UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____**

Commission File Number 001-41498

THIRD HARMONIC BIO, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-4553503**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1700 Montgomery Street, Suite 210 San Francisco, California	**94111**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (209) 727-2457

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**THRD**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the Registrant, based on the closing price of $17.00 for the shares of common stock on September 19, 2022 as reported by the Nasdaq Stock Market LLC on such date was approximately $388.0 million. The Registrant has elected to use September 19, 2022, which was the closing date of its initial public offering of common stock, as the calculation date because on June 30, 2022 (the last business day of the Registrant's most recently completed second fiscal quarter) the Registrant was a privately-held company. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

The number of shares of Registrant's Common Stock outstanding as of March 24, 2023 was 40,324,215.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2023 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. The Definitive Proxy Statement will be filed within 120 days of the Registrant's fiscal year ended December 31, 2022. Except with respect to information specifically incorporated by reference in this Form 10-K, the Definitive Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

Auditor Firm Id:	34	Auditor Name:	Deloitte & Touche LLP	Auditor Location:	Morristown, New Jersey

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements contained in this Annual Report other than statements of historical fact, including but not limited to statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of THB001 and any other product candidates, potential therapeutic benefits and economic value of our product candidates, use of net proceeds from our initial public offering, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of nonclinical studies and clinical trials, commercial collaboration with third parties, the expected impact of the ongoing COVID-19 pandemic on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors," and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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 report to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless the context indicates otherwise, as used in this Annual Report, the terms "the Company," "we," "us," and "our" refer to Third Harmonic Bio, Inc., a Delaware corporation, and its consolidated subsidiaries taken as a whole, unless otherwise noted. The mark "Third Harmonic Bio" is our registered common law trademark. This Annual Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

RISK FACTOR SUMMARY

Our business is subject to a number of risks and uncertainties, including, those described in Part I, Item 1A. “Risk Factors” in this Annual Report. The principal risks and uncertainties affecting our business includes, among others, the following:

- We have a limited operating history, have not completed any clinical trials beyond Phase 1, and have not had any product candidates 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 have announced the discontinuation of our Phase 1b clinical trial of our product candidate THB001 in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two patients enrolled in the first dose cohort.
- 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.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or nonperformance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, financial condition and results of 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 our ability to identify and develop future product candidates.
- 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 an oral KIT inhibitor 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 future product candidates.
- The ongoing 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates. Even if we believe our development plans are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the development of the next wave of medicine for the treatment of inflammatory diseases, including dermal, respiratory, and gastrointestinal diseases. We are developing next-generation, highly selective, oral small-molecule inhibitors of KIT, a cell surface receptor that serves as the master regulator of mast cell function and survival. Early clinical studies have demonstrated that KIT inhibition has the potential to address the treatment of a broad range of mast-cell-mediated inflammatory diseases, and that a titratable, oral, intracellular small molecule inhibitor may provide an optimal therapeutic profile against this target. Our initial focus is on developing a KIT inhibitor to treat chronic urticaria.

In December 2022, we announced the discontinuation of our Phase 1b clinical trial of our product candidate THB001 in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two patients enrolled in the first dose cohort. We initiated nonclinical studies to elucidate the mechanism for the observed transaminitis, which was not predicted by extensive toxicology studies including those conducted according to Good Laboratory Practices, or GLP, of THB001 nor observed in our Phase 1a clinical trial. In parallel with the early clinical development of THB001, we have conducted an extensive medicinal chemistry effort to identify chemically distinct next-generation oral wild-type KIT inhibitors and have advanced multiple candidate molecules into exploratory toxicology studies. We intend to nominate a development candidate from this program in 2023.

The Phase 1b clinical trial in chronic inducible urticaria was designed to evaluate the safety and tolerability, efficacy and pharmacokinetics of three dose levels of THB001 over 12 weeks of treatment. Five patients were enrolled in the first dose cohort of 200mg twice daily, or BID. The first subject completed the full 12-week dosing period with no signs or symptoms of liver toxicity. The second and third patients presented with elevations in alanine transaminase or ALT, and aspartate transaminase, or AST, at their week eight study visits, and dosing was halted for both patients. No alternate causes for the transaminitis have been identified, and the patients continue to be monitored per study protocol. We stopped dosing of the fourth and fifth patients enrolled at weeks four and two of dosing, respectively, and neither of these patients has shown any signs or symptoms of liver toxicity to-date. Clinical follow-up of the five enrolled patients will continue per protocol, but no additional patients will be enrolled in the trial.

Preliminary analyses showed evidence of pharmacodynamic and clinical activity at the 200mg BID dose. We plan to present the full data set from the five enrolled patients at an upcoming scientific conference, and we intend to provide an update on overall corporate strategy and outlook in early 2023.

Given the preliminary clinical activity observed in the first patients enrolled in the Phase 1b clinical trial, we plan to continue the development of a next generation oral wild-type KIT inhibitor as we believe this to be an important treatment modality for mast cell-driven inflammatory diseases.

Our Strategy

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

- **Develop next-generation KIT inhibitors in a broad range of indications across therapeutic areas where mast cell driven inflammation can benefit from a highly selective, oral small molecule, 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 opportunities represent attractive markets with clinical unmet need and established development and regulatory pathways.
- **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 knowledge base of oral small molecule KIT inhibition to potentially advance next-generation compounds and expand our pipeline in inflammatory diseases.

We are focused on developing a portfolio of highly selective, oral small molecule inhibitors 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 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.

Mast cells are a primary 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 limited 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 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. 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 urticaria represents an attractive initial clinical indication for an oral KIT inhibitor. 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.

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 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 the ability for an oral small molecule KIT inhibitor to potentially treat a range of mast cell mediated skin, respiratory and gastrointestinal conditions.

Our Team

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

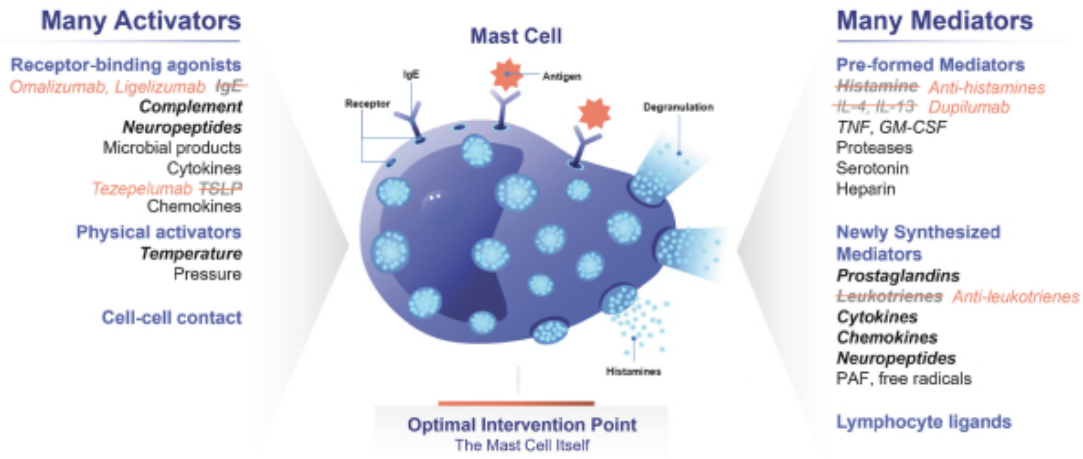
Overview of Mast Cells and KIT

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 mast cell driven 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.

