preferred Stock are entitled to certain registration rights. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

The following table summarizes the Series B Preferred Stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. The terms of these purchases were the same for all purchasers of our Series B Preferred Stock. Please refer to the section titled "Principal Stockholders" for additional information regarding the shares held by these entities.

Name of Stockholder	Shares of Series B Preferred Stock	Total Cash Purchase Price($)
General Atlantic (TH), L.P.(1)	4,026,197	$ 29,999,999.09
Atlas Venture Opportunity Fund I, L.P.(2)	1,342,065	$ 9,999,994.73
OrbiMed Private Investments VII, LP(3)	1,342,065	$ 9,999,994.73
Biotechnology Value Fund, L.P. and its affiliates(4)	1,677,582	$ 12,499,999.01

(1) Consists of shares purchased by General Atlantic (TH), L.P. General Atlantic (TH), L.P. holds more than 5% of our outstanding capital stock. Rob Perez, a member of our board of directors, is affiliated with General Atlantic.
(2) Consists of shares purchased by Atlas Venture Opportunity Fund I, L.P., which is affiliated with Atlas Venture Opportunity Fund I, L.P. and together hold more than 5% of our outstanding capital stock. Michael Gladstone and Jason Rhodes, a current and former member of our board of directors, respectively, are affiliated with Atlas.
(3) Consists of shares purchased by OrbiMed Private Investments VII, LP, which holds more than 5% of our outstanding capital stock. Dr. Bonita, a member of our board of directors, is a member of OrbiMed Advisors LLC, which is the managing member of the general partner of OrbiMed Private Investments.
(4) Consists of shares purchased by Biotechnology Value Fund, L.P. and affiliates, which holds more than 5% of our outstanding capital stock.

Consulting Agreement with Mark Iwicki

In June 2019, we entered into a consulting agreement with Mark Iwicki, the chairman of our board of directors, for consulting, advisory and related services to and for us as we may reasonably request from time to time, including advising on our corporate and research and development strategies. Pursuant to this agreement, Mr. Iwicki was granted a restricted stock award for 47,100 shares of our common stock, with 1/48th of the shares subject to the award vesting in equal monthly installments.

Consulting Agreement with H. Martin Seidel, Ph.D.

In July 2019, we entered into a consulting agreement with H. Martin Seidel, in connection with his appointment to our board of directors and scientific advisory board, for consulting services, including consulting with and advising us in his field of expertise on matters related to our business, products, research, development and technologies and provide such additional consulting and advisory services as we may reasonably request. We will make payments of $25,000 per year for such consulting services, payable quarterly in arrears. In addition, Dr. Seidel was granted a restricted stock award of 75,360 shares of our common stock, with 25% of the shares subject to the award vesting on July 25, 2020 and the remaining shares vesting in equal quarterly installments thereafter until July 25, 2023.

Novartis Agreements

We are party to a license agreement with Novartis International Pharmaceutical Ltd. See the section titled "Business—License Agreement—Novartis." Pursuant to this agreement, we entered into an investment letter whereby we have issued 5,970,000 shares of Series A-1 Preferred Stock to Novartis Institutes for Biomedical Research, Inc. As a result of such issuances, Novartis Institutes for Biomedical Research, Inc. is a holder of more than 5% of our outstanding common stock.

Loans to Executive Officers

In August 2021, we received a promissory note from Natalie Holles, our Chief Executive Officer, in connection with the purchase by Ms. Holles of shares of our common stock. The principal amount of the promissory note was $1,762,145, which accrues interest at 0.76%, compounding annually. As of December 31, 2021, the outstanding balance was approximately $1,767,428. The entire promissory note, including principal and accrued and unpaid interest, was forgiven prior to the filing of this registration statement with the SEC. See the section titled "Executive Compensation—Employment Agreements" for additional information.

Use and Occupancy Agreements

In 2021, we entered into use and occupancy agreements for a shared office space located at 300 Technology Square, Cambridge, Massachusetts from Atlas Venture Life Science Advisors, LLC, or Atlas, an entity where Mr. Gladstone and Mr. Rhodes, a current and former member of our board of directors, respectively, both serve as partner. Expenses under the agreements approximated $0.2 million for the fiscal year ended December 31, 2021.

Investors' Rights Agreement

We entered into the IRA with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated and who hold more than 5% of our outstanding common stock. These stockholders are entitled to rights with respect to the registration of their shares under the Securities Act following this offering. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

Equity Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain directors, as more fully described in the sections titled "Executive Compensation" and "Management—Non-Employee Director Compensation," respectively.

Director and Executive Officer Compensation

See the sections titled "Management—Non-Employee Director Compensation" and "Executive Compensation" for additional information.

Employment-Related Agreements

We have entered into amended and restated employment offer letters or agreements with our executive officers in connection with this offering. See the section titled "Executive Compensation—Employment Agreements" for additional information.

Indemnification Agreements

In connection with this offering, we intend to enter into new indemnification agreements with each of our directors and executive officers. The indemnification agreements, our restated certificate of incorporation and our restated bylaws will require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and executive officers. See the section titled "Executive Compensation—Limitations on Liability and Indemnification Matters" for additional information.

Policies and Procedures for Related Party Transactions

In connection with this offering, we intend to adopt a written related person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. We expect the policy to provide that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate

family members or affiliates in which the amount involved exceeds $120,000 will be presented to our audit committee (or the committee composed solely of independent directors, if applicable) for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee (or the committee composed solely of independent directors, if applicable) will consider the relevant facts and circumstances available and deemed relevant to the audit committee (or the committee composed solely of independent directors, if applicable), including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of shares of our common stock as of August 26, 2022, and as adjusted to reflect the shares of our common stock to be issued and sold in this offering, for:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of our common stock that they beneficially owned, subject to applicable community property laws.

Beneficial ownership prior to this offering is based on 27,793,935 shares of our common stock outstanding as of June 30, 2022, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the completion of this offering. Beneficial ownership after this offering is based on 38,693,935 shares of our common stock outstanding, assuming (i) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock outstanding as described above and (ii) 10,900,000 shares of our common stock issued by us in this offering, assuming that the underwriters do not exercise their option to purchase up to an additional 1,635,000 shares of our common stock from us in part or in full. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to stock options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of August 26, 2022. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Third Harmonic Bio, Inc., 300 Technology Square, 8th Floor, Cambridge, Massachusetts 02139.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Directors and Named Executive Officers:			
Natalie Holles(1)	1,342,008	4.8	3.5
Howard E. Davis, Jr., Ph.D.(2)	163,467	*	*
Stephen Yoo, M.D.(3)	367,019	1.3	*
Mark Iwicki(4)	133,864	*	*
David P. Bonita, M.D.(5)	—	*	*
Michael Gladstone(6)	—	*	*
Shao-Lee Lin, M.D., Ph.D.(7)	38,393	*	*
Rob Perez(8)	—	*	*
Jason Rhodes(6)	—	*	*
H. Martin Seidel, Ph.D.(9)	87,122	*	*
Thomas M. Soloway	—	*	*
All executive officers and directors as a group (11 persons)(10)	1,601,387	5.8	4.1
Other 5% stockholders:			
Entities affiliated with Atlas Venture Fund XI, L.P. (6)	10,607,859	38.2	27.4
Entities affiliated with BVF Partners L.P.(11)	2,471,814	8.9	6.4
General Atlantic (TH), L.P.(8)	1,782,291	6.4	4.6
Novartis Institutes for BioMedical Research, Inc.(12)	2,642,762	9.5	6.8
OrbiMed Private Investments VII, LP(5)	5,479,071	19.7	14.2

* Represents beneficial ownership of less than one percent.
(1) Consists of (i) 1,218,837 shares of our common stock all of which are subject to forfeiture, and (ii) 123,171 shares of our common stock subject to options that are exercisable within 60 days of August 26, 2022.
(2) Consists of 163,467 shares of our common stock.
(3) Consists of (i) 353,736 shares of our common stock with 123,010 shares subject to forfeiture, and (ii) 13,284 shares of our common stock subject to options that are exercisable within 60 days of August 26, 2022.
(4) Consists of (i) 128,631 shares of our common stock with 42,476 shares subject to forfeiture, and (ii) 5,233 shares of our common stock subject to options that are exercisable within 60 days of August 26, 2022.
(5) Consists of 5,479,071 shares held by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or OrbiMed GP VII is the general partner of OPI VII. OrbiMed Advisors LLC, or OrbiMed Advisors is the managing member of OrbiMed GP VII. By virtue of such relationships, OrbiMed GP VII and OrbiMed Advisors may be deemed to have voting and investment power with respect to the shares held by OPI VII and as a result may be deemed to have beneficial ownership of such shares. David P. Bonita, a member of OrbiMed Advisors, is a member of our board of directors. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and W. Carter Neild. Each of OrbiMed GP VII, OrbiMed Advisors, and David P. Bonita disclaims beneficial ownership of the shares held by OPI VII, except to the extent of its or his pecuniary interest therein if any.
(6) Consists of (i) 10,013,763 shares held by Atlas Venture Fund XI, L.P., or Atlas Fund XI, and (ii) 594,097 shares held by Atlas Venture Opportunity Fund I, L.P., or Atlas Fund I. Each of Michael Gladstone and Jason Rhodes, a current and former member of our board of directors, respectively, is a Partner at Atlas Venture Life Science Advisors, LLC, or Atlas Venture, and disclaims beneficial ownership of the shares noted herein. Atlas Venture Associates XI, L.P. is the general partner of Atlas Fund XI, and Atlas Venture Associates XI, LLC is the general partner of Atlas Venture Associates XI, L.P. Each of Atlas Venture Associates XI, L.P. and Atlas Venture Associates XI, LLC may be deemed to beneficially own the shares held by Atlas Fund XI. Atlas Venture Associates Opportunity I, L.P. is the general partner of Atlas Fund I, and Atlas Venture Associates Opportunity I, LLC, or AVAO, LLC, is the general partner of Atlas Venture Associates Opportunity I, L.P. Each of Atlas Venture Associates Opportunity I, L.P. and AVAO, LLC may be deemed to beneficially own the shares held by Atlas Fund I. Bruce Booth, Jean-Francois Formela, David Grayzel, Jason Rhodes and Kevin Bitterman are the members of Atlas Venture Associates XI, LLC and AVAO, LLC and collectively make investment decisions on behalf of Atlas Fund XI and Atlas Fund I. The mailing address of Atlas Fund XI and Atlas Fund I is 300 Technology Square, 8th Floor, Cambridge, MA 02139.
(7) Consists of (i) 38,393 shares of our common stock subject to options that are exercisable within 60 days of August 26,2022.
(8) Consists of 1,782,291 shares of common stock. The limited partners that share beneficial ownership of the shares held by General Atlantic (TH), L.P., or GA TH, are the following General Atlantic investment funds, or the GA Funds: General Atlantic Partners 100, L.P., or GAP 100; General Atlantic Partners (Bermuda) EU, L.P., or GAP Bermuda EU; General Atlantic Partners (Lux) SCSp, or GAP Lux; GAP Coinvestments III, LLC, or GAPCO III; GAP Coinvestments IV, LLC, or GAPCO IV; GAP Coinvestments V, LLC, or GAPCO V; and GAP Coinvestments CDA, L.P., or GAPCO CDA. The general partner of GA TH is General Atlantic (SPV) GP, LLC, or GA SPV. The general partner of GAP Lux is General Atlantic GenPar, (Lux) SCSp, or GA GenPar Lux, and the general partner of GA GenPar Lux is General Atlantic (Lux) S.à r.l., or GA Lux. The general partner of GAP Bermuda EU and the sole shareholder of GA Lux is ultimately controlled by GAP (Bermuda) L.P., or GAP Bermuda LP. The ultimate general partner of GAP 100 is General Atlantic, L.P., or GA LP. GA LP is the managing member of GAPCO III, GAPCO IV, and GAPCO V, the general partner of GAPCO CDA, and the sole member of GA SPV. GA LP and GAP Bermuda LP are controlled by the Management Committee of GASC MGP, LLC (the "GA Management Committee"). There are nine members of the GA Management

Committee. GA LP, GAP Bermuda LP, GA Lux, GA GenPar Lux, GA TH, GA SPV, and the GA Funds are a "group" within the meaning of Rule 13d-5 of the Securities Exchange Act of 1934, as amended. Each of the members of the GA Management Committee disclaims ownership of the shares except to the extent that he has a pecuniary interest therein. In addition, Rob Perez, a member of our board of directors, is also an Operating Partner at General Atlantic and disclaims ownership of the shares except to the extent he has a pecuniary interest therein. The mailing address of each of the foregoing entities (other than GAP Bermuda EU, GAP Lux, GA Lux, and GAP Bermuda LP) is c/o General Atlantic Service Company, L.P., 55 East 52nd Street, 33rd Floor, New York, NY 10055. The mailing address of GAP Bermuda EU and GAP Bermuda LP is Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. The mailing address of GAP Lux, GA GenPar Lux, and GA Lux is 412F, Route d'Esch, L-1471 Luxembourg.

(9) Consists of (i) 85,754 shares of our common stock with 34,113 shares subject to forfeiture, and (ii) 1,367 shares of our common stock subject to options that are exercisable within 60 days of August 26, 2022.

(10) Consists of (i) 1,433,222 shares of common stock with 1,418,436 shares subject to forfeiture and (ii) 168,165 shares of common stock subject to options that are exercisable within 60 days of August 26, 2022.

(11) Consists of (i) 1,317,426 shares held by Biotechnology Value Fund, L.P., or BVF, (ii) 999,206 shares held by Biotechnology Value Fund II, L.P., or BVF2, and (iii) 155,182 shares held by Biotechnology Value Trading OS LP, or Trading Fund OS. BVF I GP LLC, or BVF GP, as the general partner of BVF, may be deemed to beneficially own the shares beneficially owned by BVF. BVF II GP LLC, or BVF2 GP, as the general partner of BVF2, may be deemed to beneficially own the shares beneficially owned by BVF2. BVF Partners OS Ltd., or Partners OS, as the general partner of Trading Fund OS, may be deemed to beneficially own the shares beneficially owned by Trading Fund OS. BVF GP Holdings LLC, or BVF GPH, as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF and BVF2. BVF Partners L.P., or Partners, as the sole member of Partners OS, and the investment manager of BVF, BVF2 and Trading Fund OS, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF, BVF2, and Trading Fund OS. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the shares beneficially owned by Partners. Mark Lampert, as a director and officer of BVF Inc. may be deemed to beneficially own the shares beneficially owned by BVF Inc. The address for the BVF entities is located at 44 Montgomery Street, 40th Floor, San Francisco, CA 94104.

(12) Consists of 2,642,762 shares of common stock held of record by Novartis Institutes for BioMedical Research, Inc., or NIBRI. As the indirect parent of NIBRI, Novartis AG may be deemed to beneficially own these securities. The business address for NIBRI is 181 Massachusetts Avenue, Cambridge, Massachusetts 02139 and the business address for Novartis AG is Lichstrasse 35, Basel, Switzerland.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes the most important terms of our capital stock, as will be in effect following this offering. Because it is only a summary, it does not contain all the information that may be important to you. We expect to adopt a restated certificate of incorporation and restated bylaws that will become effective upon the completion of this offering, and this description summarizes provisions that are expected to be included in these documents. For a complete description, you should refer to our restated certificate of incorporation and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

General

Upon the completion of this offering, our authorized capital stock will consist of 500,000,000 shares of our common stock, $0.0001 par value per share, and 10,000,000 shares of our undesignated preferred stock, $0.0001 par value per share.

Pursuant to the provisions of our current restated certificate of incorporation, all of our Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series A-3 Preferred Stock and Series B Preferred Stock will automatically convert into common stock in connection with the completion of this offering. Each share of our Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series A-3 Preferred Stock, and our Series B Preferred Stock will convert into 0.4427 shares of our common stock. Assuming the effectiveness of this conversion as of June 30, 2022, there were 5,826,619 shares of our common stock issued (as a result of the 1-for-2.259 reverse stock split of our outstanding common stock), held by 11 stockholders of record, and 21,967,316 shares of our convertible preferred stock outstanding (as a result of the 1-for-2.259 reverse stock split of our outstanding common stock). Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled “Dividend Policy” for additional information.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation, which means that holders of a majority of the shares of our common stock will be able to elect all of our directors. Our restated certificate of incorporation will establish a classified board of directors, to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating

preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares our of preferred stock.

Preferred Stock

After the completion of this offering, no shares of our preferred stock will be outstanding. Pursuant to our restated certificate of incorporation that will become effective immediately prior to the completion of this offering, our board of directors will be authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors will also be able to increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding and not above the number of shares of that series authorized, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Stock Options

As of June 30, 2022, we had outstanding options to purchase an aggregate 1,803,079 shares of our common stock, with a weighted-average exercise price of $7.50 per share under our 2019 Plan.