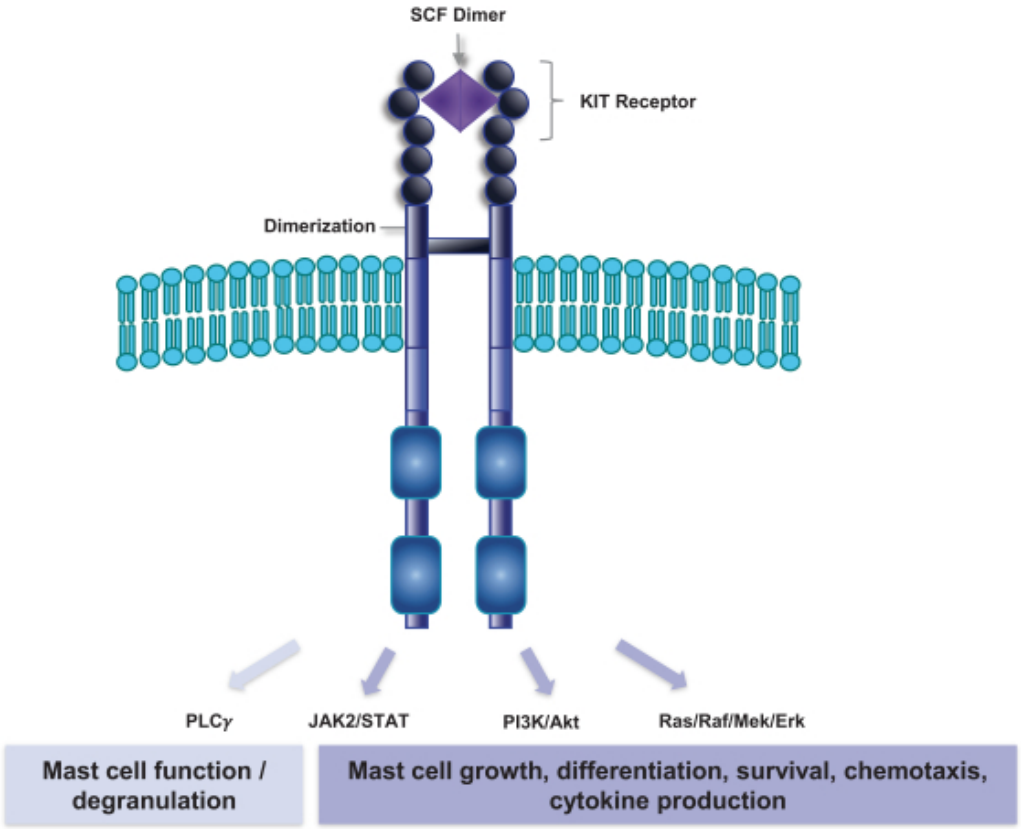
In the respiratory tract, mucosal mast cells in the nasal epithelium are activated by inhaled antigens, eliciting an immune response and resulting in airway constriction, increased mucous production and cough. Mast cells also play a role in the pathophysiology of asthma which is caused by an inflammatory 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.

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, a third party reported that 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.

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: Next Generation KIT Inhibitors

Summary

We are developing next-generation, potentially highly potent and selective, small molecule wild-type KIT inhibitors for the treatment of mast cell-mediated inflammatory diseases. Based on nonclinical and available clinical data to date, we believe an oral small molecule may be differentiated 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.
- Potentially higher selectivity for wild-type KIT relative to other commercial KIT inhibitors such as imatinib.
- Our oral small molecule inhibitors of KIT bind 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.

Although we discontinued the Phase 1b clinical trial of THB001 in chronic urticaria, we expect that data generated from the trial, along with data generated from our previously completed Phase 1a clinical trial, will be useful for the development of our next-generation, highly selective, oral KIT inhibitors.

In our 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.

Phase 1a Healthy Volunteer Trial

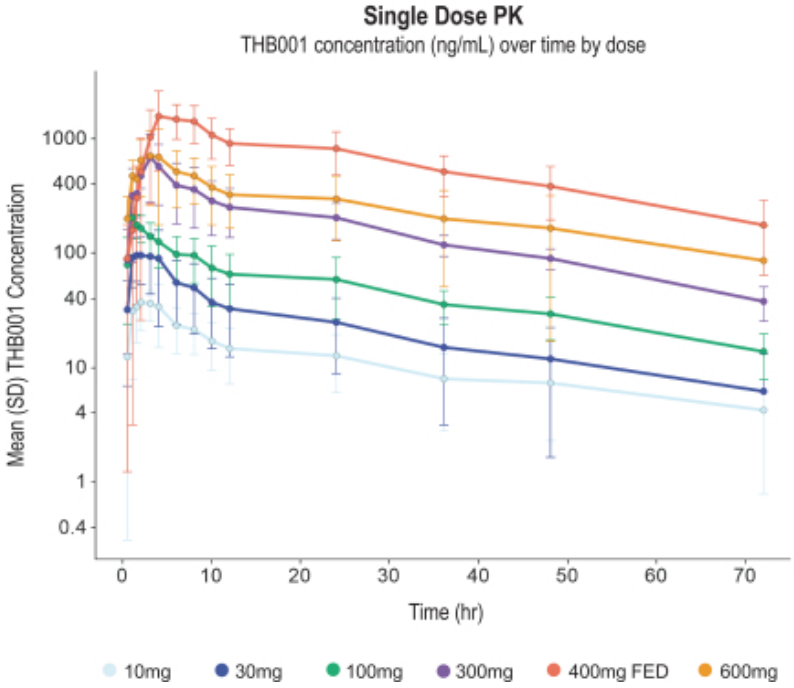
We conducted a three-part, 84 subject, Phase 1a clinical trial of THB001 in healthy adult volunteers between the ages of 18 and 65. The primary objective is to evaluate safety and tolerability. Secondary objectives include characterizing pharmacokinetics, including in the presence or absence of food 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

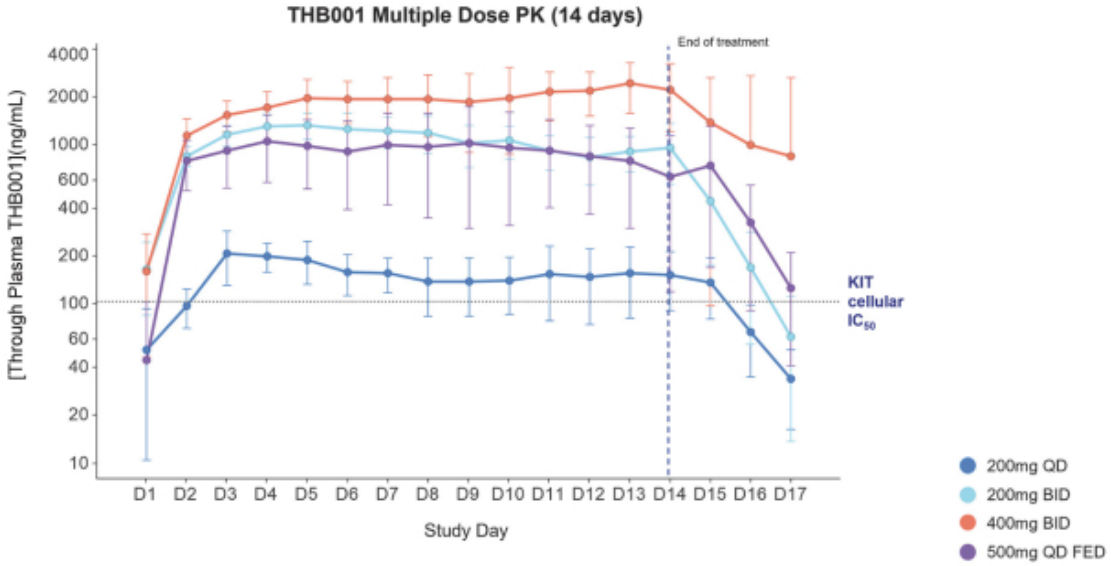
In the SAD portion of the Phase 1a trial, we observed approximately dose proportional increases in serum concentration of THB001 between the 10 mg and 300 mg doses. As reflected in the chart below at 300 mg and higher dosing levels, THB001 concentration exceeded 100 ng/ml through 24 hours, which is the 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