Registration Rights

Pursuant to the terms of our amended and restated investors' rights agreement, or IRA, immediately following this offering, the holders of 25,508,705 shares of our common stock will be entitled to rights with respect to the registration of these shares under the Securities Act as described below. We refer to these shares collectively as registrable securities. These rights are provided under the terms of the IRA between us and the holders of these shares, which was entered into in connection with our convertible preferred stock financings prior to this offering.

Demand Registration Rights

Beginning from the earlier of five years after December 17, 2021 or 180 days after the completion of this offering, the holders of not less than a majority of the registrable securities issued or issuable upon conversion of shares of preferred stock may make a request to us for the registration under the Securities Act of at least 40% of the registrable securities then outstanding, or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed $10.0 million. Within 10 days after the date such request is given, we are obligated to provide notice of such request to all holders of registrable securities and, as soon as practicable and in any event within 60 days after the date such request is given, to file a Form S-1 registration statement under the Securities Act covering all registrable securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders. We are only required to file one registration statement that is declared effective upon exercise of these demand registration rights. We may postpone taking action with respect to such filing not more than once during any 12-month period for a total period of not more than 90 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would be materially detrimental to us and our stockholders; provided that

we may not register any securities for our own account or that of any other stockholder during such 90-day period other than under certain circumstances.

The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, in proportion (as nearly as practicable), to the number of registrable securities owned by each holder or in such other proportion as shall mutually be agreed to by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities are first entirely excluded from the underwriting.

Form S-3 Registration Rights

The holders of at least 20% of the then-outstanding registrable securities can request that we register all or part of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the anticipated aggregate price to the public of the shares offered, net of selling expenses, is at least $5.0 million. Within ten days after such request is given, we are obligated to provide notice of such request to all holders of registrable securities and as soon as practicable and in any event within 45 days, file a Form S-3 registration statement, covering all registrable securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders. We are only required to file one registration statement on Form S-3 in a 12-month period. We may postpone taking action with respect to such filing not more than once during any 12-month period for a period of not more than 90 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would be materially detrimental to us and our stockholders; provided that we may not register any securities for our own account or that of any other stockholder during such 90-day period other than under certain circumstances.

The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, in proportion (as nearly as practicable), to the number of registrable securities owned by each holder or in such other proportion as shall mutually be agreed to by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities are first entirely excluded from the underwriting.

Piggyback Registration Rights

If we register any of our securities for public sale in cash, holders of then-outstanding registrable securities or their permitted transferees will have the right to include their registrable securities in the registration statement. However, this right does not apply to a registration relating to the sale or grant of securities to our employees pursuant to a stock option, stock purchase, equity incentive or similar plan, a registration relating to a Rule 145 transaction, 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 our common stock, or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered. If the underwriters determine that less than all the registrable securities requested to be registered can be included in the offering, the number of registrable shares to be registered will be allocated among holders of our registrable securities, in proportion (as nearly as practicable) to the amount of registrable securities owned by each such holder or in such other proportions as shall mutually be agreed to by all such holders. However, the number of shares to be registered by holders of registrable securities cannot be reduced unless all other securities (other than as offered by us) are first entirely excluded. The number of registrable securities included in the offering may not be reduced below 20% of the total number of securities included in such offering, except for in connection with an initial public offering, in which case the underwriters may exclude these holders entirely.

Expenses of Registration Rights

We generally will pay all expenses, including expenses of one counsel for the selling holders, other than underwriting discounts and selling commissions incurred in connection with each of the registrations described above, including the reasonable fees and disbursements, provided, however, that the registrations described above are not subsequently withdrawn at the request of the holders of a majority in interest of the registrable securities (in which case all selling holders shall bear such expenses pro rata based upon the number of registrable securities that were to be included in the withdrawn registration) unless the holders of a majority of the registrable securities agree to forfeit their right to a registration as described above.

Expiration of Registration Rights

The registration rights described above will expire, with respect to any particular holder of these rights, on the earliest to occur of (i) the closing of a deemed liquidation event, as defined in our restated certificate of incorporation, (ii) such time after this offering as the registrable securities held by such holder may be sold within any three-month period without restriction pursuant to Rule 144 or a similar exemption under the Securities Act or (iii) the third anniversary of this offering.

Anti-Takeover Provisions

The provisions of the DGCL, our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect upon the completion of this offering, could have the effect of delaying, deferring or discouraging another person from acquiring control of our Company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also executive officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 of the DGCL may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Restated Certificate of Incorporation and Restated Bylaw Provisions

Our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect upon the completion of this offering, include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our Company, including the following:

- *Board of Directors Vacancies*. Our restated certificate of incorporation and restated bylaws will authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

- *Classified Board*. Our restated certificate of incorporation and restated bylaws will provide that our board of directors is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors. See the section titled "Management—Board Composition" for additional information.

- *Stockholder Action; Special Meetings of Stockholders*. Our restated certificate of incorporation will provide that our stockholders may not take action by written consent but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws will provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors, our Chief Executive Officer, the Lead Independent Director (as defined in the restated bylaws) or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our restated bylaws will provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also will specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our Company.

- *No Cumulative Voting*. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's restated certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws will not provide for cumulative voting.

- *Directors Removed Only for Cause*. Our restated certificate of incorporation will provide that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.

- *Amendment of Charter Provisions*. Any amendment of the above expected provisions in our restated certificate of incorporation will require approval by the holders of at least two-thirds of our outstanding common stock.

- *Issuance of Undesignated Preferred Stock*. Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by merger, tender offer, proxy contest or other means.

- *Choice of Forum*. Our restated certificate of incorporation will provide that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our restated bylaws will provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which we refer to as a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal courts or other state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. While neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder also must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, executive officers, other employees or agents of our Company, which may discourage lawsuits against us and our directors, executive officers and other employees.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is American Stock Transfer & Trust Company, LLC, 6201 15th Avenue, Brooklyn, New York 11219.

The Nasdaq Global Market Listing

We have been approved to list our common stock on Nasdaq under the symbol "THRD."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of our common stock, including shares issued upon exercise of outstanding options, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon the completion of this offering, we will have a total of 40,328,935 shares of our common stock outstanding, assuming (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 21,967,316 shares of our common stock and (ii) the issuance of 12,535,000 shares of common stock in this offering (if the underwriters exercise their over-allotment option in full). Of these outstanding shares, all of the shares of our common stock sold in this offering will be freely tradable, except that any shares purchased in this offering by our affiliates, as that term is defined in Rule 144 under the Securities Act can only be sold in compliance with the Rule 144 limitations described below.

The remaining outstanding shares of our common stock will be, and shares subject to stock options will be upon issuance, deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, substantially all of our security holders have, or will have, entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below.

Lock-Up and Market Standoff Agreements

All of our directors and officers and substantially all of our security holders are subject to lock-up agreements or market standoff provisions that prohibit them from offering for sale, selling, contracting to sell, granting any option for the sale of, transferring or otherwise disposing of any shares of our common stock or options to acquire shares of our common stock or any security or instrument related to our common stock, or entering into any swap, hedge or other arrangement that transfers any of the economic consequences of ownership of our common stock, for a period of 180 days following the date of this prospectus without the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC, subject to certain exceptions. See the section titled "Underwriters" for additional information.

Rule 144

In general, Rule 144 provides that once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares of our common stock proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, Rule 144 provides that our affiliates or persons selling shares of our common stock on behalf of our affiliates are entitled to sell upon expiration of the lock-up and market standoff agreements described above, within any three-month period, a number of shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 386,939 shares immediately after the completion of this offering; or
- the average reported weekly trading volume of share of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares of our common stock on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our Company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701 and are subject to the lock-up and market standoff agreements described above.

Form S-8 Registration Statement

In connection with this offering, we intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to outstanding options, outstanding shares of restricted stock and the shares of our common stock reserved for issuance under our stock plans. We expect to file this registration statement as soon as permitted under the Securities Act. However, the shares registered on Form S-8 may be subject to the volume limitations and the manner of sale, notice and public information requirements of Rule 144 and will not be eligible for resale until expiration of the lock-up and market standoff agreements to which they are subject. Of the 1,803,079 shares of our common stock that were subject to options outstanding as of June 30, 2022, options to purchase 173,061 shares of common stock were vested as of June 30, 2022. Shares of our common stock underlying outstanding options will not be eligible for sale until the expiration of the 180-day lock-up and market standoff agreements to which they are subject.

Registration Rights

We have granted demand, piggyback and Form S-3 registration rights to certain of our stockholders to sell our common stock. Registration of the sale of these shares under the Securities Act would result in these shares becoming freely 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.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following summary describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of shares of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the alternative minimum tax or Medicare Contribution tax on net investment income and does not deal with state or local tax laws, U.S. federal gift and estate tax laws, except to the limited extent provided below, or any non-U.S. tax laws that may be relevant to Non-U.S. Holders in light of their particular circumstances.

Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as:

- insurance companies, banks, investment funds and other financial institutions;
- tax-exempt organizations (including private foundations) and tax-qualified retirement plans;
- foreign governments and international organizations;
- broker-dealers and traders in securities;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons required for U.S. federal income tax purposes to conform the timing of income accruals to their financial statements under Section 451(b) of the Code;
- "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;
- persons that own, or are deemed to own, more than 5% of our capital stock;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); and
- partnerships and other entities or arrangements treated as pass-through or disregarded entities for U.S. federal income tax purposes, and investors in such entities (regardless of their places of organization or formation).

Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

Furthermore, the discussion below is based upon the provisions of the Code, and U.S. Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, possibly retroactively, or could be subject to differing interpretations which could result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the Internal Revenue Service, or 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 will not take a contrary position regarding the tax consequences described herein, or that any such contrary position would not be sustained by a court.

PERSONS CONSIDERING THE PURCHASE OF OUR COMMON STOCK PURSUANT TO THIS OFFERING SHOULD CONSULT THEIR OWN TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS AS WELL AS ANY CONSEQUENCES ARISING UNDER THE LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL OR NON-U.S. TAX CONSEQUENCES OR ANY U.S. FEDERAL NON-INCOME TAX CONSEQUENCES, AND THE POSSIBLE APPLICATION OF TAX TREATIES.

For the purposes of this discussion, a "Non-U.S. Holder" is a beneficial owner of common stock, other than a partnership or other entity or arrangement treated as a pass-through entity that is not, for U.S. federal income tax purposes, (a) an individual who is a citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate, the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If you are an individual Non-U.S. citizen, you may, in some cases, be deemed to be a resident alien (as opposed to a nonresident alien) by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. Generally, for this purpose, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year, are counted.

Resident aliens are generally subject to U.S. federal income tax as if they were U.S. citizens. Individuals who are uncertain of their status as resident or nonresident aliens for U.S. federal income tax purposes are urged to consult their own tax advisors regarding the U.S. federal income tax consequences of the ownership or disposition of our common stock.

Distributions

We do not expect to make any distributions on our common stock in the foreseeable future. If we do make distributions on our common stock, however, such distributions will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a Non-U.S. Holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock as described below under the section titled "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders–Gain on Disposition of Our Common Stock."

Any distribution on our common stock that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the non-U.S. Holder's conduct of a trade or business in the United States will generally be subject to U.S. federal withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and generally must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own

tax advisor to determine if you are able to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to the applicable withholding agent. In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the same rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

See the section titled "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders—Foreign Accounts" for additional information on withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial entities.

Gain on Disposition of Our Common Stock

Subject to the discussions below under the sections titled "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders—Backup Withholding and Information Reporting" and "—Foreign Accounts," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of the Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that the holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien who is an individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or the Non-U.S. Holder's holding period in the common stock.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at the same U.S. federal income tax rates applicable to U.S. persons. Corporate Non-U.S. Holders described in (a) above may also be subject to the additional branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) of their effectively connected earnings and profits for the taxable year, as adjusted for certain items. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by certain U.S. source capital losses (even though you are not considered a resident of the United States), provided you have timely filed U.S. federal income tax returns with respect to such losses. With respect to (c) above, in general, we would be a United States real property holding corporation if U.S. real property interests as defined in the Code and the U.S. Treasury Regulations comprised (by fair market value) at least half of the sum of our worldwide real property interests plus our other assets used or held for use in a trade or business. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. However, there can be no assurance that we will not become a United States real property holding corporation in the future. Even if we were to be treated as a U.S. real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock would not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly or constructively, no more than five percent of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the Non-U.S. Holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will qualify as regularly traded on an established securities market.

U.S. Federal Estate Tax

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and, therefore, will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise. The terms "resident" and "nonresident" are defined differently for U.S. federal estate tax purposes than for U.S. federal income tax purposes. Investors are urged to consult their own tax advisors regarding the U.S. federal estate tax consequences of the ownership or disposition of our common stock.

Backup Withholding and Information Reporting

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. federal backup withholding. U.S. federal backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8 ECI, as applicable, or otherwise establishes an exemption, *provided that* the applicable withholding agent does not have actual knowledge or reason to know the holder is a U.S. person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. broker or a U.S. office of any broker, U.S. or non-U.S., unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, or IRS Form W-8 ECI, as applicable, or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements 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-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine whether you have overpaid your U.S. federal income tax, and whether you are able to obtain a tax refund or credit of the overpaid amount.

Foreign Accounts

In addition, U.S. federal withholding taxes may apply under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments, including dividends paid to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution agrees to undertake certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the United States. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring,

among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally also would apply to payments of gross proceeds from the sale or other disposition of common stock. Under proposed regulations, however, no withholding will apply with respect to payments of gross proceeds. The preamble to the proposed regulations specifies that taxpayers are permitted to rely on such proposed regulations pending finalization.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS SUCH AS ESTATE AND GIFT TAX OR UNDER ANY APPLICABLE TAX TREATY.

UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	4,360,000
Jefferies LLC	2,997,500
Cowen and Company, LLC	2,779,500
LifeSci Capital LLC	763,000
Total:	10,900,000

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below. The offering of the shares of common stock by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $0.714 per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,635,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 1,635,000 shares of our common stock.

	Per Share	Total	
		No Exercise	Full Exercise
Public offering price	$ 17.00	$ 185,300,000	$ 213,095,000
Underwriting discounts and commissions to be paid by us	$ 1.19	$ 12,971,000	$ 14,916,650
Proceeds, before expenses, to us	$ 15.81	$ 172,329,000	$ 198,178,350

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $3.3 million. We have also agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to $35,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

In addition, we have requested that the underwriters make issuer directed allocations in the aggregate of shares of our common stock to certain investors.

We have been approved to list our common stock on Nasdaq under the trading symbol "THRD".