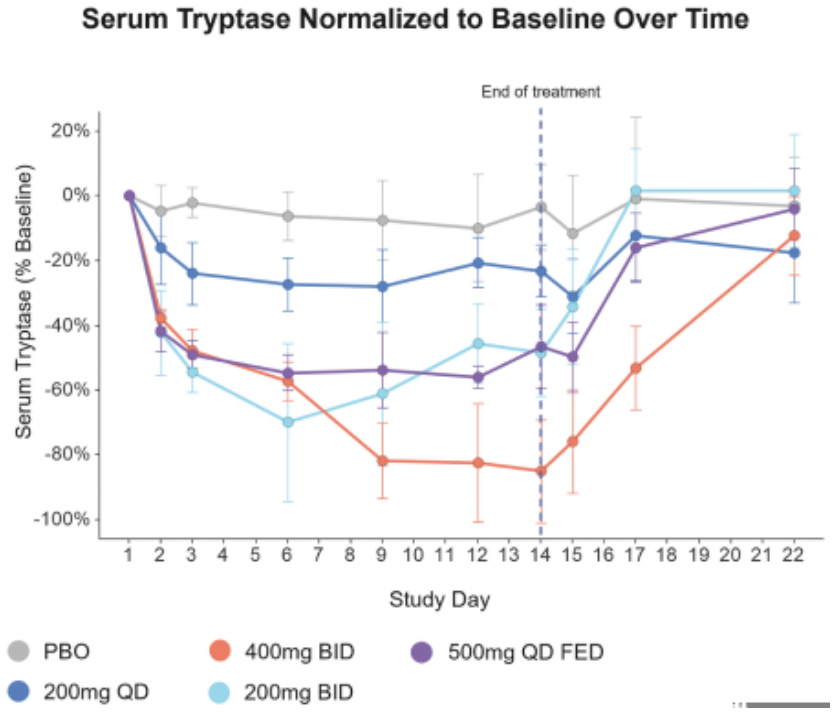
In the MAD portion of the trial, the increase in THB001 dosage from 200 mg BID to 400 mg BID was observed to generate approximately dose proportional increases in THB001 serum concentration levels which provided a trough value difference between THB001 and the protein binding adjusted KIT IC_{50} of 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}



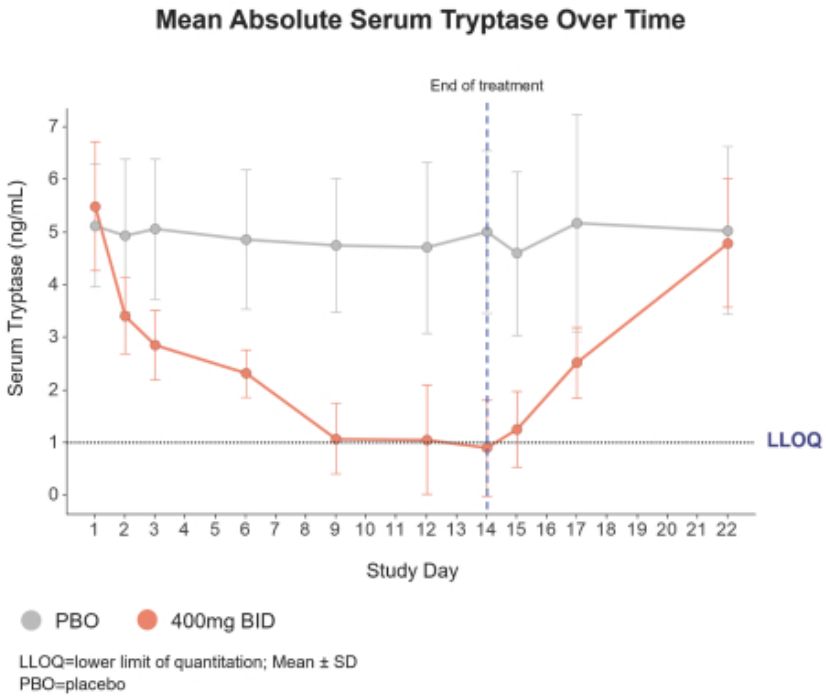
Dose levels of 200 mg per day or greater, given QD or BID, were observed to result in dose dependent declines in serum tryptase concentrations, a key biomarker of mast cell activity which has been demonstrated to correlate with clinical benefit in chronic urticaria, as compared to placebo, or PBO, as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



Mast Cell-Mediated Diseases Addressable by KIT Inhibition

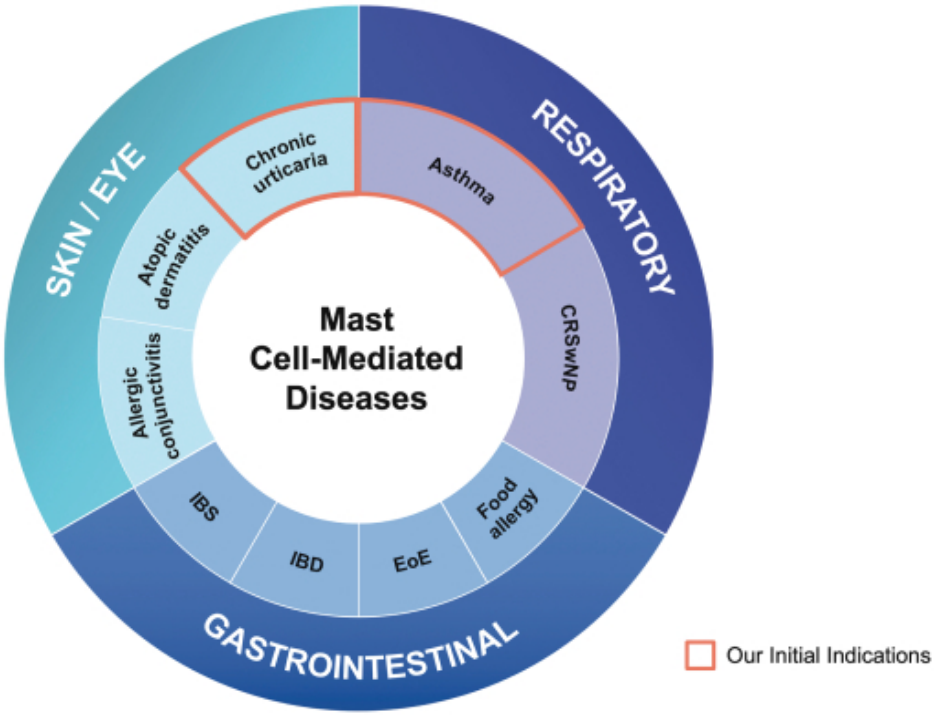
Dysfunctional mast cell activity has been implicated in the pathophysiology of a broad range of inflammatory disorders that impact the skin, eye, respiratory tract and gastrointestinal tract. Given KIT is the master regulator of mast cell function and survival, we believe that KIT inhibition is the optimal approach to treat many of these mast cell mediated diseases.

Related to the skin and eye, potential indications addressable with KIT inhibition include chronic urticaria, systemic sclerosis, atopic dermatitis and allergic conjunctivitis.

In the respiratory tract, potential indications addressable with KIT inhibition include asthma and chronic rhinosinusitis with nasal polyposis, or CRSwNP.

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

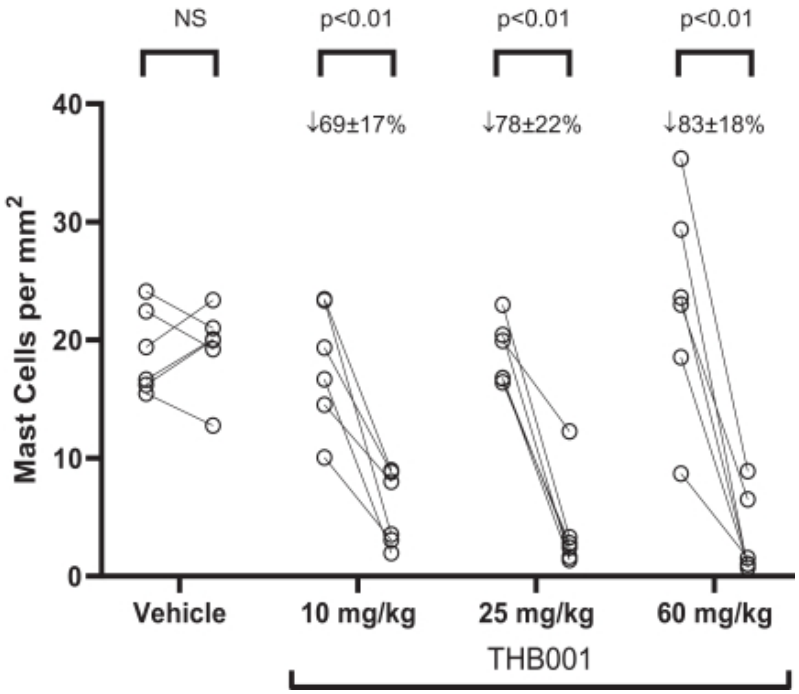


An oral KIT inhibitor's Therapeutic Potential in Other Mast Cell Driven Inflammatory Diseases

Nonclinical studies of THB001 provide evidence of the ability for an oral KIT inhibitor 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.

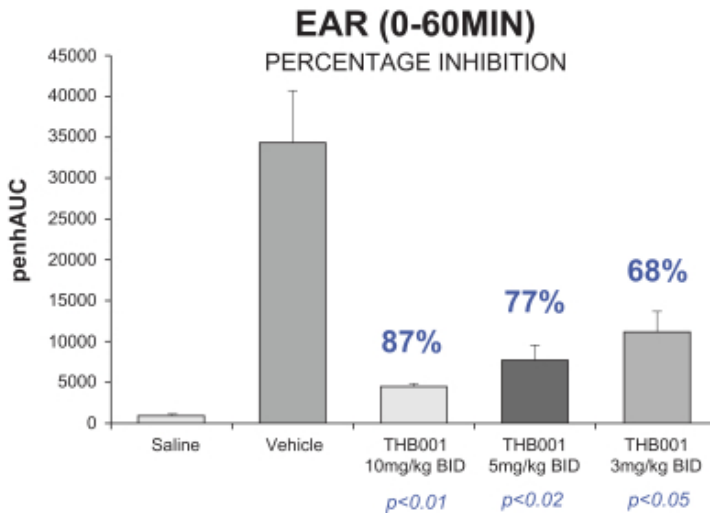
THB001 generated dose-dependent mast cell depletion in a 14-day repeat dose study in dogs.



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	Fce R1a	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.

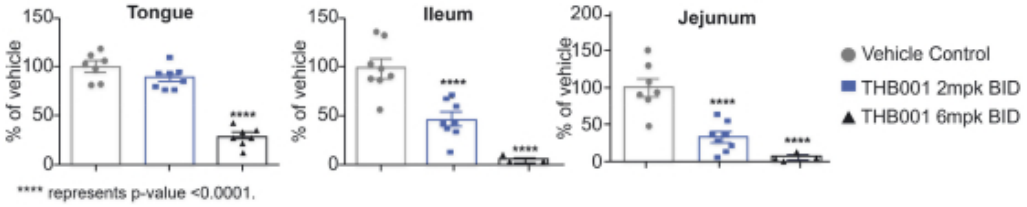
The Therapeutic Benefit of an Oral KIT Inhibitor May Extend to a Range of Tissues

We are exploring development opportunities across a range of other indications where an oral KIT inhibitor 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, 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 (2,642,762 shares of common stock following the conversion of such preferred stock in connection with our initial public offering, or IPO), 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. 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, for development and manufacture of future development candidates.

We used two geographically-distributed CDMOs to supply THB001 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 used three geographically-distributed CDMOs for THB001 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.

As of January 2023, we paused all manufacturing activities on THB001. For our future development candidates, we plan to continue operations with these existing manufacturing CDMOs to support toxicology and clinical studies. Additional manufacturing 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 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 mast cell driven 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 oral KIT inhibitor 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 February 9, 2023, our overall patent portfolio contains eleven 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 prior product candidate THB001, pharmaceutical compositions, methods of use, as well as claims directed to other KIT inhibitor compounds.

THB001

As of February 9, 2023, we exclusively license 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 February 9, 2023, we exclusively license 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 17 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 U.S. patent application, one pending European patent application, and one pending Japanese 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 February 9, 2023, we exclusively license 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 February 9, 2023, we solely own 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 February 9, 2023, we solely owned two pending U.S. provisional applications directed to methods of treating certain indications using THB001. Any U.S. or foreign patents that issue from an application claiming priority to these provisional applications, 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 February 9, 2023, we exclusively license 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, 22 patents, collectively, in Europe, Japan, Canada, China, Mexico and other foreign countries, as well as 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. Additionally, as of February 9, 2023, we solely own two pending U.S. provisional applications directed to additional KIT inhibitor compounds. Any U.S. or foreign patents that issue from an application claiming priority to these provisional applications, 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.

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 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 to such investigational drug.

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 labeling 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. Healthcare reform initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will eliminate, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA also allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected, with the negotiated price taking effect two years after the selection year. 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 2022 for Medicare Part D and January 2023 for Medicare Part B, penalize drug manufacturers that increase prices of Medicare Part D and Part B 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates, if approved, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees and Human Capital Resources

As of December 31, 2022, we had 28 employees, all of whom were full-time and 18 of whom were engaged in research and development activities. Eleven 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 currently lease various office space in Cambridge, Massachusetts and in San Francisco, California. Our principal executive office is located at 1700 Montgomery Street, Suite 210, San Francisco, CA, 94111, and our telephone number is (209) 727-2457.

Corporate Information and Trademarks

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

We use various trademarks and trade names in our business, including, without limitation, our corporate name and logo. All other service marks, trademarks and trade names appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this Annual Report 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 trade names.

Additional Information

Our Internet website address is https://thirdharmonicbio.com. On our website, we make available, free of charge, our annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after the company electronically files such material with, or furnishes such material to, the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding us and other companies that file materials with the SEC electronically.