We and all of our directors and officers and the holders of substantially all of our outstanding securities have agreed that, without the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the "restricted period"):

(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 common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;

(2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock; or

(3) confidentially submit any draft registration statement or file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;

whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person have agreed that, without the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC on behalf of the underwriters, we or such other person will not, and will not publicly disclose intention to, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph do not apply to our directors, officers and securityholders with respect to:

(1) transactions relating to shares of common stock or other securities acquired in this offering or in open market transactions after the completion of the this offering, provided that no filing under Section 16(a) of the Exchange Act or other public announcement shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in this offering or in such open market transactions during the restricted period, and to the extent a filing under Section 16(a) of the Exchange Act (or on Schedule 13D (or 13D/A), Schedule 13G (or 13G/A) or Form 13F) is required during the restricted period as a result of transaction described in this paragraph (1), it shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this paragraph (1);

(2) transfers or distributions of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift or charitable contribution, (ii) by will or intestacy or to any member of the holder's immediate family or to a trust for the direct or indirect benefit of the holder and/or any member of the holder's immediate family, (iii) to any corporation,

partnership, limited liability company or other business entity, all of the beneficial ownership interests of which, in each such case, are held by the holder or any member of the holder's immediate family, (iv) if the holder is an entity, to general or limited partners, beneficiaries, direct or indirect members, stockholders or holders of similar equity interests in the holder, or (v) if the holder is an entity, to another corporation, partnership, limited liability company, trust or other business entity including any subsidiaries of the undersigned, that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the holder, or to any investment fund or other entity that controls or manages, is controlled or managed by or is under common control or common management with the holder or affiliated with, or an investment manager of, the holder; provided that, in the case of any transfer or distribution pursuant to this clause (2), (A) each transferee, donee or distributee shall sign and deliver a lock-up agreement, (B) such transfer or distribution does not involve a disposition for value, and (C) no filing under Section 16(a) of the Exchange Act or other public announcement reporting a reduction in beneficial ownership of shares of common stock or any securities convertible into or exercisable or exchangeable for common stock shall be required or shall be voluntarily made during the restricted period (other than, in the case of a transfer or other disposition pursuant to clause (i) or (ii) above, a Form 5 required to be filed under the Exchange Act if the holder is subject to Section 16 reporting with respect to us under the Exchange Act, any such filing will indicate by footnote disclosure or otherwise the nature of the transfer or disposition);

(3) transfers of shares of common stock or any security convertible into or exercisable or exchangeable for shares of common stock by operation of law pursuant to a qualified domestic order or other court order or in connection with a divorce settlement; provided that (i) any filing under Section 16(a) of the Exchange Act made during the restricted period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described in this clause (3) and (B) no securities were sold by the holder, (ii) the holder does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period, and (iii) each transferee shall sign and deliver a lock-up agreement;

(4) the exercise of options or other similar awards or the vesting or settlement of awards granted pursuant to our equity incentive plans as described in this prospectus and outstanding on the date of the underwriting agreement (including the delivery and receipt of shares of common stock, other awards or any securities convertible into or exercisable or exchangeable for shares of common stock in connection with such exercise, vesting or settlement), or (ii) the transfer or disposition of shares of common stock or any securities convertible into shares of common stock by the holder to us (or the purchase and cancellation of the same by us) upon a vesting or settlement event of our securities or upon the exercise of options to purchase our securities expiring during the restricted period, on a "cashless" or "net exercise" basis solely to the extent permitted by the instruments representing such options, in each case pursuant to our equity incentive plans as described in this prospectus and solely to cover withholding tax obligations in connection with such transaction and any transfer to us for the payment of taxes as a result of such transaction, provided that (A) the shares of common stock received upon the exercise, vesting, or settlement of the options or other awards described in this clause (4) are subject to the terms of the lock-up agreement, (B) no public disclosure or filing under Section 16(a) of the Exchange Act shall be voluntarily made during the restricted period, (C) to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers described in clause (4)(i), it shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in clause (4)(i) and that the shares of common stock received upon the exercise, vesting, or settlement of such options or other awards are subject the lock-up agreement, and (D) with respect to any transfers or dispositions described in clause (4)(ii) above, no public disclosure or filing shall be made during the restricted period within 60 days after the date of this prospectus (unless such equity award would otherwise expire during such period), and after such 60th day, if the holder is required to file a report reporting a reduction in beneficial ownership of shares of common stock during the restricted period, the holder shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in clause (4)(ii) and that the shares of common stock received upon such exercise or settlement are subject to the lock-up agreement;

(5) transfers to us pursuant to the repurchase of shares of common stock in connection with the termination of the holder's employment with us or other service relationship with us pursuant to contractual agreements with us as in effect as of the date of this prospectus and disclosed in this prospectus, provided that, if the holder is required to file a report reporting a reduction in beneficial ownership of shares of common stock during the restricted period, the holder shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (5) and no public disclosure or filing shall be voluntarily made;

(6) transfers of shares of common stock or any security convertible into or exercisable or exchangeable for shares of common stock that are required to effect the recapitalization of us as described in this prospectus and completed prior to the completion of this offering, including the conversion of our outstanding preferred shares, provided that (A) any shares of common stock received upon the exercise or exchange of any such convertible securities remain subject to the terms of the lock-up agreement and (B) no filing under Section 16(a) of the Exchange Act or other public filing, report or announcement shall be voluntarily made and, if any filing under Section 16(a) of the Exchange Act, or other public filing, report or announcement reporting a reduction in beneficial ownership of shares of common stock in connection with such transfer or distribution shall be legally required during the restricted period, such filing, report or announcement shall clearly indicate in the footnotes thereto the nature and conditions of such transfer;

(7) facilitating the establishment of a trading plan on behalf of a stockholder, officer, or director of ours pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the holder or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period; or

(8) transfers pursuant to a bona fide third-party tender offer, merger, amalgamation, consolidation or other similar transaction approved by our board of directors and made to all holders of our securities involving a "change of control" of us (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the holder may agree to transfer, sell, tender or otherwise dispose of shares of common stock or other such securities in connection with such transaction, or vote any shares of common stock or other such securities in favor of any such transaction); provided that in the event that such tender offer, merger, amalgamation, consolidation or other such transaction is not completed, such securities held by the holder shall remain subject to the provisions of the lock-up agreement.

The restrictions on transfers or other dispositions by us described above do not apply to (1) the shares to be sold in this offering, (2) the issuance by us of shares of common stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus as described in the registration statement and this prospectus, (3) facilitating the establishment of a trading plan on behalf of a stockholder, officer or director of ours pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period, (4) grants of options, restricted stock or other equity awards and the issuance of common stock or securities convertible into or exercisable for common stock to our employees, officers, directors, advisors, or consultants pursuant to the terms of a plan in effect on the date of this prospectus and described in the registration statement and this prospectus, provided that we shall cause each recipient of such grants of options, restricted stock or other equity awards to execute and deliver to the representatives a lock-up agreement if such recipient has not already delivered one,

(5) the filing of a registration statement on Form S-8 to register common stock issuable pursuant to any employee benefit plans, qualified stock option plans or other employee compensation plans described in the registration statement and this prospectus and provided that the recipients of such securities provide to the representatives a signed lock-up agreement, and (6) the issuance by us of shares of common stock or any securities convertible into or exercisable or exchangeable for, common stock, or the entrance into an agreement to issue common stock or any securities convertible into, or exercisable or exchangeable for, common stock, in connection with any merger, joint venture, strategic alliances, commercial or other collaborative transaction or the acquisition or license of the business, property, technology or other assets of another individual or entity or the assumption of an employee benefit plan in connection with a merger or acquisition; provided that the aggregate number of shares of common stock or any securities convertible into, or exercisable or exchangeable for, common stock that we may issue or agree to issue pursuant to this clause (6) shall not exceed 5% of our total outstanding share capital immediately following the issuance of the shares; and provided, further, that the recipients of such securities provide the representatives with a signed lock-up agreement.

Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

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. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares 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 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.

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 offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or

(iii) 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 any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

United Kingdom

Each underwriter has represented and agreed that:

(i) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, or the FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(ii) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the 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:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) 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

(iii) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require us or any of the representatives 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.

This prospectus is only for distribution to and directed at: (i) in the United Kingdom, persons having professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and high net worth entities falling within Article 49(2)(a) to (d) of the Order; (ii) persons who are outside the United Kingdom; and (iii) any other person to whom it can otherwise be lawfully distributed, or all such persons together, Relevant Persons. Any investment or investment activity to which this prospectus relates is available only to and will be engaged in only with Relevant Persons, and any person who is not a Relevant Person should not rely on it.

Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (ii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the securities were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(i) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor;

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to us, the offering, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offering of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or the FINMA, and the offering of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the shares.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or the DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under

section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring the shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions, or the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Fenwick & West LLP, San Francisco, California. Cooley LLP, San Diego, California, is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The consolidated financial statements of Third Harmonic Bio, Inc. as of December 31, 2020 and 2021, and for each of the two years in the period ended December 31, 2021, included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority 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 (File Number 333-267022) under the Securities Act with respect to the shares of our 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 filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus concerning the contents of any contract or any document are not necessarily complete. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

We currently do not file periodic reports with the SEC. Upon the completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We also maintain a website at www.thirdharmonicbio.com. Upon completion of this offering, you may access these materials at our website free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus. We have included our website in this prospectus solely as a textual reference.

Third Harmonic Bio, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements for the Years Ended December 31, 2020 and 2021:

Unaudited Interim Condensed Consolidated Financial Statements for the Six Months Ended June 30, 2021 and 2022:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Third Harmonic Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Third Harmonic Bio, Inc. and subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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/ Deloitte & Touche LLP

Parsippany, New Jersey
May 13, 2022 (September 8, 2022, as to the effects of the 1-for-2.259 stock split described in Note 14)

We have served as the Company's auditor since 2022.

THIRD HARMONIC BIO, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2020	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 8,277	$128,280
Prepaid expenses and other current assets	156	884
Total current assets	8,433	129,164
Total assets	$ 8,433	$129,164
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 581	$ 1,797
Accrued expenses and other current liabilities	1,633	3,889
Total current liabilities	2,214	5,686
Preferred stock tranche liability	4,994	—
Anti-dilution liability	883	—
Total liabilities	8,091	5,686
Commitments and contingencies (Note 11)		
Series A-1 redeemable convertible preferred stock, par value $0.0001. 13,970,000 shares authorized as of December 31, 2020 and 2021; 12,746,691 and 13,970,000 shares issued and outstanding as of December 31, 2020 and 2021, respectively; liquidation preference of $12,747 and $13,970 as of December 31, 2020 and 2021, respectively	11,008	12,574
Series A-2 redeemable convertible preferred stock, par value $0.0001. 20,000,000 and 13,750,000 shares authorized as of December 31, 2020 and 2021, respectively; 6,875,000 and 13,750,000 shares issued and outstanding as of December 31, 2020 and 2021, respectively; liquidation preference of $11,000 and $22,000 as of December 31, 2020 and 2021, respectively	7,691	19,476
Series A-3 redeemable convertible preferred stock, par value $0.0001. — and 7,812,501 shares authorized as of December 31, 2020 and 2021, respectively; — and 7,812,501 shares issued and outstanding as of December 31, 2020 and 2021, respectively; liquidation preference of — and $20,000 as of December 31, 2020 and 2021, respectively	—	33,288
Series B redeemable convertible preferred stock, par value $0.0001. — and 14,091,689 shares authorized as of December 31, 2020 and 2021, respectively; —and 14,091,686 shares issued and outstanding as of December 31, 2020 and 2021, respectively; liquidation preference of — and $105,000 as of December 31, 2020 and 2021, respectively	—	104,846
Stockholders' deficit:		
Common stock, par value $0.0001. 50,000,000 and 72,731,000 shares authorized as of December 31, 2020 and 2021, respectively; 3,866,138 and 4,237,290 shares issued and outstanding as of December 31, 2020 and 2021, respectively.	1	1
Additional paid-in capital	274	1,534
Accumulated deficit	(18,632)	(48,241)
Total stockholders' deficit	(18,357)	(46,706)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 8,433	$129,164

The accompanying notes are an integral part of these consolidated financial statements.

THIRD HARMONIC BIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	December 31, 2020	December 31, 2021
Operating expenses:		
Research and development	$ 9,953	$ 15,748
General and administrative	1,166	3,256
Total operating expenses	11,119	19,004
Loss from operations	11,119	19,004
Other (income) expense, net:		
Change in fair value of anti-dilution right liability	607	682
Change in fair value of preferred stock tranche liability	1,081	9,928
Other income	—	(5)
Total other income (expense), net	1,688	10,605
Net loss	$ 12,807	$ 29,609
Net loss per share of common stock, basic and diluted	$ 3.49	$ 7.32
Weighted-average common stock outstanding, basic and diluted	3,668,072	4,043,416

The accompanying notes are an integral part of these consolidated financial statements.

THIRD HARMONIC BIO, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock												
	Series A-1		Series A-2		Series A-3		Series B		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2020	11,449,808	$ 9,996	—	$ —	—	$ —	—	$ —	3,591,540	$ 1	$ 79	$ (5,825)	$ (5,745)
Issuance of Series A-1 redeemable convertible preferred stock under anti-dilution liability	1,297,153	1,012	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series A-2 redeemable convertible preferred stock, net of issuance costs of $174	—	—	6,875,000	7,691	—	—	—	—	—	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	—	—	274,598	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	195		195
Net loss	—	—	—	—	—	—	—	—	—	—		(12,807)	(12,807)
Balance at December 31, 2020	12,746,961	$11,008	6,875,000	$ 7,691	—	$ —	—	$ —	3,866,138	$ 1	$ 274	$ (18,632)	$ (18,357)
Issuance of Series A-2 redeemable convertible preferred stock under Series A-2 Second Tranche, net of issuance costs of $40	—	—	6,875,000	11,785	—	—	—	—	—	—	—	—	—
Gain on extinguishment of Series A-2 redeemable convertible preferred stock tranche liability	—	—	—	—	—	—	—	—	—	—	750	—	750
Issuance of Series A-1 redeemable convertible preferred stock under anti-dilution liability	1,223,039	1,566	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series A-3 redeemable convertible preferred stock, net of issuance costs of $58	—	—	—	—	7,812,501	33,288	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $154	—	—	—	—	—	—	14,091,686	104,846	—	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	—	—	371,152	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—			510		510
Net loss	—	—	—	—	—	—	—	—				(29,609)	(29,609)
Balance at December 31, 2021	13,970,000	$12,574	13,750,000	$19,476	7,812,501	$33,288	14,091,686	$104,846	4,237,290	$ 1	$ 1,534	$ (48,241)	$ (46,706)

The accompanying notes are an integral part of these consolidated financial statements.

THIRD HARMONIC BIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share amounts)

	December 31,	
	2020	2021
Cash flows from operating activities:		
Net loss	$(12,807)	$ (29,609)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	195	510
Change in fair value of preferred stock tranche liability	1,081	9,928
Change in fair value of anti-dilution liability	607	682
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(157)	(728)
Accounts payable	324	1,216
Accrued expenses and other current liabilities	1,570	2,255
Net cash used in operating activities	(9,187)	(15,746)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of issuance costs	10,825	135,749
Net cash provided by financing activities	10,825	135,749
Net increase in cash and cash equivalents	1,638	120,003
Cash and cash equivalents at beginning of period	6,639	8,277
Cash and cash equivalents at end of period	$ 8,277	$128,280
Supplemental disclosure of non-cash financing activity:		
Preferred stock tranche liability established in connection with the issuance of redeemable convertible preferred stock	$ 3,135	$ 2,979
Issuance of redeemable convertible preferred stock in settlement of preferred stock tranche liability	$ —	$ 17,149
Gain on extinguishment of preferred stock tranche liability recorded to additional paid in capital	$ —	$ 750
Issuance of redeemable convertible preferred stock in settlement of anti-dilution right liability	$ 1,012	$ 1,566

The accompanying notes are an integral part of these consolidated financial statements.

THIRD HARMONIC BIO, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business

Third Harmonic Bio, Inc., ("Third Harmonic" or the "Company") is a clinical-stage biopharmaceutical company focused on development of the next wave of medicine for the treatment of allergic and inflammatory diseases.

The Company was incorporated in 2019 as a Delaware corporation, and has principal offices in Cambridge, Massachusetts. In December 2021, the Company formed THB MS, Inc., a Delaware corporation and wholly-owned subsidiary of the Company, which is classified as a Security Corporation in Massachusetts.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, completion and success of clinical testing, development by competitors of new technological innovations, compliance with governmental regulations, dependence on key personnel and protection of proprietary technology and the ability to secure additional capital to fund operations. THB001 will require extensive clinical testing prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Liquidity

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for THB001 and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future.

Since its inception, the Company has funded its operations primarily with proceeds from sales of shares of its redeemable convertible preferred stock. The Company has incurred recurring losses since its inception, including net losses of $12.8 million and $29.6 million for the years ended December 31, 2020, and 2021, respectively. In addition, as of December 31, 2021, the Company had an accumulated deficit of $48.2 million. To date the Company has not generated any revenues and expects to continue to generate operating losses for the foreseeable future.

As of May 13, 2022, the issuance date of these consolidated financial statements, the Company expects that its existing cash and cash equivalents of $128.3 million as of December 31, 2021, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of these consolidated financial statements.

COVID-19 Pandemic

The global coronavirus disease 2019 ("COVID-19"), pandemic continues to evolve, and we will continue to monitor the COVID-19 situation. The extent of the impact of the COVID-19 pandemic on the Company's

business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's contract development and manufacturing organizations ("CDMOs"), contract research organizations ("CROs"), and other third parties with whom the Company does business, as well as its impact on regulatory authorities and key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. The Company's financial results for the years ended December 31, 2020, and 2021 were not significantly impacted by COVID-19, however, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its financial condition, operations, and business plans for 2022, including the timing and enrollment of patients in its planned clinical trials and other expected milestones of its lead product candidate.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the operations of Third Harmonic Bio, Inc. and its wholly-owned subsidiary. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and as amended by Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"). All intercompany accounts, transactions, and balances have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses, and the valuations of common stock, preferred stock tranche liability, and anti-dilution right liability. The Company bases its estimates on historical experience when available, known trends and other market-specific data, or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's focus is the research and development of the treatment of allergic and inflammatory diseases. The Company's chief operating decision maker, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include standard checking accounts and amounts held in money market funds.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. Periodically, the Company maintains deposits in federally insured

financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. As of December 31, 2020 and 2021, all of the Company's cash was held at one accredited financial institution. The Company has no financial instruments with off-balance-sheet risk of loss and has not experienced any losses on such accounts.

The Company is dependent on third-party CDMO's and CROs with whom it does business. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The Company's preferred stock tranche liability and anti-dilution right liability are carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above.

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

Research and Development Expenses

Research and development costs are charged to expense as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation expense, clinical trial costs, contracted research services, research-related manufacturing, and other external costs.

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities, and others for provisions of goods and services. These agreements are generally

cancelable, and the related costs are recorded as research and development expenses as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation and amortization, stock-based compensation, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, nonclinical and clinical development activities, and clinical trials as well as to manufacture clinical trial materials, and other costs.

Upfront payments, milestone payments and annual maintenance fees under license agreements are expensed in the period in which they are incurred, if the technology licensed has not reached technological feasibility and has no alternative future use.