Also available on our website is information relating to our corporate governance and our board of directors, including our corporate governance guidelines; our code of business conduct (for our directors, officers and employees); and our board committee charters. We will provide any of the foregoing information without charge upon written request to our Secretary, Third Harmonic Bio, Inc., 1700 Montgomery Street, Suite 210, San Francisco, CA 94111.

Item 1A. 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 Annual Report, 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 Annual Report. 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 have not had any product candidates 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 biopharmaceutical company with a limited operating history on which to base your investment decision. We commenced operations in 2019, and none of our prior or any future oral KIT inhibitor 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 prior product candidate THB001. In December 2022, we announced the discontinuation of our Phase 1b clinical trial of our prior product candidate, THB001, in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two patients enrolled in the first dose cohort. 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 preferred stock prior to the completion of our IPO, as well as the net proceeds from our IPO. Our net losses were $35.2 million and $29.6 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $83.4 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 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 any future product candidates through nonclinical studies and clinical development;
- discover and develop new oral KIT inhibitor product candidates;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- manufacture, or have manufactured, nonclinical, clinical and potentially commercial supplies of any future oral KIT inhibitor product candidates;
- seek regulatory approvals for any future oral KIT inhibitor product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any future oral KIT inhibitor 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;
- experience delays related to the ongoing 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 any future oral KIT inhibitor product candidates that 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 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 FDA, the 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 any future oral KIT inhibitor 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.

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 any future oral KIT inhibitor 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 our prior product candidate, THB001, and will require significant funds to conduct further research and development and nonclinical testing and clinical trials of any future oral KIT inhibitor product candidates, to seek regulatory approvals for any future oral KIT inhibitor product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect to incur additional costs associated with operating as a public company. See "*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."* Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

Nonclinical studies and clinical trials for any future oral KIT inhibitor product candidates, will require substantial funds to complete. As of December 31, 2022 we had $288.9 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next twelve months. 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 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 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 any future oral KIT inhibitor product candidates are approved for sale, including marketing, sales and distribution costs;

- the availability of capital in the technology and life sciences industries following the closure of Silicon Valley Bank, or SVB, and liquidity concerns at other financial institutions;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of product candidates;
- the continued effect of the ongoing 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or nonperformance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, and its financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. The Department of the Treasury, the Federal Reserve and the FDIC released a joint statement on March 12, 2023, stating that all depositors of SVB would have access to all of their funds on March 13, 2023, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our future lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds.

We either hold the vast majority of our financial assets in our name and custody them at a third-party financial institution, or we have transferred them out of SVB. Although we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations, our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations, financial condition and results of 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.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. During the preparation of our consolidated financial statements for the year ended December 31, 2021, we identified a material weakness in our internal control over financial reporting. The material weakness has not yet been fully remediated and the same weakness remained at the time of the preparation of our financial statements for the year ended December 31, 2022. 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.

During the year ended December 31, 2022, our management team implemented 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 have implemented 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. 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 our ability to identify and develop future product candidates.

Our future performance is substantially dependent on our ability to timely identify and develop future oral KIT inhibitor product candidates, obtain regulatory approval for, and then successfully commercialize future oral KIT inhibitor product candidates. We are early in our development efforts and we announced in December 2022 the discontinuation of our Phase 1b trial of our prior product candidate, THB001, in chronic inducible urticaria. While we are devoting significant resources to research and development activities, we have not yet identified additional oral KIT inhibitor product candidates. We currently have no products that are approved for sale in any jurisdiction. There can be no assurance that any future oral KIT inhibitor product candidates we develop will achieve success in their clinical trials or obtain regulatory approval.

We plan to seek regulatory approval to commercialize future oral KIT inhibitor 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 any future oral KIT inhibitor 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 future product candidates. The success of future product candidates 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates' intended indications;
- launching commercial sales of any future oral KIT inhibitor product candidates, if approved, whether alone or in collaboration with third parties;
- acceptance of any future oral KIT inhibitor 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 ongoing COVID-19 pandemic or other major natural disaster or significant political event;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of any future oral KIT inhibitor product candidates through clinical trials and following regulatory approval.

Many of these factors are beyond our control, and it is possible that none of our prior or future oral KIT inhibitor 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 any 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 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 any future oral KIT inhibitor 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 an oral KIT inhibitor or any future product candidates.

We currently do not have any product candidates in clinical development. In December 2022, we announced the discontinuation of our Phase 1b clinical trial of our prior product candidate, THB001, in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two patients enrolled in the first dose cohort. It is impossible to predict when or if any future oral KIT inhibitor product candidate will prove effective and safe in humans or will receive regulatory approval. 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 any future oral KIT inhibitor 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 for product candidates 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 patients 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 patients 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 future oral KIT inhibitor product candidates may be greater than we anticipate;
- the quality of any future oral KIT inhibitor product candidates or other materials necessary to conduct clinical trials of any future product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize any future oral KIT inhibitor 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 have faced and could in the future 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 for future oral KIT inhibitor product candidates. 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 any future oral KIT inhibitor product candidates warrant marketing approval, the FDA, EMA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials for future oral KIT inhibitor product candidates, 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. In particular, in December 2022, we announced the discontinuation of our Phase 1b clinical trial of our prior product candidate, THB001, in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two patients enrolled in the first dose cohort, which was not predicted by our completed nonclinical toxicology studies of THB001 nor observed in our Phase 1a clinical trial. Mechanistic studies are being conducted to understand the likely cause of hepatotoxicity observed with THB001. 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 on-target side effects will be reversible following discontinuation of treatment with an oral KIT inhibitor 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 our future oral KIT inhibitor product candidates, 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 oral KIT inhibitor drugs, our future oral KIT inhibitor product candidates may have adverse effects on the fetus and if approved, may require the concomitant use of appropriate birth control measures. AEs and serious adverse events, or SAEs, that emerge during clinical investigation of any of our future oral KIT inhibitor product candidates, or other compounds acting through similar biological pathways, may be deemed to be related to our future oral KIT inhibitor product candidates. 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 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 any future oral KIT inhibitor 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 patients 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates may be subject to similar risks.

If safety problems occur or are identified after any future oral KIT inhibitor 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 such products.

The ongoing 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 patients 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 ongoing 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidate are adversely impacted by restrictions resulting from the ongoing 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 ongoing COVID-19 pandemic on our current timelines. Measures we have taken in response to the ongoing 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 our prior product candidate THB001, but the negative impacts could be exacerbated as the ongoing COVID-19 pandemic and the response to it continue to evolve. The ongoing 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 any future oral KIT inhibitor product candidate. The extent to which the ongoing 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. The ongoing 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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. An oral KIT inhibitor, 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 any of our future oral KIT inhibitor 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 any future oral KIT inhibitor 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. 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 barzolvolimab 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 future oral KIT inhibitor product candidates, the ease with which any future oral KIT inhibitor 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 any future oral KIT inhibitor 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.

Any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 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 any future oral KIT inhibitor product candidates as demonstrated in clinical trials;
- the prevalence and severity of any adverse side effects associated with any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates;
- the willingness of patients to accept any new methods of administration;
- unfavorable publicity relating to our current product candidates or any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications any future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor product candidates are approved, the number of patients that may be eligible for treatment, or willing to be treated, with any future oral KIT inhibitor product candidates may turn out to be much lower than expected. Even if we obtain significant market share for any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 future oral KIT inhibitor product candidates if we obtain approval to market.