Nonrefundable advance payments for goods and services to be received in the future for use in research and development activities are recorded as prepaid expenses and expenses as the related goods are delivered or the services are performed.

Accrued Research and Development Expenses

The Company has entered into various research and development contracts. The payments under these contracts are generally cancellable and are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes the progress of the research and development activities, including the phase or completion of events, invoices received and contracted costs. Significant judgements and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations.

Leases

The Company adopted FASB ASC 842 with an effective date of January 1, 2020, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use ("ROU") asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate

implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

Redeemable Convertible Preferred Stock

The Company has classified redeemable convertible preferred stock ("Preferred Stock") as temporary equity in the accompanying consolidated balance sheets due to terms that allow for redemption of the shares upon certain events that are outside of the Company's control. Costs incurred in connection with the issuance of redeemable convertible preferred stock, as well as the recognition of the preferred stock tranche liability, are recorded as a reduction of gross proceeds from issuance. The Company does not accrete the carrying values of the preferred stock to the redemption values since the occurrence of these events was not considered probable as of December 31, 2020 and 2021. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that these events will occur.

Preferred Stock Tranche Liability

The Company classifies the preferred stock tranche liability for the future purchase, and option to purchase, preferred stock as a liability on its balance sheets as the preferred stock tranche liability is a freestanding financial instrument that will require the Company to transfer equity instruments upon subsequent closings of the preferred stock financings. The preferred stock tranche liability was initially recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the preferred stock tranche liability are recognized as a component of other income and expense in the statements of operations. Changes in the fair value of the preferred stock tranche liability were recognized until the tranche liability were fulfilled or otherwise extinguished. As of December 31, 2021, the preferred stock tranche liability has been fulfilled or otherwise extinguished (see Note 6) in full.

Anti-Dilution Right Liability

The Company classifies the anti-dilution right under its license agreement with Novartis International Pharmaceutical Ltd. ("Novartis") as a derivative liability on its consolidated balance sheets as the anti-dilution right represents a freestanding financial instrument that may require the Company to transfer equity instruments upon future equity closings. The anti-dilution right liability was initially recorded at fair value upon the date of issuance and is subsequently remeasured to fair value at each reporting date. The issuance date fair value of the anti-dilution right liability was recognized as a research and development expense upon entering into the agreement with Novartis. Changes in the fair value of the anti-dilution right liability are recognized as a component of other income and expense in the statements of operations. Changes in the fair value of the antidilution right liability were recognized until the anti-dilution right with Novartis was satisfied in the first quarter of 2021, in connection with the closing of the second tranche of the Series A-2 redeemable convertible preferred stock ("Series A-2 Preferred Stock") and the issuance and sale of the Series A-3 redeemable convertible preferred stock ("Series A-3 Preferred Stock").

Stock-Based Compensation

The Company accounts for all share-based payment awards granted to employees and non-employees as stock-based compensation expense at fair value, based on the date of the grant, and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company's share-based payments include stock options and grants of restricted stock awards. For stock-based awards with service-based vesting conditions, the Company recognizes compensation expense using the straight-line method. For awards with both performance and service-based vesting conditions, the Company

records expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management's best estimates.

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

- *Fair Value of Common Stock*—We determined that based on our stage of development and other relevant factors, it was most appropriate to prepare our common stock valuations using the option-pricing method, or OPM, which used a market approach to estimate our enterprise value.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the options.
- *Expected Volatility*—Because we have been privately held and do not have any trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *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 awards.
- *Dividend Yield*—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.

The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date. The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has 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* (the "Practice Aid"), 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:

- contemporaneous valuations performed by an independent third-party valuation firm;
- our stage of development and material risks related to our business;
- the progress of our research and development programs, including the status and results of nonclinical studies and clinical trials;
- our business conditions and projections;
- sales of our preferred stock;
- the rights, preferences and privileges of our preferred stock relative to those of our common stock;
- lack of marketability of our common and preferred stock as a private company;
- our operating results and financial performance;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, in light of prevailing market conditions;
- the trends, developments and conditions in the life sciences and biopharmaceutical industry sectors;
- analysis of initial public offerings and the market performance and stock price volatility of similar public companies in the life sciences and biopharmaceutical sectors; and
- the economy in general.

Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The Company adopted ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07") at inception of the 2019 Stock Incentive Plan, prior to the issuance of any stock option grants. The measurement date for non-employee awards is the date of grant without changes in the fair value of the award. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis.

Stock-based compensation expense is classified in the accompanying consolidated statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients service payments are classified.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

Deferred tax assets are recognized to the extent that the Company believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (i) the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

Interest and penalties are recognized related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2020 and 2021, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2020 and December 31, 2021, there was no difference between net loss and comprehensive loss and accordingly a statement of comprehensive income is not presented.

Net Income (Loss) Per Share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities, which include the Company's redeemable convertible preferred stock, according to dividends declared or accumulated and participation rights in

undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is antidilutive. The Company reported a net loss attributable to common stockholders for years ended December 31, 2020, and 2021.

Basic net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of diluted securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For the purpose of this calculation, unvested restricted common stock, outstanding stock options, and redeemable convertible preferred stock are considered potential dilutive common shares.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with certain new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. As noted below, certain new or revised accounting standards were early adopted.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

The Company early adopted ASU 2020-06, *Debt – Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging – Contracts in Entity's Own Equity* (Subtopic 815-40) ("ASU 2020-06"). The update simplifies the accounting for convertible debt instruments and convertible preferred stock by reducing the number of accounting models and limiting the number of embedded conversion features separately recognized from the primary contract. The guidance also includes targeted improvements to

the disclosures for convertible instruments and earnings per share. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU 2020-06 effective January 1, 2021, using the modified retrospective method. The adoption did not have a material impact on the Company's financial statements.

In October 2020, the FASB issued ASU No. 2020-10 ("ASU-2010"), *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company adopted this accounting standard as of January 1, 2021 with no material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the Financial Accounting Standards Board (FASB) issued ASU No. 2019-12 ("ASU 2019-12") *Simplifying the Accounting for Income Tax*. The standard contains several provisions that reduce financial statement complexity including removing the exception to the incremental approach for intra-period tax expense allocation when a company has a loss from continuing operations and income from other items not included in continuing operations. The new guidance is effective for the year beginning January 1, 2022 with optional adoption prior to the effective date. The Company does not expect that the new standard will have a material impact on the Company's consolidated financial statements.

3. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

		December 31, 2020		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Liabilities				
Preferred stock tranche liability	$4,994			$ 4,994
Anti-dilution liability	883			883
Total financial liabilities	$5,877	$ —	$ —	$ 5,877

		December 31, 2021		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets				
Money market funds	$22,505	$ 22,505		
Total financial assets	$22,505	$ 22,505	$ —	$ —

As of December 31, 2020, the Company had no financial assets that required fair value measurement. As of December 31, 2021, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment.

As of December 31, 2020, the Company had Level 3 financial liabilities that were measured at fair value on a recurring basis. The Company's preferred stock tranche liability and anti-dilution right liability were carried at fair value determined using Level 3 inputs in the fair value hierarchy. As of December 31, 2021, the preferred stock tranche liability and anti-dilution right liability have been waived or satisfied, and as such, there are no liabilities recorded as of December 31, 2021.

During the years ended December 31, 2020, and 2021 there were no transfers or reclassifications between fair value measure levels of liabilities. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Preferred Stock Tranche Liability

In connection with the issuance of the Series A-1 redeemable convertible preferred stock ("Series A-1 Preferred Stock"), Series A-2 Preferred Stock and Series A-3 Preferred Stock (see Note 6), the Company granted investors future tranche rights to purchase the respective preferred stock, which was classified as a liability on its consolidated balance sheets, as the preferred stock tranche liability is a freestanding financial instrument as it was determined to be legally detachable and required the Company to transfer the equity instruments at a fixed price upon the occurrence of certain events.

The fair value of the preferred stock tranche liabilities recognized in connection with the Company's Series A-1 Preferred Stock financing in July 2019, Series A-2 Preferred Stock financing in July 2020, and Series A-3 Preferred Stock financing in February 2021 were estimated based on results of a third party valuation performed in connection with each redeemable convertible preferred stock issuance.

The fair value of the preferred stock tranche liability was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. A change in the assumptions related to the valuation of the preferred stock tranche liability could have a significant impact on the fair value. The preferred stock tranche liability was valued as a forward contract, using an option pricing model, specifically the Black-Scholes option pricing model. In determining the fair value of the preferred stock tranche liability, estimates and assumptions impacting the fair value included the estimated future values of the Company's Preferred Stock, discount rates, estimated time to tranche closing, and probability of each tranche closing. The Company remeasured the preferred stock tranche liability at each reporting period and prior to settlement.

The following table provides a rollforward of the aggregate fair value of the Company's preferred stock tranche liability (in thousands):

	Preferred Stock Tranche Liability
Balance as of December 31, 2019	$ 778
Change in fair value	1,081
Fair value of liability established in connection with the issuance of Series A-2 Preferred Stock	3,135
Balance as of December 31, 2020	4,994
Change in fair value	9,927
Settlement of liability in connection with the issuance of Series A-2 Preferred Stock	(825)
Extinguishment of Series A-2 tranche liability recorded to additional paid in capital	(750)
Fair value of liability established in connection with the issuance of Series A-3 Preferred Stock	2,978
Settlement of liability in connection with the issuance of Series A-3 Preferred Stock	(16,324)
Balance as of December 31, 2021	$ —

Anti-Dilution Right Liability

The anti-dilution right liability recognized in connection with the anti-dilution provisions set forth in the Company's license agreement with Novartis (see Note 5), represented a freestanding financial instrument that required the Company to transfer equity instruments upon future equity issuances for no additional consideration.

The fair value of the anti-dilution right liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value was estimated using a Monte Carlo analysis to simulate the fair value of the preferred stock to be issued to maintain the fully diluted ownership percentages based on the expected financing dates. Changes in the estimated fair value and the probability of achieving different financing scenarios can have a significant impact on the fair value of the anti-dilution right liability. The Company remeasured the anti-dilution right liability at each reporting period and prior to settlement.

The following table provides a rollforward of the aggregate fair value of the Company's anti-dilution right liability (in thousands):

	Anti-Dilution Right Liability
Balance as of December 31, 2019	$ 1,288
Settlement of liability in connection with the issuance of Series A-1 Preferred Stock	(1,012)
Change in fair value	607
Balance as of December 31, 2020	883
Settlement of liability in connection with the issuance of Series A-1 Preferred Stock	(1,565)
Change in fair value	682
Balance as of December 31, 2021	$ —

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2020	2021
Accrued research and development expenses	$1,163	$2,685
Professional fees	65	450
Employee compensation and related benefits	339	752
Other	66	2
Total accrued expenses and other current liabilities	$1,633	$3,889

5. Novartis License Agreement

On June 28, 2019, the Company entered into a License Agreement (the "Novartis License Agreement") with Novartis Pharma AG, formerly known as Novartis International Pharmaceutical Ltd, ("Novartis"). Pursuant to the Novartis License Agreement, the Company has been granted an exclusive, worldwide, royalty-bearing, sublicensable license under specified patent rights and know-how related to two licensed compounds to develop, make, use and sell certain products incorporating or comprising a licensed compound, including THB001 to certain intellectual property rights owned or controlled by Novartis (the "Licensed IP"), to research, develop, make, use, sell, and commercialize products containing the Licensed IP. Under the Novartis License Agreement, the Company is solely responsible for all research, development, regulatory and commercialization activities related to the Licensed IP. The Company is required to use commercially reasonable efforts to develop and seek regulatory approval for, and commercialize, at least one licensed product in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

In exchange for these rights, the Company made an upfront cash payment of $0.4 million and issued 3,449,808 shares of Series A-1 Preferred Stock with a fair value of $3.0 million to Novartis. The total initial consideration of $3.4 million transferred to Novartis was expensed as research and development expense upon entering into the agreement in 2019. The Company determined that the Novartis License Agreement represented an asset acquisition as it did not meet the definition of a business. The Company recorded the initial consideration transferred to Novartis as research and development expense in the statement of operations because the acquired Licensed IP represented in-process research and development with no alternative future use.

In addition, under the Novartis License Agreement, an anti-dilution right was issued to Novartis, in which Novartis is entitled to receive shares of Series A-1 Preferred Stock, guaranteeing them a 15% ownership interest of the fully diluted capitalization of the Company. The Company was obligated to issue additional shares of Series A-1 Preferred Stock until the Company had (1) raised aggregate cumulative proceeds of $30.0 million from sales of equity securities since its inception; or (2) issued and sold any securities that generate proceeds in excess of $30.0 million. Additionally, the Company was not obligated to issue more than 6,383,142 shares of the Series A-1 Preferred Stock to Novartis under the anti-dilution right. The Company assessed the Novartis anti-dilution right and determined that the right (i) meets the definition of a freestanding financial instrument that was not indexed to the Company's own stock and (ii) meets the definition of a derivative and did not qualify for equity classification. The initial fair value of the anti-dilution right liability of $1.0 million was recorded as research and development expense in July 2019, as part of the initial consideration in the license agreement. The Company remeasured the liability associated with the anti-dilution right at each reporting date and at each issuance of Series A-1 Preferred Stock under the anti-dilution right. Changes in the fair value were recorded as other income and expense in the statement of operations until the anti-dilution right was satisfied in February 2021 upon the Company raising aggregate cumulative proceeds of $30.0 million in sales of equity securities. As part of the anti-dilution right, the Company issued a total of 5,970,000 shares of Series A-1 Preferred Stock to Novartis. During the years ended December 31, 2020 and 2021, the Company recorded expense associated with changes in fair value of the anti-dilution right liability of $0.6 million and $0.7 million, respectively. Refer to Note 3 for a summary in the changes of the anti-dilution rights during the years ended December 31, 2020 and December 31, 2021.

Under the Novartis License Agreement, the Company is obligated to make aggregate milestone payments of up to $231.7 million related to the achievement of specified development, commercialization, and sales milestones. The Company records the milestone payments as research and development expense when the milestones occur and consideration is paid or becomes payable. As of December 31, 2021, the Company has made two development milestone payments under the Novartis Agreement totaling $1.0 million, of which $0.4 million achieved and paid in 2019, and $0.6 million was achieved and paid in the year ended December 31, 2020, which have been recorded as research and development expense. No other milestones have occurred or have been paid have been made under the Novartis License Agreement.

As part of the Novartis License Agreement, the Company also agreed to pay tiered royalties based on future net sales of all products licensed under the agreement, of which the royalty percentage ranged within the single digits.

6. Redeemable Convertible Preferred Stock

As of December 31, 2020 and 2021, the Company's certificate of incorporation, as amended and restated (the "Amended and Restated Certificate of Incorporation") authorized the Company to issue 33,970,000 and 49,624,190 shares of preferred stock, respectively, with a par value of $0.0001 per share.

Series A-1 Redeemable Convertible Preferred Stock

In June 2019, the Company's board of directors (the "Board") authorized the issuance and sale of 14,383,142 shares of Series A-1 Preferred Stock. On July 3, 2019, the Company entered into a Series A-1 Preferred Stock purchase agreement (the "Series A-1 Agreement") with Atlas Venture Fund XI, L.P. ("Atlas"), in

which the Company issued and sold an aggregate of 8,000,000 shares of Series A-1 Preferred Stock with a par value of $0.0001 and at a purchase price of $1.00 per share, resulting in gross proceeds of $8.0 million (the "Series A-1 First Tranche Closing"). Included within the Series A-1 Agreement were two additional future tranche obligations (the "Series A Second Tranche" and "Series A Third Tranche") for the Company to issue and sell shares of Series A-2 Preferred Stock. Upon execution of the Company's license agreement with Novartis in July 2019, the Company issued an additional 3,449,808 shares of Series A-1 Preferred Stock (see Note 5).

The Series A Second Tranche obligated the Company to issue and sell 2,666,667 shares of Series A-2 Preferred Stock to Atlas, and up to 2,666,667 shares of Series A-2 Preferred Stock to additional investors, each at a purchase price of $1.50 per share. The issuance of shares under the Series A Second Tranche was contingent to occur following a determination by the holders of a majority of the then outstanding Series A-1 Preferred Stock.

The Series A Third Tranche obligated the Company to issue and sell 4,666,667 shares of Series A-2 Preferred Stock to Atlas, and up to 4,666,667 shares of Series A-2 Preferred Stock to additional investors, each at a purchase price of $1.50 per share. The issuance of shares under the Series A Third Tranche was contingent to occur following a determination by the holders of a majority of the combined voting power of the then outstanding shares of Series A-1 Preferred Stock and Series A-2 Preferred Stock, calculated on an as converted common stock basis.

The Company concluded that the rights to participate in the Series A Second Tranche and Series A Third Tranche met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A-1 Preferred Stock and (ii) required the Company to transfer equity instruments upon future events. Upon the issuance of the Series A-1 Preferred Stock, the Company recognized a preferred stock tranche liability of $1.0 million, with a corresponding reduction to the carrying value of the Series A Preferred Stock. At the issuance of the Series A-1 Preferred Stock in July 2019, the carrying value was $7.0 million, equal to the gross proceeds of $8.0 million, reduced by the fair value of the preferred stock tranche liability of $1.0 million, and issuance costs of $55 thousand. Both the Series A Second Tranche and Series A Third Tranche were foregone by the investors in July 2020, upon entering into the Series A-2 Preferred Stock Agreement (as defined below). At the time, the Company wrote down the liability associated with the Series A Second Tranche and Series A Third Tranche liability to zero, resulting in a gain of $0.8 million recorded in the Company's consolidated statements of operations within other income (expense), net during the year ended December 31, 2020.

In July 2020, upon entering into the Series A-2 Agreement (as defined below), the Company issued an additional 1,297,153 shares of Series A-1 Preferred Stock to Novartis, and in February 2021, upon the closing of the Series A-2 Second Tranche (as defined below) and entering into the Series A-3 Agreement (as defined below), the Company issued an additional 1,223,039 shares of Series A-1 Preferred Stock to Novartis, which issuances were pursuant to the anti-dilution right clause included in the Novartis License (see Note 5).

Series A-2 Redeemable Convertible Preferred Stock

In June 2019, at the same time the Board authorized the issuance of the Series A-1 Preferred Stock, the Board authorized the issuance of 14,666,667 shares of Series A-2 Preferred Stock. On July 13, 2020, the Company entered into a Series A-2 Preferred Stock purchase agreement (the "Series A-2 Agreement") with Atlas and OrbiMed Private Investments VII, LP ("OrbiMed"), in which the Company issued and sold an aggregate of 6,875,000 shares of Series A-2 Preferred Stock with a par value of $0.0001 and at a purchase price of $1.60 per share, resulting in gross proceeds of $11.0 million (the "Series A-2 First Tranche Closing"). Included within the Series A-2 Agreement were two additional future tranches obligations (the "Series A-2 Second Tranche" and "Series A-2 Third Tranche") for the Company to issue and sell shares of Series A-2 Preferred Stock.

The Series A-2 Second Tranche obligated the Company to issue and sell an aggregate of 6,875,000 shares of Series A-2 Preferred Stock to Atlas and OrbiMed, each at a purchase price of $1.60 per share. The issuance of

shares under the Series A-2 Second Tranche was contingent upon Atlas and OrbiMed's waiver or approval and satisfaction of the Company's GLP Toxicology Studies of the Company's lead compound (the "Series A-2 Second Tranche Milestone Event").

The Series A-2 Third Tranche obligated the Company to issue and sell an aggregate of 6,250,000 shares of Series A-2 redeemable convertible preferred stock to Atlas and OrbiMed, each at a purchase price of $1.60 per share. The issuance of shares under the Series A-2 Third Tranche was contingent upon Atlas and OrbiMed's waiver or approval and satisfaction of safety data from the Phase 1a trial of the Company's lead compound (the "Series A-2 Third Tranche Milestone Event").

The Company concluded that the rights to participate in the Series A-2 Second Tranche and Series A-2 Third Tranche met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A-2 Preferred Stock and (ii) required the Company to transfer equity instruments upon future events. Upon the issuance of the Series A-2 Preferred Stock, the Company recognized a preferred stock tranche liability of $3.1 million, with a corresponding reduction to the carrying value of the Series A-2 Preferred Stock. At the issuance of the Series A-2 Preferred Stock in July 2020, the carrying value was $7.7 million, equal to the gross proceeds of $11.0 million, reduced by the fair value of the preferred stock tranche liability of $3.1 million, and issuance costs of $0.2 million.

In February 2021, upon waiver by Atlas and Orbimed, an aggregate of 6,875,000 shares of Series A-2 Preferred Stock were issued and sold under the Series A-2 Second Tranche, resulting in gross proceeds of $11.0 million. Prior to the issuance and sale of shares under Series A-2 Second Tranche, the Company remeasured the tranche liability associated with the Series A-2 Second Tranche and Series A-2 Third Tranche, which resulted in a gain of $3.4 million that was recorded to other income and expense during the year ended December 31, 2021. The fair value of the Series A-2 tranche liability at the time of the closing of the Series A-2 Second Tranche of $0.8 million was recorded a part of the carrying value of the Series A-2 Preferred Stock. The Series A-2 Third Tranche was forgone by Atlas and OrbiMed upon entering into the Series A-3 Preferred Stock Agreement (as defined below). The Company wrote off the fair value of the Series A-2 Third Tranche liability, which resulted in a gain of $0.8 million that was recorded to additional paid-in capital during the year ended December 31, 2021.

Series A-3 Redeemable Convertible Preferred Stock

In February 2021, the Board authorized the issuance and sale of 7,812,501 shares of Series A-3 Preferred Stock. On February 24, 2021, the Company entered into a Series A-3 Preferred Stock purchase agreement (the "Series A-3 Agreement") with Biotechnology Value Fund, LP ("BVF"), in which the Company issued and sold an aggregate of 1,953,125 shares of Series A-3 Preferred Stock with a par value of $0.0001 and at a purchase price of $2.56 per share, resulting in gross proceeds of $5.0 million (the "Series A-3 First Tranche Closing"). Included within the Series A-3 Agreement was an additional future tranche liability (the "Series A-3 Second Tranche") for the Company to issue and sell shares of Series A-3 Preferred Stock.

The Series A-3 Second Tranche obligated the Company to issue and sell an aggregate of 5,859,376 shares of Series A-3 Preferred Stock to Atlas, OrbiMed, and BVF (collectively the "Existing Investors") each at a purchase price of $2.56 per share. The issuance of shares under the Series A-3 Second Tranche was contingent upon the determination by the Board that certain data from the Company's Phase 1a clinical trial for its lead compound supported the progression to a Phase 1b clinical trial (the "Series A-3 Second Tranche Milestone Event") or a waiver by the Existing Investors.

The Company concluded that the rights to participate in the Series A-3 Second Tranche met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A-3 Preferred Stock and (ii) required the Company to transfer equity instruments upon future events. Upon the issuance of the Series A-3 Preferred Stock, the

Company recognized a preferred stock tranche liability of $3.0 million, with a corresponding reduction to the carrying value of the Series A-3 Preferred Stock. At the issuance of the Series A-3 Preferred Stock in February 2021, the carrying value was $2.0 million, equal to the gross proceeds of $5.0 million, reduced by the fair value of the preferred stock tranche liability of $3.0 million, and issuance costs of $40 thousand.

In November 2021, upon waiver by the Existing Investors, 5,859,376 shares of Series A-3 Preferred Stock were issued and sold to the Existing Investors under the Series A-3 Second Tranche, resulting in gross proceeds of $15.0 million. Prior to the issuance and sale of shares under Series A-3 Second Tranche, the Company remeasured the tranche liability associated with the Series A-3 Second Tranche, which resulted in expense of $13.3 million that was recorded to other income and expense during the year ended December 31, 2021. The fair value of the tranche liability at the time of the closing of the Series A-3 Second Tranche of $16.3 million was recorded a part of the carrying value of the Series A-3 Preferred Stock.

Series B Redeemable Convertible Preferred Stock

In December 2021, the Board authorized the issuance and sale of 14,091,689 shares of Series B redeemable convertible preferred stock ("Series B Preferred Stock"). On December 17, 2021, the Company entered into a Series B Preferred Stock purchase agreement (the "Series B Agreement") with various investors, both new and existing, in which the Company issued and sold an aggregate of 14,091,686 shares of Series B Preferred Stock with a par value of $0.0001 and at a purchase price of $7.45 per share, resulting in gross proceeds of $105.0 million. At the issuance of the Series B Preferred Stock, the carrying value was $104.8 million, equal to the gross proceeds of $105.0 million, reduced by issuance costs of $0.2 million.

Upon issuance of each class of Series A and Series B Preferred Stock, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

As of each balance sheet date, the Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2020				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	13,970,000	12,746,961	$11,008	$ 12,747	5,642,745
Series A-2 Preferred Stock	20,000,000	6,875,000	7,691	11,000	3,043,381
Total	33,970,000	19,621,961	$18,699	$ 23,747	8,686,126

	December 31, 2021				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	13,970,000	13,970,000	$ 12,574	$ 13,970	6,184,150
Series A-2 Preferred Stock	13,750,000	13,750,000	19,476	22,000	6,086,762
Series A-3 Preferred Stock	7,812,501	7,812,501	33,288	20,000	3,458,386
Series B Preferred Stock	14,091,689	14,091,686	104,846	105,000	6,238,018
Total	49,624,190	49,624,187	$ 170,184	$ 160,970	21,967,316

The holders of the Preferred Stock have the following rights, preferences and privileges:

Voting

The holder of each share of Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters presented to the stockholders of the Company.

The holders of Series A Preferred Stock, voting exclusively and as a separate class, are entitled to elect four directors of the Company. The holders of Series B Preferred Stock, voting exclusively and as a separate class, are entitled to elect one director of the Company.

Conversion

Each share of Preferred Stock is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the original issue price by the conversion price for each series of Preferred Stock (as defined below). The conversion price, and the rate at which each series of preferred stock may be converted into common stock, are subject to adjustment from time to time to reflect future share dividends, splits, combinations, recapitalizations and similar events.

Further, each share of Preferred Stock shall automatically be converted into shares of common stock at the conversion rate at the time in effect for such series of Preferred Stock immediately upon either of: (i) the closing of the Company's sale of common stock to the public at a price per share of at least $16.83 per share in an initial public offering (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the applicable class of common stock), resulting in at least $75.0 million of proceeds, net of the underwriting discount and commissions; or (ii) the date and time, or occurrence of an event, specified by vote or written consent of the requisite holders of at least 65% of the combined voting power of the shares of Preferred Stock then outstanding as calculated on an as-converted to common stock basis.

Dividends

The holders of the Preferred Stock are entitled to receive dividends at the rate of 8% of the applicable original issue price per annum. Dividends shall not be cumulative or compounded and shall be payable only when, as and if declared by the Board and in preference and in priority to any dividends on common stock. There have been no dividends declared by the Board as of December 31, 2020 and 2021.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company ("Liquidation Event"), the holders of Preferred Stock (first to the holders of Series B Preferred Stock, then to the holders of Series A-3 Preferred Stock, then to the holders of Series A-2 Preferred Stock, then to the holders of Series A-1 Preferred Stock) are entitled to receive prior and in preference to the holders of common stock, an amount equal to an amount per share equal to the greater of the original issue price, plus all declared and unpaid dividends on the Preferred Stock or the price per share that would be received if the Preferred Stock were converted to common stock. If the assets and funds available to be distributed to all holders of Preferred Stock are insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to holders of the Preferred Stock shall be distributed ratably among the holders of Preferred Stock, acting as a single class, at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

After the payment of the full liquidation preference of the Preferred Stock as set forth above, the remaining assets of the Company legally available for distribution in such liquidation event shall be distributed ratably to the holders of shares of common stock.

Redemption

The Preferred Stock is not redeemable at the option of the holder thereof except for in the event of a Liquidation Event if the corporation does not effect a dissolution under the general corporation law within 90 days after such Liquidation Event.

7. Common Stock

As of December 31, 2020 and 2021, the Company's Amended and Restated Certificate of Incorporation authorized the Company to issue 50,000,000 and 72,731,000 shares of common stock, respectively, with a par value of $0.0001.

The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, preferences and privileges of the holders of the preferred stock as set forth above.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), provided however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to the Amended and Restated Certificate of Incorporation. There are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Amended and Restated Certificate of Incorporation.

As of December 31, 2020, and 2021, the Company has reserved the following shares of common stock for the potential conversion of outstanding preferred stock, the exercise of stock options, and the vesting of restricted common stock:

	December 31,	
	2020	2021
Preferred stock, as converted	8,686,126	21,967,316
Options to purchase common stock	384,396	394,254
Unvested restricted common stock	1,059,418	1,907,102
Remaining shares reserved for future issuance	3,294,458	2,065,764
Total	13,424,398	26,334,436

8. Stock-Based Compensation

2019 Stock Incentive Plan

The Company adopted the 2019 Stock Incentive Plan (the "2019 Plan") in July 2019 pursuant to which the Company can issue incentive stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. The 2019 Plan is administered by the Board or, at the discretion of the Board, by a committee delegated by Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company's Board values the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third party valuation specialists as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. The 2019 Plan was subsequently amended on various dates throughout 2020 and 2021, with each amendment increasing the number of awards issuable under the plan. As of December 31, 2021, there were 5,063,021 shares of common stock that were issuable under the 2019 Plan, of which there were 394,254 stock options granted and 2,603,003 restricted stock granted. As of December 31, 2021, 2,065,764 shares of common stock remained available for future grant under the 2019 Plan.

Shares that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Stock Options

The Company has granted stock options with both service-based and performance-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant. For accounting purposes, a retrospective fair value assessment of the common stock was performed to determine the fair value of the Company's common stock and to calculate stock-based compensation expense. These reassessed values were based, in part, upon third-party valuations of our common stock prepared as of each grant date on a retrospective basis. The third-party valuations were prepared using the hybrid method and used market approaches to determine our enterprise value.

The Company utilized the Black-Scholes option-pricing model to estimate the fair value of stock options awarded to employees. The Black-Scholes option-pricing model requires several key assumptions. The key assumptions used to apply this pricing model were as follows:

	December 31,	
	2020	2021
Expected term (in years)	6.06	6.06
Expected volatility	84.0 - 85.6%	82.4 - 84.2%
Risk-free interest rate	0.37 - 0.54%	0.87 - 1.20%
Expected dividend yield	—	—
Fair value of common stock	$ 1.03	$ 1.90

The following table summarizes the Company's stock option activity under the 2019 Plan:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	384,396	0.45	9.91	$ 321
Granted	159,204	1.44		
Exercised	—	—		
Forfeited or cancelled	(149,346)	0.45		
Outstanding as of December 31, 2021	394,254	0.85	9.08	$ 3,297
Options vested and exercisable as of December 31, 2021	46,617	0.45	8.80	$ 409
Options unvested as of December 31, 2021	347,637	0.90	9.12	$ 2,889

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2020 and 2021 was $0.84 and $1.41, respectively. As of December 31, 2021, there was $0.3 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 3.45 years.

The total fair value of options vested during the year ended December 31, 2021was $40 thousand.

Included within the total stock options outstanding are 135,071 stock options to purchase common stock which have performance-based vesting criteria and were granted to certain employees, officers and consultants of the Company on various dates during the years ended December 31, 2020 and 2021 (collectively, the "Performance Stock Options"). Vesting of 37,133 of the Performance Stock Options was contingent on the closing of the Series A-2 Second Tranche, which occurred on February 24, 2021, and vesting of the remaining 97,938 Performance Stock Options was contingent on the closing of the Series A-3 Second Tranche, which occurred on November 15, 2021. The vesting commencement date of the Performance Stock Options was the date in which the performance condition is met, and vesting occurs based on the accelerated attribution method over four years from the vesting commencement date. The Company began to recognize expense associated with the Performance Stock Options on the date in which each respective performance criteria was met and recognized total stock-based compensation expense associated with the Performance Stock Options of $30 thousand for the year ended December 31, 2021. No expense associated with the Performance Stock Options was recognized prior to the year ended December 31, 2021.

Restricted Common Stock Awards

The Company has granted restricted common stock awards with service and performance and service based vesting conditions to employees of the Company. Unvested shares of restricted common stock may not be sold or transferred by the holder, except for transfers for estate planning purposes in which the transferee agrees to remain bound by all restrictions set forth in the original common stock purchase agreement. These restrictions lapse over the vesting term of each award, which is typically four years. The purchase price of each share of restricted common stock was $0.0001 per share.

On August 9, 2021, the Company's chief executive office ("CEO") purchased 1,218,836 shares of common stock at a purchase price of 1.44 per share, under the terms of a restricted common stock award granted under the 2019 Plan. These shares were purchased in exchange for a promissory note (the "Promissory Note") of $1.8 million. The shares granted include both service and performance-based vesting criteria. Of the shares granted, (i) 269,044 shares are to vest upon the completion of one year of service measured from August 9, 2021 (the "Vesting Commencement Date"); (ii) 807,134 shares are to vest in a series of successive equal quarterly installments of 6.25% upon the CEO's completion of each additional quarter of service over a three year period from the first anniversary of the Vesting Commencement Date; and (iii) 142,658 shares (the "Performance Shares") are subject to vesting upon the occurrence of the Series A-3 Second Tranche closing, which occurred on November 15, 2021. Upon the occurrence of the Series A-3 Second Tranche closing, 35,664 of the Performance Shares vest on the first anniversary of the Vesting Commencement Date, and the remaining 106,994 Performance Shares vest in a series of successive equal quarterly installments of 6.25% upon the CEO's completion of each additional quarter of service over a three year period from the first anniversary of the Vesting Commencement Date. The Company may purchase all of the unvested shares following the employee's termination at the original purchase price. As of December 31, 2021, none of the shares granted have vested.