With respect to the commercialization of all or certain of any future oral KIT inhibitor 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 future oral KIT inhibitor product candidates if any receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing any future oral KIT inhibitor 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 future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any future oral KIT inhibitor 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 December 31, 2022 we had 28 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 any of our future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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, any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 facilities in Cambridge, Massachusetts and San Francisco, California. These regions contain the 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 any future oral KIT inhibitor product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any future oral KIT inhibitor product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates and ultimately commercialize any future oral KIT inhibitor 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 ongoing 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 ongoing 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 ongoing 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 any of our future oral KIT inhibitor product candidates could be delayed. In addition, the loss of clinical trial data for any other future oral KIT inhibitor 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 any future oral KIT inhibitor 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 patients enrolled in such clinical trial unless we are able to transfer those patients 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 any other future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates.

We may seek third-party collaborators for the development and commercialization of any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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, any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty transferring the manufacturing of any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 prior 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 mast cell driven 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates and modifications that we may need to apply to any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 of our future oral KIT inhibitor 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, any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates. Even if we believe our development plans are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

Any of our future oral KIT inhibitor product candidates will be 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, 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 any of our future oral KIT inhibitor product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our future oral KIT inhibitor 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 oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any future oral KIT inhibitor product candidates may provide better safety or effectiveness as compared to approved products, if we do not study any future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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.

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 only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected, with the negotiated price taking effect two years after the selection year. 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. Beginning in October 2022 for Medicare Part D and January 2023 for Medicare Part B, the law also penalizes drug manufacturers that increase prices of Medicare Part D and Part B 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 any future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any of our future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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

An active and liquid trading market for our common stock may never be sustained and you may not be able to resell your shares of common stock at or above the purchase price, if at all.

An active trading market for our shares may never develop or be sustained. The market value of our common stock may decrease from the purchase 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 purchase 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 any future oral KIT inhibitor 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 future oral KIT inhibitor product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- the continuing effect of the ongoing COVID-19 pandemic on our business and operations;
- regulatory developments affecting any future oral KIT inhibitor 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 is likely to continue 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 ongoing COVID-19 pandemic. As a result of this volatility, investors may not be able to sell their common stock at or above the price initially paid for the stock. 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor 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 ongoing COVID-19 pandemic; and
- general economic, industry and market conditions, including rising interest rates and inflation, the government closure of SVB and liquidity concerns at other financial institutions, and the potential for local and/or global economic recessions.

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.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell in the public market, the market price of our stock could decline significantly.

Moreover, the holders of an aggregate of 25,508,705 shares of our outstanding common stock as of December 31, 2022, 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 have registered shares of common stock that we may issue under our equity incentive plans. These shares are freely tradeable in the public market.

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 December 31, 2022, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a substantial portion of our outstanding voting stock. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent 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 or 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 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.

We could be an "emerging growth company" until December 31, 2027, 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 $1.235 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 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" 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 Reports 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 our Annual Report on Form 10-K 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 "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 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 the Board, or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified Board so that not all members of our Board are elected at one time;
- permit only the Board 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 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 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, to the fullest extent permitted by law, provides 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 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 is 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. If no or few securities or industry analysts continue or 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, 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.

We are 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

As of December 31, 2022, we lease office space at 130 Prospect Street in Cambridge, Massachusetts, which is where our corporate headquarters are located, and which consists of 10,356 rentable square feet. We also lease office space at 1700 Montgomery Street in San Francisco, California, which consists of 4,703 rentable square feet. We believe our current office space is sufficient to meet our office needs until the expiration of the leases in 2028.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

On September 15, 2022 our common stock began trading on the Nasdaq Stock Market LLC under the symbol "THRD". Prior to such time, there was no public market for our common stock.

Stockholders

As of March 24, 2023, there were 24 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

During the year ended December 31, 2022, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Use of Proceeds from Public Offering of Common Stock

On September 14, 2022, our Registration Statement on Form S-1, as amended (Registration No. 333-267022) was declared effective by the SEC for our IPO. At the closing of the offering on September 19, 2022, we sold 12,535,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,635,000 additional shares of common stock, at a public offering price of $17.00 per share. The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise and after underwriting discounts and offering expenses, were approximately $198.2 million. Morgan Stanley & Co. LLC, Jeffries LLC and Cowen and Company, LLC acted as joint book-running managers for the offering. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on September 15, 2022.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item will be included in our Definitive Proxy Statement, or Proxy Statement, for the 2023 Annual Meeting of Stockholders, to be filed within 120 days of the fiscal year ended December 31, 2022, and is incorporated by reference.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Item 6. [Reserved]

Item 7. 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 in conjunction with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report.

As discussed in the section titled "Special Note Regarding Forward Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth in the section titled "Risk Factors" under Part I, Item 1A.

Overview

We are a biopharmaceutical company focused on the development of the next wave of medicine for the treatment of inflammatory diseases, including dermal, respiratory, and gastrointestinal diseases. We are developing next-generation, highly selective, oral small-molecule inhibitors of KIT, a cell surface receptor that serves as the master regulator of mast cell function and survival. Early clinical studies have demonstrated that KIT inhibition has the potential to address the treatment of a broad range of mast-cell-mediated inflammatory diseases, and that a titratable, oral, intracellular small molecule inhibitor may provide an attractive therapeutic profile against this target. Our initial focus is on developing a KIT inhibitor to treat chronic urticaria.

In December 2022, we announced the discontinuation of our Phase 1b clinical trial of our product candidate THB001 in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two patients enrolled in the first dose cohort. We initiated nonclinical studies to elucidate the mechanism for the observed transaminitis, which was not predicted by extensive toxicology studies including those conducted according to GLP of THB001 nor observed in our Phase 1a clinical trial. In parallel with the early clinical development of THB001, we have conducted an extensive medicinal chemistry effort to identify chemically distinct next-generation oral wild-type KIT inhibitors and have advanced multiple candidate molecules into exploratory toxicology studies. We intend to nominate a development candidate from this program in 2023.

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 and our IPO of our common 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 future product candidates. Our net losses were $29.6 million and $35.2 million for the year ended December 31, 2021 and 2022, respectively. As of December 31, 2022, we had an accumulated deficit of $83.4 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 any future KIT inhibitor product candidates through nonclinical studies and clinical development;
- 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 any future oral KIT inhibitor product candidates;
- seek regulatory approvals for any future oral KIT inhibitor product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any future oral KIT inhibitor 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;
- experience delays related to the ongoing 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 any future oral KIT inhibitor 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 government closure of SVB and liquidity concerns at other financial institutions, from potential recessions, 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 mast cell driven 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 any future oral KIT inhibitor product candidates for our clinical trials. The manufacturing process has readily-sourced available raw materials and straightforward scalability. 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 December 31, 2022, we had $288.9 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, will be sufficient to fund our operations and capital expenses through at least the next twelve months. 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, 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 (2,642,7621 shares of common stock following the conversion of such preferred stock in connection with our IPO), 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. 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 Note 5 to our audited consolidated financial statements included elsewhere in this Annual Report.

Impact of COVID-19 on Our Business

The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the impact of variants, evolving travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. For additional details regarding the ongoing 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 ongoing COVID-19 pandemic could adversely impact our business, including the conduct of our research activities.

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 any 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 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. 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 continue to discover and develop additional product candidates, expand our headcount and maintain, expand and enforce our intellectual property portfolio. If 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 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 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 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 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, 2022, we had U.S. federal and state net operating loss carryforwards of $38.9 million and $34.1 million, respectively, which may be available to offset future income tax liabilities and expire at various dates beginning in 2039. As of the years ended December 31, 2021 and 2022, we have recorded a full valuation allowance against our deferred tax assets.

Results of Operations

Comparison of the year ended December 31, 2021 and 2022

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

	Year Ended December 31,			
	2021	2022	$ Change	% Change
Operating expenses:				
Research and development	$ 15,748	$ 24,407	$ 8,659	55%
General and administrative	3,256	13,301	10,045	309
Total operating expenses	19,004	37,708	18,704	98
Loss from operations	19,004	37,708	18,704	98
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	9,928	—	(9,928)	(100)
Other income	(5)	(2,553)	(2,548)	*
Total other (income) expense, net	10,605	(2,553)	(13,158)	(124)
Net loss	$ 29,609	$ 35,155	$ 5,546	19%

**Percentage not meaningful.*

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,			
	2021	2022	$ Change	% Change
Direct costs:				
THB001	$ 11,062	$ 11,130	$ 68	1%
Other discovery and development	2,105	7,129	5,024	239
Indirect costs:				
Personnel-related	2,569	6,023	3,454	134
Facilities and other	12	125	113	942
Total research and development expenses	$ 15,748	$ 24,407	$ 8,659	55%

Research and development expenses increased by $8.7 million from $15.7 million for the year ended December 31, 2021 to $24.4 million for the year ended December 31, 2022. The increase was primarily attributable to the following:

- a $0.1 million increase in costs related to the clinical development of THB001 as part of the Phase1b clinical trial phase which was discontinued in December 2022;
- a $5.0 million increase in other discovery and development costs, relating to the research and nonclinical development of the next generation molecules, discovery compounds and other programs;
- a $3.5 million increase in personnel related costs, including a $1.7 million in stock-based compensation expense, primarily due to an increase in headcount in 2022 to support the advancement of our developmental efforts and the increase in fair value of the awards that were granted in October 2022;
- a $0.1 million increase in facilities and other costs, driven by the increase in office space.

General and Administrative Expenses

General and administrative expenses increased by $10.0 million from $3.3 million for the year ended December 31, 2021 to $13.3 million for the year ended December 31, 2022, primarily driven by the increases in costs associated with personnel-related expenses and the IPO.

Total Other (Income) Expense, Net

Total other (income) expense, net decreased by approximately $13.2 million from $10.6 million of expense for the year ended December 31, 2021 to $2.6 million of income for the year ended December 31, 2022. This increase was primarily attributable to changes in fair value of anti-dilution right liability and preferred stock tranche liability that was recognized during the year ended December 31, 2021 and the increase in interest income received as the Company's cash balance has increased.

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.

On September 19, 2022, we completed our IPO at which time we issued 12,535,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,635,000 additional shares of common stock, at a public offering price of $17.00 per share. We received $198.2 million, net of underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were $2.3 million. Prior to our IPO, we funded our operations primarily with gross proceeds from sales of our preferred stock.

As of December 31, 2022, we had $288.9 million in cash and cash equivalents, and we had an accumulated deficit of $83.4 million.

Cash Flows

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

	Year Ended December 31,	
	2021	**2022**
Net cash used in operating activities	$ (15,746)	$ (34,917)
Net cash used in investing activities	—	(36)
Net cash provided by financing activities	135,749	195,991
Net increase in cash and cash equivalents	$ 120,003	$ 161,038

Net Cash Used in Operating Activities

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, adjusted for non-cash charge of $9.9 million related to the change in fair value of the preferred stock tranche liability, a non-cash charge of $0.7 million related to the change in fair value of the anti-dilution right liability, $0.5 million non-cash stock-based compensation expense and net changes in working capital of $2.8 million.

Net cash used in operating activities for the year ended December 31, 2022 was $34.9 million, and was primarily due to our net loss of $35.2 million, adjusted for $4.8 million non-cash stock-based compensation expense, an increase of $1.0 million in other assets relating to deferred compensation, and net changes in working capital of $3.5 million.

Net Cash Used in Investing Activities

We had no investing activities for the year ended December 31, 2021. Net cash used in investing activities for the year ended December 31, 2022 was $36 thousand, and was related to purchases of property, plant, and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 was $135.7 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, 2022 was $196.0 million, and was primarily driven from the proceeds of our IPO, net of issuance costs and underwriting fees of $195.9 million, and $0.1 million related to the exercise of stock options.

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. Following the closing of our IPO, we expect to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations and capital expenses through at least the next twelve months. 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 any future oral KIT inhibitor 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 any future oral KIT inhibitor product or development candidates 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 Note 6 to our consolidated financial statements included elsewhere in this Annual Report.

Lease Obligations

On October 21, 2022, the Company entered into two separate lease agreements, one for office space located in Cambridge, Massachusetts, or the Cambridge Lease Agreement, and one for office space located in San Francisco, California, or the San Francisco Lease Agreement. The Cambridge Lease Agreement and the San Francisco Lease Agreement each commenced in December 2022, and each have an initial term of 63 months. The aggregate estimated rental payments due over the initial term of the Cambridge Lease Agreement is approximately $4.0 million, and the aggregate estimated rental payments due over the initial term of the San Francisco Lease Agreement is approximately $1.8 million. For additional information regarding the lease accounting policies see Note 2 to our consolidated financial statements included elsewhere in this Annual Report and for additional information regarding the lease obligations see Note 12 to our consolidated financial statements included elsewhere in this Annual Report.

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-cancellable 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. 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 Form 10-K, 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.

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—Due to our limited operating history and lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility 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 Annual Report 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, 2021 and 2022.

Common Stock Valuations

Historically, for all periods prior to our IPO that was completed on September 19, 2022, as there was no public market for our common stock, 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.

Once a public trading market for our common stock was established in connection with the completion of our IPO, the fair value of our common stock is 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.

During the preparation of our consolidated financial statements for the year ended December 31, 2021, we identified a material weakness in our internal control over financial reporting. The material weakness has not yet been fully remediated and the same weakness remained at the time of the preparation of our financial statements for the year ended December 31, 2022. 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 have implemented 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. 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 Annual Report. 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) December 31, 2027; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 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 our IPO was less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We will continue to be a smaller reporting company until either (i) the market value of our stock held by non-affiliates is more than $250.0 million or (ii) our annual revenue is more than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is more 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 consolidated financial statements included elsewhere in this Annual Report, such standards do not have a material impact on our financial statements or do not otherwise apply to our operations.

Item 7A. 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 Annual Report.

As of December 31, 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 Annual Report.