The Promissory Note accrues interest at a rate of 0.76% per annum, compounded annually, and are repayable at the earlier of (i) the seventh anniversary from the date of the Promissory Note; (ii) ninety days after termination of the CEO's service to the Company; or (iii) a change in control of the Company. Further, the principal and accrued but unpaid interest of the Promissory Note is to be repaid prior to the Company becoming an issuer within the meaning of the Sarbanes-Oxley Act of 2022. The Promissory Note is collateralized by a pledge of certain assets of the employee, and is a partial recourse note. The Company has accounted for the Promissory Note as non-recourse in its entirety as the recourse and non-recourse portion of the Promissory Note are not directly aligned with a corresponding percentage of the underlying shares. The non-recourse notes received by the Company as consideration for the issuance of the restricted stock has been considered a stock option for accounting purposes as the substance is similar to the grant of an option until the note is settled. The fair value of the restricted stock granted to the CEO in exchange for the Promissory Note is estimated on the grant date using the Black-Scholes option pricing model. The exercise price is the principal due on the Promissory Note. The fair value of the award is recognized over the requisite service period (not the term of the

Promissory Note) through a charge to compensation cost. The grant date fair value of the restricted stock granted to the CEO was estimated using the following assumptions:

	December 31, 2021
Expected term (in years)	6.53
Expected volatility	82.4%
Risk-free interest rate	0.92%
Expected dividend yield	—
Fair value of common stock	$ 1.90

A summary of the activity of the restricted common stock under the 2019 Plan was as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2020	1,059,418	$ 0.71
Granted	1,218,836	1.43
Vested	(371,152)	0.84
Unvested at December 31, 2021	1,907,102	$ 1.17

The weighted-average grant-date fair value per share of restricted common stock awards granted during the years ended December 31, 2020, and 2021 was $1.03 and $1.43, respectively. The aggregate fair value of restricted stock awards that vested during the year ended December 31, 2020 and 2021 was $0.2 million and $0.3 million, respectively. Stock-based compensation expense recognized for the restricted stock granted was $0.2 million and $0.5 million as of December 31, 2020 and 2021, respectively. As of December 31, 2021 there was unrecognized expense of $2.0 million related to the restricted stock, which is expected to be recognized over a weighted-average period of 3.25 years.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's consolidated statements of operations was as follows (in thousands):

	December 31,	
	2020	2021
Research and development	$134	$224
General and administrative	61	286
Total stock-based compensation expense	$195	$510

9. Income Taxes

Income (loss) before provision for income taxes consisted of the following (in thousands):

	December 31,	
	2020	2021
Domestic	$(12,807)	$(29,609)
Foreign	—	—
Loss before provision for income taxes	$(12,807)	$(29,609)

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	December 31,	
	2020	2021
Income at US statutory rate	21.00%	21.00%
State taxes, net of federal benefit	6.07	3.43
Permanent differences	(2.11)	(7.36)
Tax credits	2.39	1.03
Tax law change	0.00	0.00
Foreign rate differential	0.00	0.00
Valuation allowance	(27.35)	(18.21)
Other	0.00	0.00
Total	0.00%	0.00%

The net deferred income tax asset balance related to the following (in thousands):

	December 31,	
	2020	2021
Intangibles	$ 1,205	$ 1,613
Accrued expenses & other	90	252
Anti-dilution liability	241	—
Net operating loss carryforwards	3,232	7,935
Credits	413	774
Total deferred tax assets	5,181	10,574
Valuation allowance	(5,181)	(10,574)
Net deferred tax assets (liability)	$ —	$ —

As of December 31, 2020 and 2021, the Company had a federal net operating loss carryforward of $11.9 million and $29.8 million, which can be carried forward indefinitely. As of December 31, 2020 and 2021, the Company has state NOL carryforwards of $11.8 million and $26.7 million. The state net operating loss carryforwards begin to expire in 2039.

As of December 31, 2021, the Company also has federal and state tax credits of $0.7 million and $0.2 million, which being to expire in 2039 and 2039, respectively.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2020 and 2021, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2020 and 2021.

Under Internal Revenue Code Section 382, 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 may be limited. We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple ownership changes since we became a "loss corporation" as defined in

Section 382. Future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change." In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an "ownership change." If an "ownership change" has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to us.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which we operate or do business in. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

We record uncertain tax positions as liabilities in accordance with ASC 740 and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2020 and 2021, we have not recorded any uncertain tax positions in our financial statements.

We recognize interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2020and 2021, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax years are still open under statute from December 31, 2018, to the present. The resolution of tax matters is not expected to have a material effect on the Company's consolidated financial statements.

10. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented (in thousands, except share and per share amounts):

	December 31,	
	2020	2021
Numerator:		
Net loss	$ 12,807	$ 29,609
Net loss attributable to common stockholders, basic and diluted	$ 12,807	$ 29,609
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	3,668,072	4,043,416
Net loss per share of common stock, basic and diluted	$ 3.49	$ 7.32

The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2020 and 2021 because including them would have had an anti-dilutive effect:

	December 31,	
	2020	2021
Redeemable convertible preferred stock	8,686,126	21,967,316
Options to purchase common stock	384,396	394,254
Unvested restricted stock	1,059,418	1,907,102
Total	10,129,940	24,268,672

11. Commitments and Contingencies

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of December 31, 2020 and 2021, there were no matters which would have a material impact on the Company's financial results.

Leases

The Company's operating leases are comprised of month-to-month office space leases entered into with Atlas for various office suites located at 400 Technology Square in Cambridge, Massachusetts, with the Company acting as a subtenant. Given the short-term nature of the leases, and as the Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet, as further described in Note 2, no operating lease ROU asset and liability has been recognized as of December 31, 2020, and 2021. For the years ended December 31, 2020, and 2021, the Company has recognized short-term lease expense of $48 thousand and $0.1 million, respectively.

12. Related Party Transactions

Atlas

Atlas is a significant beneficial owner of the Company, holding more than 5% of the total outstanding stock of the Company, as of December 31, 2020, and 2021. The Company leases various office space from Atlas for use in its daily operations. During each of the years ended December 31, 2020 and 2021 the Company made payments of $0.2 million associated with the lease agreements with Atlas, which was recorded within general and administrative expense.

Novartis

Novartis is a significant beneficial owner of the Company, holding more than 5% of the total outstanding stock of the Company, as of December 31, 2020, and 2021. The Company has an in-license agreement with Novartis, which required the Company to make an upfront payment and issue shares of Series A-1 Preferred Stock to Novartis, and further includes future milestone payments upon the occurrence of certain events and royalty payments upon future sales. Refer to Note 5.

CEO Promissory Note

On August 9, 2021, the Company entered into the Promissory Note with the CEO for an amount of $1.8 million, which was used to allow the CEO to purchase 1,218,836 shares of common stock granted in the form of a restricted stock award under the 2019 Plan. The Promissory Note has a stated interest rate of 0.76%,

which is compounded annually, and matures upon the earlier of (i) the seventh anniversary from the date of the Promissory Note; (ii) ninety days after termination of the CEO's service to the Company; or (iii) a change in control of the Company. Further, the principal and accrued but unpaid interest of the Promissory Note is to be repaid prior to the Company becoming an issuer within the meaning of the Sarbanes-Oxley Act of 2022. As of December 31, 2021, the entire amount of the Promissory Note remained outstanding. See Note 8.

Consulting Agreements

In June 2019, the Company entered into a consulting agreement with Mark Iwicki, the chairman of the Board, for consulting services. Pursuant to this agreement, Mr. Iwicki was granted a restricted stock award for 47,100 shares of the Company's common stock, with 1/48th of the shares subject to the award vesting in equal monthly installments. The Company recognized stock-based compensation of $8 thousand for the years ended December 31, 2020 and 2021, associated with the agreement which was recorded within general and administrative expense.

In July 2019, the Company entered into a consulting agreement with H. Martin Seidel, in connection with his appointment to the Board and the Company's scientific advisory board, for consulting services. The Company will make payments of $25,000 per year for such consulting services, payable quarterly in arrears. In addition, Dr. Seidel was granted a restricted stock award of 75,360 shares of the Company's common stock, with 25% of the shares subject to the award vesting on July 25, 2020 and the remaining shares vesting in equal quarterly installments thereafter until July 25, 2023. The Company recognized stock-based compensation of $13 thousand for the years ended December 31, 2020 and 2021, associated with the agreement which was recorded within general and administrative expense.

13. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 401(k) Plan for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. Since inception of the plan and through the year ended December 31, 2021 the Company has not made any contributions to the 401(k) Plan.

14. Subsequent Events

The Company has completed an evaluation of all subsequent events after the audited balance sheet date of December 31, 2021 through May 13, 2022, the date these financial statements were issued, and September 9, 2022 for the reverse stock split referenced below. to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of December 31, 2020 and 2021 and events which occurred subsequently but were not recognized in the accompanying consolidated financial statements. No subsequent events have occurred that require disclosure, except for those referenced below.

The Company's Board approved a one-for-2.259 reverse stock split of its issued and outstanding common stock and stock options effective as of September 7, 2022. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2021	June 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 128,280	$ 112,731
Prepaid expenses and other current assets	884	610
Total current assets	129,164	113,341
Other assets	—	1,090
Total assets	$ 129,164	$ 114,431
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,797	$ 2,436
Accrued expenses and other current liabilities	3,889	2,368
Total current liabilities	5,686	4,804
Total liabilities	5,686	4,804
Commitments and contingencies (Note 11)		
Series A-1 redeemable convertible preferred stock, par value $0.0001. 13,970,000 shares authorized as of December 31, 2021 and June 30, 2022; 13,970,000 shares issued and outstanding as of December 31, 2021 and June 30, 2022; liquidation preference of $13,970 as of December 31, 2021 and June 30, 2022	12,574	12,574
Series A-2 redeemable convertible preferred stock, par value $0.0001. 13,750,000 shares authorized as of December 31, 2021 and June 30, 2022; 13,750,000 shares issued and outstanding as of December 31, 2021 and June 30, 2022; liquidation preference of $22,000 as of December 31, 2021 and June 30, 2022	19,476	19,476
Series A-3 redeemable convertible preferred stock, par value $0.0001. 7,812,501 shares authorized as of December 31, 2021 and June 30, 2022; 7,812,501 shares issued and outstanding as of December 31, 2021 and June 30, 2022; liquidation preference of $20,000 as of December 31, 2021 and June 30, 2022	33,288	33,288
Series B redeemable convertible preferred stock, par value $0.0001. 14,091,689 shares authorized as of December 31, 2021 and June 30, 2022; 14,091,686 shares issued and outstanding as of December 31, 2021 and June 30, 2022; liquidation preference of $105,000 as of December 31, 2021 and June 30, 2022	104,846	104,846
Stockholders' deficit:		
Common stock, par value $0.0001. 72,731,000 shares authorized as of December 31, 2021 and June 30, 2022; 4,237,290 and 4,416,054 shares issued and outstanding as of December 31, 2021 and June 30, 2022, respectively	1	1
Additional paid-in capital	1,534	3,143
Accumulated deficit	(48,241)	(63,701)
Total stockholders' deficit	(46,706)	(60,557)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 129,164	$ 114,431

The accompanying notes are an integral part of these condensed consolidated financial statements.

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Six Months Ended June 30,	
	2021	2022
Operating expenses:		
Research and development	$ 6,546	$ 10,393
General and administrative	1,010	5,177
Total operating expenses	7,556	15,570
Loss from operations	7,556	15,570
Other (income) expense, net:		
Change in fair value of anti-dilution right liability	682	—
Change in fair value of preferred stock tranche liability	(1,790)	—
Other income	(2)	(110)
Total other (income) expense, net	(1,110)	(110)
Net loss	$ 6,446	$ 15,460
Net loss per share of common stock, basic and diluted	$ 1.64	$ 3.58
Weighted-average common stock outstanding, basic and diluted	3,939,670	4,321,267

The accompanying notes are an integral part of these condensed consolidated financial statements.

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)
(Unaudited)

	Redeemable Convertible Preferred Stock										
	Series A-1		Series A-2		Series A-3		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	12,746,961	$11,008	6,875,000	$ 7,691	—	$ —	3,866,138	$ 1	$ 274	(18,632)	$ (18,357)
Issuance of Series A-2 redeemable convertible preferred stock under Series A-2 Second Tranche, net of issuance costs of $40	—	—	6,875,000	11,785	—	—	—	—	—	—	—
Gain on extinguishment of Series A-2 redeemable convertible preferred stock tranche liability	—	—	—	—	—	—	—	—	750	—	750
Issuance of Series A-1 redeemable convertible preferred stock under anti-dilution liability	1,223,039	1,566	—	—	—	—	—	—	—	—	—
Issuance of Series A-3 redeemable convertible preferred stock, net of issuance costs of $40	—	—	—	—	1,953,125	1,982	—	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	203,108	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	138	—	138
Net loss	—	—	—	—	—	—	—	—	—	(6,446)	(6,446)
Balance at June 30, 2021	13,970,000	$12,574	13,750,000	$19,476	1,953,125	$1,982	4,069,246	$ 1	$ 1,162	(25,078)	$ (23,915)

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)
(Unaudited) (continued)

	Redeemable Convertible Preferred Stock												Tot
	Series A-1		Series A-2		Series A-3		Series B		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockh Defi
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	13,970,000	$12,574	13,750,000	$19,476	7,812,501	$33,288	14,091,686	$104,846	4,237,290	$ 1	$ 1,534	$ (48,241)	$ (4
Vesting of restricted stock	—	—	—	—	—	—	—	—	178,764	—	—	—	
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,609	—	
Net loss	—	—	—	—	—	—	—	—	—	—	—	(15,460)	(1
Balance at June 30, 2022	13,970,000	$12,574	13,750,000	$19,476	7,812,501	$33,288	14,091,686	$104,846	4,416,054	$ 1	$ 3,143	$ (63,701)	$ (6

The accompanying notes are an integral part of these condensed consolidated financial statements.

THIRD HARMONIC BIO, INC.
CODENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share amounts)
(Unaudited)

	Six Months Ended June 30,	
	2021	2022
Cash flows from operating activities:		
Net loss	$ (6,446)	$ (15,460)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	138	1,609
Change in fair value of preferred stock tranche liability	(1,790)	—
Change in fair value of anti-dilution liability	682	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(316)	274
Other assets	—	—
Accounts payable	885	365
Accrued expenses and other current liabilities	(404)	(1,640)
Net cash used in operating activities	(7,251)	(14,852)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of issuance costs	15,921	—
Payment of offering costs	—	(697)
Net cash provided by (used in) financing activities	15,921	(697)
Net increase (decrease) in cash and cash equivalents	8,670	(15,549)
Cash and cash equivalents at beginning of period	8,277	128,280
Cash and cash equivalents at end of period	$ 16,946	$ 112,731
Supplemental disclosure of cash flows:		
Deferred offering costs in accounts payable and accrued expenses	$ —	$ 393
Supplemental disclosure of non-cash financing activity:		
Preferred stock tranche liability established in connection with the issuance of redeemable convertible preferred stock	$ 2,979	$ —
Issuance of redeemable convertible preferred stock in settlement of preferred stock tranche liability	$ 825	$ —
Gain on extinguishment of preferred stock tranche liability recorded to additional paid in capital	$ 750	$ —
Issuance of redeemable convertible preferred stock in settlement of anti-dilution right liability	$ 1,565	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

THIRD HARMONIC BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of the Business

Third Harmonic Bio, Inc., ("Third Harmonic" or the "Company") is a clinical-stage biopharmaceutical company focused on development of the next wave of medicine for the treatment of allergic and inflammatory diseases.

The Company was incorporated in 2019 as a Delaware corporation, and has principal offices in Cambridge, Massachusetts. In December 2021, the Company formed THB MS, Inc., a Delaware corporation and wholly-owned subsidiary of the Company, which is classified as a Security Corporation in Massachusetts.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, completion and success of clinical testing, development by competitors of new technological innovations, compliance with governmental regulations, dependence on key personnel and protection of proprietary technology and the ability to secure additional capital to fund operations. THB001 will require extensive clinical testing prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Liquidity

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying condensed consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for THB001 and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future.

Since its inception, the Company has funded its operations primarily with proceeds from sales of shares of its redeemable convertible preferred stock. The Company has incurred recurring losses since its inception, including net losses of $6.4 million and $15.5 million for the six months ended June 30, 2021 and 2022, respectively. As of June 30, 2022, the Company had an accumulated deficit of $63.7 million. To date the Company has not generated any revenues and expects to continue to generate operating losses for the foreseeable future.

The Company expects that its existing cash and cash equivalents of $112.7 million as of June 30, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of these condensed consolidated financial statements.

COVID-19 Pandemic

The global coronavirus disease 2019 ("COVID-19") pandemic continues to evolve, and the Company will continue to monitor the ongoing COVID-19 pandemic. The extent of the impact of the ongoing COVID-19

pandemic on the Company's business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's contract development and manufacturing organizations ("CDMOs"), contract research organizations ("CROs"), and other third parties with whom the Company does business, as well as its impact on regulatory authorities and key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. The Company's financial results for the periods ended December 31, 2021 and June 30, 2022 were not significantly impacted by the ongoing COVID-19 pandemic, however, the Company cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on its financial condition, operations, and business plans for 2022, including the timing and enrollment of patients in its planned clinical trials and other expected milestones of its lead product candidate.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated annual financial statements for the years ended December 31, 2020 and 2021, included elsewhere in this prospectus. Since the date of those annual financial statements, there have been no changes to the Company's significant accounting policies, except as noted below.

Unaudited Interim Financial Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated annual financial statements for the years ended December 31, 2020 and 2021, and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's condensed consolidated balance sheet as of June 30, 2022, the condensed consolidated statements of operations for the six months ended June 30, 2021 and 2022, the condensed consolidated statements of changes in redeemable convertible preferred stock and stockholders' deficit for the six months ended June 30, 2021 and 2022 and condensed consolidated statements of cash flows for the six months ended June 30, 2021 and 2022. The financial data and other information disclosed in these notes related to the six months ended June 30, 2021 and 2022 are unaudited. The results for the six months ended June 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period.

Deferred Issuance Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with the in-process equity financing as deferred issuance costs until such financing is consummated. After consummation of such equity financing, these costs are recorded as a reduction of the proceeds generated as a result of the offering within additional paid in capital. Should the planned equity financing be abandoned, the deferred issuance costs, currently recorded within other assets, will be expensed immediately as a charge to operating expenses in the statements of operations. The Company did not record any deferred issuance costs as of December 31, 2021, and recorded deferred issuance costs of $1.1 million within other assets as of June 30, 2022.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condensed consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with certain new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

In December 2019, the FASB issued ASU No. 2019-12 ("ASU-2019-12"), *Simplifying the Accounting for Income Tax*, which contains several provisions that reduce financial statement complexity including removing the exception to the incremental approach for intra-period tax expense allocation when a company has a loss from continuing operations and income from other items not included in continuing operations. The Company adopted this accounting standard as of January 1, 2022 with no material impact on its condensed consolidated financial statements.

3. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

		December 31, 2021		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets				
Money market funds	$22,505	$ 22,505	—	—
Total financial assets	$22,505	$ 22,505	$ —	$ —

		June 30, 2022		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets				
Money market funds	$26,013	$ 26,013	—	—
Total financial liabilities	$26,013	$ 26,013	$ —	$ —

As of December 31, 2021 and June 30, 2022, the Company had no financial liabilities that required fair value measurement. As of December 31, 2021 and June 30, 2022, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment.

During the year ended December 31, 2021 and six months ended June 30, 2022 there were no transfers or reclassifications between fair value measurement levels of assets or liabilities. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2021	June 30, 2022
Accrued research and development expenses	$ 2,685	$1,217
Professional fees	450	447
Employee compensation and related benefits	752	704
Other	2	—
Total accrued expenses and other current liabilities	$ 3,889	$2,368

5. Novartis License Agreement

On June 28, 2019, the Company entered into a License Agreement (the "Novartis License Agreement") with Novartis Pharma AG, formerly known as Novartis International Pharmaceutical Ltd, ("Novartis"). Pursuant to the Novartis License Agreement, the Company has been granted an exclusive, worldwide, royalty-bearing, sublicensable license under specified patent rights and know-how related to two licensed compounds, to develop, make, use and sell certain products incorporating or comprising a licensed compound, including THB001, to certain intellectual property rights owned or controlled by Novartis (the "Licensed IP"), to research, develop, make, use, sell, and commercialize products containing the Licensed IP.

Under the Novartis License Agreement, the Company is solely responsible for all research, development, regulatory and commercialization activities related to the Licensed IP. The Company is required to use commercially reasonable efforts to develop and seek regulatory approval for, and commercialize, at least one licensed product in each of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

In exchange for these rights, the Company made an upfront cash payment of $0.4 million and issued 3,449,808 shares of Series A-1 Preferred Stock with a fair value of $3.0 million to Novartis. Upon entering into the Novartis License Agreement in 2019, the total initial consideration of $3.4 million transferred to Novartis was charged to expenses as research and development expense. The Company determined that the Novartis License Agreement represented an asset acquisition as it did not meet the definition of a business. The Company recorded the initial consideration transferred to Novartis as research and development expense in the statement of operations because the acquired Licensed IP represented in-process research and development with no alternative future use.

In addition, under the Novartis License Agreement, an anti-dilution right was issued to Novartis, in which Novartis is entitled to receive shares of Series A-1 Preferred Stock, guaranteeing them a 15% ownership interest of the fully diluted capitalization of the Company. The Company was obligated to issue additional shares of Series A-1 Preferred Stock until the Company had (1) raised aggregate cumulative proceeds of $30.0 million from sales of equity securities since its inception; or (2) issued and sold any securities that generate proceeds in excess of $30.0 million. Additionally, the Company was not obligated to issue more than 6,383,142 shares of the Series A-1 Preferred Stock to Novartis under the anti-dilution right. The Company assessed the Novartis anti-dilution right and determined that the right (i) meets the definition of a freestanding financial instrument that is not indexed to the Company's own stock and (ii) meets the definition of a derivative and does not qualify for equity classification. The initial fair value of the anti-dilution right liability of $1.0 million was recorded as research and development expense in July 2019, as part of the initial consideration in the license agreement. The Company remeasured the liability associated with the anti-dilution right at each reporting date and at each issuance of Series A-1 Preferred Stock under the anti-dilution right. Changes in the fair value were recorded as other income and expense in the statement of operations until the anti-dilution right was satisfied in February 2021 upon the Company raising aggregate cumulative proceeds of $30.0 million in sales of equity securities. As part of the anti-dilution right, the Company issued a total of 5,970,000 shares of Series A-1 Preferred Stock to Novartis. During the six months ended June 30, 2021, the Company recorded an expense associated with changes in fair value of the anti-dilution right liability of $0.7 million. No expense was recognized during the six months ended June 30, 2022 as the anti-dilution liability was satisfied in February 2021.

Under the Novartis License Agreement, the Company is obligated to make aggregate milestone payments of up to $231.7 million related to the achievement of specified development, commercialization, and sales milestones. The Company records the milestone payments as research and development expenses when the milestones occur and consideration is paid or becomes payable. As of June 30, 2022, the Company has made two development milestone payments under the Novartis Agreement totaling $1.0 million, of which $0.4 million was achieved and paid in 2019, and $0.6 million was achieved and paid in 2020, which have been recorded as research and development expense. No other milestones have occurred or have been paid have been made under the Novartis License Agreement.

As part of the Novartis License Agreement, the Company also agreed to pay tiered royalties based on future net sales of all products licensed under the agreement, of which the royalty percentage ranged within the single digits.

6. Redeemable Convertible Preferred Stock

As of December 31, 2021 and June 30, 2022, the Company's certificate of incorporation, as amended and restated (the "Amended and Restated Certificate of Incorporation") authorized the Company to issue 49,624,187 shares of preferred stock, with a par value of $0.0001 per share.

Series A-1 Redeemable Convertible Preferred Stock

In June 2019, the Company's board of directors (the "Board") authorized the issuance and sale of 14,383,142 shares of Series A-1 Preferred Stock. On July 3, 2019, the Company entered into a Series A-1 Preferred Stock purchase agreement (the "Series A-1 Agreement") with Atlas Venture Fund XI, L.P. ("Atlas"), in which the Company issued and sold an aggregate of 8,000,000 shares of Series A-1 Preferred Stock with a par value of $0.0001 and at a purchase price of $1.00 per share, resulting in gross proceeds of $8.0 million (the "Series A-1 First Tranche Closing"). Included within the Series A-1 Agreement were two additional future tranche obligations (the "Series A Second Tranche" and "Series A Third Tranche") for the Company to issue and sell shares of Series A-2 Preferred Stock. Upon execution of the Company's license agreement with Novartis in July 2019, the Company issued an additional 3,449,808 shares of Series A-1 Preferred Stock (see Note 5).

The Series A Second Tranche obligated the Company to issue and sell 2,666,667 shares of Series A-2 Preferred Stock to Atlas, and up to 2,666,667 shares of Series A-2 Preferred Stock to additional investors, each at a purchase price of $1.50 per share. The issuance of shares under the Series A Second Tranche was contingent to occur following a determination by the holders of a majority of the then outstanding Series A-1 Preferred Stock.

The Series A Third Tranche obligated the Company to issue and sell 4,666,667 shares of Series A-2 Preferred Stock to Atlas, and up to 4,666,667 shares of Series A-2 Preferred Stock to additional investors, each at a purchase price of $1.50 per share. The issuance of shares under the Series A Third Tranche was contingent to occur following a determination by the holders of a majority of the combined voting power of the then outstanding shares of Series A-1 Preferred Stock and Series A-2 Preferred Stock, calculated on an as converted common stock basis.

The Company concluded that the rights to participate in the Series A Second Tranche and Series A Third Tranche met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A-1 Preferred Stock and (ii) required the Company to transfer equity instruments upon future events. Upon the issuance of the Series A-1 Preferred Stock, the Company recognized a preferred stock tranche liability of $1.0 million, with a corresponding reduction to the carrying value of the Series A Preferred Stock. At the issuance of the Series A-1 Preferred Stock in July 2019, the carrying value was $7.0 million, equal to the gross proceeds of $8.0 million, reduced by the fair value of the preferred stock tranche liability of $1.0 million, and issuance costs of $55 thousand. Both the Series A Second Tranche and Series A Third Tranche were foregone by the investors in July 2020, upon entering into the Series A-2 Preferred Stock Agreement (as defined below). At the time, the Company wrote down the liability associated with the Series A Second Tranche and Series A Third Tranche liability to zero, resulting in a gain of $0.8 million recorded in the Company's consolidated statements of operations within other (income) expense, net during the year ended December 31, 2020.

In July 2020, upon entering into the Series A-2 Agreement (as defined below), the Company issued an additional 1,297,153 shares of Series A-1 Preferred Stock to Novartis, and in February 2021, upon the closing of the Series A-2 Second Tranche (as defined below) and entering into the Series A-3 Agreement (as defined below), the Company issued an additional 1,223,039 shares of Series A-1 Preferred Stock to Novartis, which issuances were pursuant to the anti-dilution right clause included in the Novartis License (see Note 5).

Series A-2 Redeemable Convertible Preferred Stock

In June 2019, at the same time the Board authorized the issuance of the Series A-1 Preferred Stock, the Board authorized the issuance of 14,666,667 shares of Series A-2 Preferred Stock. On July 13, 2020, the Company entered into a Series A-2 Preferred Stock purchase agreement (the "Series A-2 Agreement") with Atlas and OrbiMed Private Investments VII, LP ("OrbiMed"), in which the Company issued and sold an aggregate of 6,875,000 shares of Series A-2 Preferred Stock with a par value of $0.0001 and at a purchase price of $1.60 per share, resulting in gross proceeds of $11.0 million (the "Series A-2 First Tranche Closing"). Included within the Series A-2 Agreement were two additional future tranches obligations (the "Series A-2 Second Tranche" and "Series A-2 Third Tranche") for the Company to issue and sell shares of Series A-2 Preferred Stock.

The Series A-2 Second Tranche obligated the Company to issue and sell an aggregate of 6,875,000 shares of Series A-2 Preferred Stock to Atlas and OrbiMed, each at a purchase price of $1.60 per share. The issuance of shares under the Series A-2 Second Tranche was contingent upon Atlas and OrbiMed's waiver or approval and satisfaction of the Company's GLP Toxicology Studies of the Company's lead compound (the "Series A-2 Second Tranche Milestone Event").

The Series A-2 Third Tranche obligated the Company to issue and sell an aggregate of 6,250,000 shares of Series A-2 redeemable convertible preferred stock to Atlas and OrbiMed, each at a purchase price of $1.60 per share. The issuance of shares under the Series A-2 Third Tranche was contingent upon Atlas and OrbiMed's waiver or approval and satisfaction of safety data from the Phase 1a trial of the Company's lead compound (the "Series A-2 Third Tranche Milestone Event").

The Company concluded that the rights to participate in the Series A-2 Second Tranche and Series A-2 Third Tranche met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A-2 Preferred Stock and (ii) required the Company to transfer equity instruments upon future events. Upon the issuance of the Series A-2 Preferred Stock, the Company recognized a preferred stock tranche liability of $3.1 million, with a corresponding reduction to the carrying value of the Series A-2 Preferred Stock. At the issuance of the Series A-2 Preferred Stock in July 2020, the carrying value was $7.7 million, equal to the gross proceeds of $11.0 million, reduced by the fair value of the preferred stock tranche liability of $3.1 million, and issuance costs of $0.2 million.

In February 2021, upon waiver by Atlas and OrbiMed, an aggregate of 6,875,000 shares of Series A-2 Preferred Stock were issued and sold under the Series A-2 Second Tranche, resulting in gross proceeds of $11.0 million. Prior to the issuance and sale of shares under Series A-2 Second Tranche, the Company remeasured the tranche liability associated with the Series A-2 Second Tranche and Series A-2 Third Tranche, which resulted in a gain of $3.4 million that was recorded to other income and expense during the year ended December 31, 2021. The fair value of the Series A-2 tranche liability at the time of the closing of the Series A-2 Second Tranche of $0.8 million was recorded a part of the carrying value of the Series A-2 Preferred Stock. The Series A-2 Third Tranche was forgone by Atlas and OrbiMed upon entering into the Series A-3 Preferred Stock Agreement (as defined below). The Company wrote off the fair value of the Series A-2 Third Tranche liability, which resulted in a gain of $0.8 million that was recorded to additional paid-in capital during the year ended December 31, 2021.

Series A-3 Redeemable Convertible Preferred Stock

In February 2021, the Board authorized the issuance and sale of 7,812,501 shares of Series A-3 Preferred Stock. On February 24, 2021, the Company entered into a Series A-3 Preferred Stock purchase agreement (the "Series A-3 Agreement") with Biotechnology Value Fund, LP ("BVF"), in which the Company issued and sold an aggregate of 1,953,125 shares of Series A-3 Preferred Stock with a par value of $0.0001 and at a purchase price of $2.56 per share, resulting in gross proceeds of $5.0 million (the "Series A-3 First Tranche Closing"). Included within the Series A-3 Agreement was an additional future tranche liability (the "Series A-3 Second Tranche") for the Company to issue and sell shares of Series A-3 Preferred Stock.

The Series A-3 Second Tranche obligated the Company to issue and sell an aggregate of 5,859,376 shares of Series A-3 Preferred Stock to Atlas, OrbiMed, and BVF (collectively the "Existing Investors") each at a purchase price of $2.56 per share. The issuance of shares under the Series A-3 Second Tranche was contingent upon the determination by the Board that certain data from the Company's Phase 1a clinical trial for its lead compound supported the progression to a Phase 1b clinical trial (the "Series A-3 Second Tranche Milestone Event") or a waiver by the Existing Investors.

The Company concluded that the rights to participate in the Series A-3 Second Tranche met the definition of a freestanding financial instrument that was required to be recognized as a liability at fair value as (i) the instruments were legally detachable from the Series A-3 Preferred Stock and (ii) required the Company to transfer equity instruments upon future events. Upon the issuance of the Series A-3 Preferred Stock, the Company recognized a preferred stock tranche liability of $3.0 million, with a corresponding reduction to the carrying value of the Series A-3 Preferred Stock. At the issuance of the Series A-3 Preferred Stock in February 2021, the carrying value was $2.0 million, equal to the gross proceeds of $5.0 million, reduced by the fair value of the preferred stock tranche liability of $3.0 million, and issuance costs of $40 thousand.

In November 2021, upon waiver by the Existing Investors, 5,859,376 shares of Series A-3 Preferred Stock were issued and sold to the Existing Investors under the Series A-3 Second Tranche, resulting in gross proceeds of $15.0 million. Prior to the issuance and sale of shares under Series A-3 Second Tranche, the Company remeasured the tranche liability associated with the Series A-3 Second Tranche, which resulted in expense of $13.3 million that was recorded to other income and expense during the year ended December 31, 2021. The fair value of the tranche liability at the time of the closing of the Series A-3 Second Tranche of $16.3 million was recorded a part of the carrying value of the Series A-3 Preferred Stock.

Series B Redeemable Convertible Preferred Stock

In December 2021, the Board authorized the issuance and sale of 14,091,689 shares of Series B redeemable convertible preferred stock ("Series B Preferred Stock"). On December 17, 2021, the Company entered into a Series B Preferred Stock purchase agreement (the "Series B Agreement") with various investors, both new and existing, in which the Company issued and sold an aggregate of 14,091,686 shares of Series B Preferred Stock with a par value of $0.0001 and at a purchase price of $7.45 per share, resulting in gross proceeds of $105.0 million. At the issuance of the Series B Preferred Stock, the carrying value was $104.8 million, equal to the gross proceeds of $105.0 million, reduced by issuance costs of $0.2 million.

Upon issuance of each class of Series A and Series B Preferred Stock, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

As of December 31, 2021 and June 30, 2022, the redeemable convertible preferred stock consisted of the following (in thousands, except share amounts):

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	13,970,000	13,970,000	$ 12,574	$ 13,970	6,184,150
Series A-2 Preferred Stock	13,750,000	13,750,000	19,476	22,000	6,086,762
Series A-3 Preferred Stock	7,812,501	7,812,501	33,288	20,000	3,458,386
Series B Preferred Stock	14,091,689	14,091,686	104,846	105,000	6,238,018
Total	49,624,190	49,624,187	$ 170,184	$ 160,970	21,967,316

The holders of the preferred stock have the following rights, preferences and privileges:

Voting

The holder of each share of preferred stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters presented to the stockholders of the Company.

The holders of Series A Preferred Stock, voting exclusively and as a separate class, are entitled to elect four directors of the Company. The holders of Series B Preferred Stock, voting exclusively and as a separate class, are entitled to elect one director of the Company.

Conversion

Each share of preferred stock is convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the original issue price by the conversion price for each series of preferred stock (as defined below). The conversion price, and the rate at which each series of preferred stock may be converted into common stock, are subject to adjustment from time to time to reflect future share dividends, splits, combinations, recapitalizations and similar events.

Further, each share of preferred stock shall automatically be converted into shares of common stock at the conversion rate at the time in effect for such series of preferred stock immediately upon either of: (i) the closing of the Company's sale of common stock to the public at a price per share of at least $16.83 per share in an initial public offering (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the applicable class of common stock), resulting in at least $75.0 million of proceeds, net of the underwriting discount and commissions; or (ii) the date and time, or occurrence of an event, specified by vote or written consent of the requisite holders of at least 65% of the combined voting power of the shares of preferred stock then outstanding as calculated on an as-converted to common stock basis.

Dividends

The holders of the preferred stock are entitled to receive dividends at the rate of 8% of the applicable original issue price per annum. Dividends shall not be cumulative or compounded and shall be payable only when, as and if declared by the Board and in preference and in priority to any dividends on common stock. There have been no dividends declared by the Board as of December 31, 2021 and June 30, 2022.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company ("Liquidation Event"), the holders of preferred stock (first to the holders of Series B Preferred Stock, then to the holders of Series A-3 Preferred Stock, then to the holders of Series A-2 Preferred Stock, then to the holders of Series A-1 Preferred Stock) are entitled to receive prior and in preference to the holders of common stock, an amount equal to an amount per share equal to the greater of the original issue price, plus all declared and unpaid dividends on the preferred stock or the price per share that would be received if the preferred stock were converted to common stock. If the assets and funds available to be distributed to all holders of preferred stock are insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to holders of the preferred stock shall be distributed ratably among the holders of preferred stock, acting as a single class, at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

After the payment of the full liquidation preference of the preferred stock as set forth above, the remaining assets of the Company legally available for distribution in such liquidation event shall be distributed ratably to the holders of shares of common stock.

Redemption

The preferred stock is not redeemable at the option of the holder thereof except for in the event of a Liquidation Event if the corporation does not effect a dissolution under the general corporation law within 90 days after such Liquidation Event.

7. Common Stock

As of December 31, 2021 and June 30, 2022, the Company's Amended and Restated Certificate of Incorporation authorized the Company to issue 72,731,000 shares of common stock, with a par value of $0.0001.

The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, preferences and privileges of the holders of the preferred stock as set forth above.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), provided however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to the Amended and Restated Certificate of Incorporation. There are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Amended and Restated Certificate of Incorporation.

As of December 31, 2021 and June 30, 2022, the Company has reserved the following shares of common stock for the potential conversion of outstanding preferred stock, the exercise of stock options, and the vesting of restricted common stock:

	December 31, 2021	June 30, 2022
Preferred stock, as converted	21,697,316	21,967,316
Options to purchase common stock	394,254	1,803,079
Unvested restricted common stock	1,907,102	1,410,565
Remaining shares reserved for future issuance	2,065,764	656,940
Total	26,334,436	25,837,900

8. Stock-Based Compensation

2019 Stock Incentive Plan

The Company adopted the 2019 Stock Incentive Plan (the "2019 Plan") in July 2019 pursuant to which the Company can issue incentive stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. The 2019 Plan is administered by the Board or, at the discretion of the Board, by a committee delegated by Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company's Board values the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third party valuation specialists as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. The 2019 Plan was subsequently amended on various dates

throughout 2020 and 2021, with each amendment increasing the number of awards issuable under the plan. As of June 30, 2022, there were 5,063,021 shares of common stock that were issuable under the 2019 Plan, of which there were 1,803,079 stock options granted and 2,603,003 restricted stock granted. As of June 30, 2022, 656,940 shares of common stock remained available for future grant under the 2019 Plan.

Shares that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Stock Options

The Company has granted stock options with both service-based and performance-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant. For accounting purposes, a retrospective fair value assessment of the common stock was performed to determine the fair value of the Company's common stock and to calculate stock-based compensation expense. These reassessed values were based, in part, upon third-party valuations of the Company's common stock prepared as of each grant date on a retrospective basis. The third-party valuations were prepared using the hybrid method and used market approaches to determine the Company's enterprise value.

The Company utilized the Black-Scholes option-pricing model to estimate the fair value of stock options awarded to employees. The Black-Scholes option-pricing model requires several key assumptions. The key assumptions used to apply this pricing model during the six months ended June 30, 2021 and 2022 were as follows:

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2022
Expected term (in years)	6.06	5.71-6.53
Expected volatility	84.2%	81.9-82.7%
Risk-free interest rate	1.2%	1.7-2.56%
Expected dividend yield	—	—
Fair value of common stock	$ 1.90	$ 8.61

The following table summarizes the Company's stock option activity under the 2019 Plan:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	394,254	$ 0.85	9.08	$ 3,297
Granted	1,594,934	9.22		
Exercised	—	—		
Forfeited or cancelled	(186,109)	8.15		
Outstanding as of June 30, 2022	1,803,079	$ 7.50	9.74	$ 2,870
Options vested and exercisable as of June 30, 2022	173,061	$ 4.30	9.10	$ 822
Options unvested as of June 30, 2022	1,630,018	$ 7.89	9.25	$ 2,235

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted-average grant-date fair value per share of stock options granted during the six months ended June 30, 2022 was $6.61. As of June 30, 2022, there was $9.1 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 0.37 years.

The total fair value of options vested during the six months ended June 30, 2022 was $0.6 million.

Included within the total stock options outstanding are 116,186 stock options to purchase common stock which have performance-based vesting criteria and were granted to certain employees, officers and consultants of the Company on various dates during the years ended December 31, 2020 and 2021 (collectively, the "Performance Stock Options"). Vesting of 37,133 of the Performance Stock Options was contingent on the closing of the Series A-2 Second Tranche, which occurred on February 24, 2021, and vesting of the remaining 97,938 Performance Stock Options was contingent on the closing of the Series A-3 Second Tranche, which occurred on November 15, 2021. The vesting commencement date of the Performance Stock Options was the date in which the performance condition is met, and vesting occurs based on the accelerated attribution method over four years from the vesting commencement date. The Company began to recognize expense associated with the Performance Stock Options on the date in which each respective performance criteria was met and recognized total stock-based compensation expense associated with the Performance Stock Options of $58 thousand for the six months ended June 30, 2022. No expense associated with the Performance Stock Options was recognized prior to the year ended December 31, 2021.

Restricted Common Stock Awards

The Company has granted restricted common stock awards with service and performance and service based vesting conditions to employees of the Company. Unvested shares of restricted common stock may not be sold or transferred by the holder, except for transfers for estate planning purposes in which the transferee agrees to remain bound by all restrictions set forth in the original common stock purchase agreement. These restrictions lapse over the vesting term of each award, which is typically four years. The purchase price of each share of restricted common stock was $0.0001 per share.

On August 9, 2021, the Company's chief executive office ("CEO") purchased 1,218,836 shares of common stock at a purchase price of $1.44 per share, under the terms of a restricted common stock award granted under the 2019 Plan. These shares were purchased in exchange for a promissory note (the "Promissory Note") of $1.8 million. The shares granted include both service and performance-based vesting criteria. Of the shares granted, (i) 269,044 shares are to vest upon the completion of one year of service measured from August 9, 2021 (the "Vesting Commencement Date"); (ii) 807,134 shares are to vest in a series of successive equal quarterly installments of 6.25% upon the CEO's completion of each additional quarter of service over a three year period from the first anniversary of the Vesting Commencement Date; and (iii) 142,658 shares (the "Performance Shares") are subject to vesting upon the occurrence of the Series A-3 Second Tranche closing, which occurred on November 15, 2021. Upon the occurrence of the Series A-3 Second Tranche closing, 35,664 of the Performance Shares vest on the first anniversary of the Vesting Commencement Date, and the remaining 106,994 Performance Shares vest in a series of successive equal quarterly installments of 6.25% upon the CEO's completion of each additional quarter of service over a three year period from the first anniversary of the Vesting Commencement Date. The Company may purchase all of the unvested shares following the employee's termination at the original purchase price. As of June 30, 2022, none of the shares granted have vested.

The Promissory Note accrues interest at a rate of 0.76% per annum, compounded annually, and are repayable at the earlier of (i) the seventh anniversary from the date of the Promissory Note; (ii) ninety days after termination of the CEO's service to the Company; or (iii) a change in control of the Company. Further, the principal and accrued but unpaid interest of the Promissory Note is to be repaid prior to the Company becoming an issuer within the meaning of the Sarbanes-Oxley Act of 2022. The Promissory Note is collateralized by a pledge of certain assets of the employee, and is a partial recourse note. The Company has accounted for the Promissory Note as non-recourse in its entirety as the recourse and non-recourse portion of the Promissory Note are not directly aligned with a corresponding percentage of the underlying shares. The non-recourse notes

received by the Company as consideration for the issuance of the restricted stock has been considered a stock option for accounting purposes as the substance is similar to the grant of an option until the note is settled. The fair value of the restricted stock granted to the CEO in exchange for the Promissory Note is estimated on the grant date using the Black-Scholes option pricing model. The exercise price is the principal due on the Promissory Note. The fair value of the award is recognized over the requisite service period (not the term of the Promissory Note) through a charge to compensation cost.

A summary of the activity of the restricted common stock under the 2019 Plan was as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2021	1,907,102	$ 1.17
Granted	—	—
Vested	(178,764)	0.85
Cancelled or forfeited	(317,773)	0.71
Unvested at June 30, 2022	1,410,565	$ 1.06

The weighted-average grant-date fair value per share of restricted common stock awards granted during the six months ended June 30, 2022 was zero as no shares were granted in the period. The aggregate fair value of restricted stock awards that vested during the six months ended June 30, 2022 was $0.1 million. Stock-based compensation expense recognized for the restricted stock granted was $0.7 million for the six months ended June 30, 2022. As of June 30, 2022, there was unrecognized expense of $1.6 million related to the restricted stock, which is expected to be recognized over a weighted-average period of 0.21 years.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's condensed consolidated statements of operations was as follows (in thousands):

	Six Months Ended June 30,	
	2021	2022
Research and development	$ 87	$ 381
General and administrative	51	1,228
Total stock-based compensation expense	$138	$ 1,609

9. Income Taxes

During the three and six months ended June 30, 2022 and 2021, the Company recorded no income tax provision or benefit.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of June 30, 2022, the Company has maintained a full valuation allowance against its remaining net deferred tax assets.

10. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented (in thousands, except share and per share amounts):

	Six Months Ended June 30,	
	2021	2022
Numerator:		
Net loss	$ 6,446	$ 15,460
Net loss attributable to common stockholders, basic and diluted	$ 6,446	$ 15,460
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	3,939,670	4,321,267
Net loss per share of common stock, basic and diluted	$ 1.64	$ 3.58

The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of June 30, 2021 and 2022 because including them would have had an anti-dilutive effect:

	June 30,	
	2021	2022
Redeemable convertible preferred stock	13,135,509	21,967,316
Options to purchase common stock	436,298	1,803,079
Unvested restricted stock	856,310	1,410,565
Total	14,428,117	25,180,960

11. Commitments and Contingencies

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of December 31, 2021 and June 30, 2022, there were no litigation matters which would have a material impact on the Company's financial results.

Leases

The Company's operating leases are comprised of month-to-month office space leases entered into with Atlas for various office suites located at 400 Technology Square in Cambridge, Massachusetts, with the Company acting as a subtenant. Given the short-term nature of the leases, and as the Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet, no operating lease ROU asset and liability has been recognized as of December 31, 2021 and June 30, 2022. The Company incurred $31 thousand and $39 thousand of expenses during the six months ended June 30, 2021 and 2022, respectively.

12. Related Party Transactions

Atlas

Atlas is a significant beneficial owner of the Company, holding more than 5% of the total outstanding stock of the Company, as of December 31, 2021 and June 30, 2022. The Company leases various office spaces from Atlas for use in its daily operations.

During each of the six months ended June 30, 2021 and 2022 the Company made payments of $31 thousand and $39 thousand, respectively associated with the lease agreements with Atlas, which was recorded within the general and administrative expense.

Novartis

Novartis is a significant beneficial owner of the Company, holding more than 5% of the total outstanding stock of the Company, as of December 31, 2021 and June 30, 2022. The Company has an in-license agreement with Novartis, which required the Company to make an upfront payment and issue shares of Series A-1 Preferred Stock to Novartis, and further includes future milestone payments upon the occurrence of certain events and royalty payments upon future sales. Refer to Note 5.

CEO Promissory Note

On August 9, 2021, the Company entered into the Promissory Note with the CEO for an amount of $1.8 million, which was used to allow the CEO to purchase 1,218,836 shares of common stock granted in the form of a restricted stock award under the 2019 Plan. The Promissory Note has a stated interest rate of 0.76%, which is compounded annually, and matures upon the earlier of (i) the seventh anniversary from the date of the Promissory Note; (ii) ninety days after termination of the CEO's service to the Company; or (iii) a change in control of the Company. Further, the principal and accrued but unpaid interest of the Promissory Note is to be repaid prior to the Company becoming an issuer within the meaning of the Sarbanes-Oxley Act of 2022. As of June 30, 2022, the entire amount of the Promissory Note remained outstanding. See Note 8.

Consulting Agreements

In June 2019, the Company entered into a consulting agreement with Mark Iwicki, the chairman of the Board, for consulting services. Pursuant to this agreement, Mr. Iwicki was granted a restricted stock award for 47,100 shares of the Company's common stock, with 1/48th of the shares subject to the award vesting in equal monthly installments. The Company recognized stock-based compensation of $4 thousand and $4 thousand, respectively, for the six months ended June 30, 2021 and 2022 associated with the agreement which was recorded within general and administrative expense.

In July 2019, the Company entered into a consulting agreement with H. Martin Seidel, in connection with his appointment to the Board and the Company's scientific advisory board, for consulting services. The Company will make payments of $25,000 per year for such consulting services, payable quarterly in arrears. In addition, Dr. Seidel was granted a restricted stock award of 75,360 shares of the Company's common stock, with 25% of the shares subject to the award vesting on July 25, 2020 and the remaining shares vesting in equal quarterly installments thereafter until July 25, 2023. The Company recognized stock-based compensation of $6 thousand and $6 thousand, respectively, for the six months ended June 30, 2021 and 2022 associated with the agreement which was recorded within general and administrative expense.

13. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 401(k) Plan for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. Since inception of the plan and through the six months ended June 30, 2022, the Company has not made any contributions to the 401(k) Plan.

14. Subsequent Events

On July 28, 2022, the Company amended the 2019 Stock Incentive Plan to increase the number of available awards issuable by 254,537 shares of common stock (the "Plan Increase"). As a result, the total number of shares issuable under the 2019 Plan is 5,317,559 shares of common stock. The Plan Increase was adopted by the majority of the securityholders of the Company's outstanding Preferred Stock on August 9, 2022.

On August 22, 2022, the Promissory Note (as defined within Note 8) provided by the CEO, including principal of $1.8 million and accrued and unpaid interest, was forgiven. The Company will account for the forgiveness of the Promissory Note as a modification to the original restricted stock award during the third quarter of 2022. The impact to the modification may be material to the stock-based compensation recorded within the financial statements.

The Company's Board approved a one-for-2.259 reverse stock split of its issued and outstanding common stock and stock options effective as of September 7, 2022. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

10,900,000 Shares

Common Stock

PROSPECTUS

MORGAN STANLEY ***JEFFERIES*** ***COWEN***

LIFESCI CAPITAL

Until October 9, 2022, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

September 14, 2022