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.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements for the Years Ended December 31, 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, 2022 and 2021, the related consolidated statements of operations, changes in redeemable convertible preferred stock and shareholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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

Morristown, NJ

March 29, 2023

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, 2021	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 128,280	$ 288,877
Prepaid expenses and other current assets	884	3,958
Total current assets	129,164	292,835
Restricted cash	—	441
Property and equipment, net	—	35
Right of use asset	—	4,327
Other assets	—	1,037
Total assets	$ 129,164	$ 298,675
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,797	$ 2,087
Accrued expenses and other current liabilities	3,889	3,181
Operating lease liability, current	—	385
Total current liabilities	5,686	5,653
Operating lease liability, noncurrent	—	3,954
Preferred stock tranche liability	—	—
Anti-dilution liability	—	—
Total liabilities	5,686	9,607
Commitments and contingencies (Note 13)		
Series A-1 redeemable convertible preferred stock, par value $0.0001. 13,970,000 and - shares authorized as of December 31, 2021 and December 31, 2022, respectively; 13,970,000 and - shares issued and outstanding as of December 31, 2021 and December 31, 2022 respectively; liquidation preference of $13,970 and $- as of December 31, 2021, and December 31, 2022, respectively	12,574	—
Series A-2 redeemable convertible preferred stock, par value $0.0001. 13,750,000 and - shares authorized as of December 31, 2021 and December 31, 2022, respectively; 13,750,000 and - shares issued and outstanding as of December 31, 2021- and December 31, 2022, respectively; liquidation preference of $22,000 and $-, as of December 31, 2021, and December 31, 2022, respectively	19,476	—
Series A-3 redeemable convertible preferred stock, par value $0.0001. 7,812,501 and - shares authorized as of December 31, 2021 and December 31, 2022, respectively; 7,812,501 and - shares issued and outstanding as of December 31, 2021 and December 31, 2022, respectively; liquidation preference of $20,000 and $- as of December 31, 2021 and December 31, 2022, respectively	33,288	—
Series B redeemable convertible preferred stock, par value $0.0001. 14,091,689 and - shares authorized as of December 31, 2021, and December 31, 2022 respectively; 14,091,686 and - shares issued and outstanding as of December 31, 2021, and December 31, 2022, respectively; liquidation preference of $105,000 and $- as of December 31, 2021, and December 31, 2022, respectively	104,846	—
Stockholders' deficit:		
Common stock, $0.0001 par value, 72,731,000 and 500,000,000 shares authorized at December 31, 2021 and December 31, 2022; 4,237,290 and 39,377,222 shares issued and outstanding at December 31, 2021 and December 31, 2022, respectively	1	4
Preferred stock, $0.0001 par value, - and 10,000,000 shares authorized at December 31, 2021 and December 31, 2022; - and - shares issued and outstanding at December 31, 2021 and December 31, 2022, respectively	—	—
Additional paid-in capital	1,534	372,460
Accumulated deficit	(48,241)	(83,396)
Total stockholders' (deficit) equity	(46,706)	289,068
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	$ 129,164	$ 298,675

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)

	Year Ended December 31,	
	2021	2022
Operating expenses:		
Research and development	$ 15,748	$ 24,407
General and administrative	3,256	13,301
Total operating expenses	19,004	37,708
Loss from operations	19,004	37,708
Other (income) expense, net:		
Change in fair value of anti-dilution right liability	682	—
Change in fair value of preferred stock tranche liability	9,928	—
Other (income)	(5)	(2,553)
Total other (income) expense, net	10,605	(2,553)
Net loss	$ 29,609	$ 35,155
Net loss per share of common stock, basic and diluted	$ 7.32	$ 2.62
Weighted-average common stock outstanding, basic and diluted	4,043,416	13,426,066

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
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	—	—	—	—	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 30, 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)

THIRD HARMONIC BIO, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts)
(continued)

	Redeemable Convertible Preferred Stock												
	Series A-1		Series A-2		Series A-3		Series B		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
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)
Vesting of restricted stock	—	—	—	—	—	—	—	—	624,334	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—		—	4,751	—	4,751
Exercise of stock options	—	—	—	—	—	—	—	—	13,282	—	107	—	107
Conversion of convertible preferred stock into common stock upon closing of initial public offering	(13,970,000)	(12,574)	(13,750,000)	(19,476)	(7,812,501)	(33,288)	(14,091,686)	(104,846)	21,967,316	2	170,184	—	170,186
Issuance of common stock upon closing of initial public offering, net of issuance costs and underwriting fees of $2.3M	—	—	—	—	—	—	—	—	12,535,000	1	195,884	—	195,885
Net loss	—	—	—	—	—	—	—	—	—	—	—	(35,155)	(35,155)
Balance at December 30, 2022	—	$ —	—	$ —	—	$ —	—	$ —	39,377,222	$ 4	$ 372,460	$ (83,396)	$ 289,068

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)

	Year Ended December 31,	
	2021	**2022**
Cash flows from operating activities:		
Net loss	$ (29,609)	$ (35,155)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	510	4,751
Depreciation	—	1
Change in fair value of preferred stock tranche liability	9,928	—
Change in fair value of anti-dilution liability	682	—
Noncash operating lease expense	—	37
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(728)	(3,071)
Other assets	—	(1,037)
Accounts payable	1,216	290
Accrued expenses and other current liabilities	2,255	(708)
Changes in operating lease liabilities	—	(25)
Net cash used in operating activities	(15,746)	(34,917)
Cash flows from investing activities:		
Purchase of property and equipment	—	(36)
Net cash used in investing activities	—	(36)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of issuance costs	135,749	—
Proceeds from issuance of common stock in initial public offering, net of issuance costs and underwriting fees	—	198,178
Proceeds from the exercise of stock options	—	107
Payment of offering costs	—	(2,294)
Net cash provided by financing activities	135,749	195,991
Net increase in cash, cash equivalents and restricted cash	120,003	161,038
Cash, cash equivalents and restricted cash at beginning of period	8,277	128,280
Cash, cash equivalents and restricted cash at end of period	$ 128,280	$ 289,318
Supplemental disclosure of cash flows:		
Right of use asset obtained in exchange for operating lease liability	$ —	$ 4,364
Conversion of preferred stock into common stock	$ —	$ 170,184
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	$ 17,149	$ —
Gain on extinguishment of preferred stock tranche liability record to additional paid in capital	$ 750	$ —
Issuance of redeemable convertible preferred stock in settlement of anti-dilution right liability	$ 1,566	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business

Third Harmonic Bio, Inc., or the Company, is a biopharmaceutical company focused on advancing the next wave of medicine for the treatment of inflammatory disease, including dermal, respiratory, and gastrointestinal diseases.

The Company was incorporated in 2019 as a Delaware corporation, and we have two offices located in San Francisco, California and 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. Development of a drug candidate requires extensive research and development and 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.

Initial public offering

On September 19, 2022, the Company closed its initial public offering, or the IPO, and issued 12,535,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,635,000 additional shares of common stock, at a public offering price of $17.00 per share. The Company received $198.2 million, net of underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were $2.3 million. Immediately prior to the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 21,967,316 shares of common stock (see Note 8). In connection with the closing of its IPO, on September 19, 2022, the Company amended its certificate of incorporation to authorize the issuance of up to 500,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock.

Reverse stock split

On September 7, 2022, the Company effected a 1-for-2.259 reverse stock split of the Company's outstanding common stock. All common stock, stock options and per share information presented in the consolidated financial statements have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock. The ratio by which shares of preferred stock are convertible into shares of common stock was adjusted to reflect the effects of the reverse stock split.

Liquidity

In accordance with Accounting Standards Codification, or 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 an oral KIT inhibitor 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 and most recently with proceeds from the IPO. The Company has incurred recurring losses since its inception, including net losses of $29.6 million and $35.2 million for the years ended December 31, 2021 and 2022, respectively. As of December 31, 2022, the Company had an accumulated deficit of $83.4 million. To date the Company has not generated any revenues and expects to continue to generate operating losses for the foreseeable future. As of the issuance date of these consolidated financial statements, the Company expects that its existing cash and cash equivalents of $288.9 million as of December 31, 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 consolidated financial statements.

COVID-19 Pandemic

The global coronavirus disease 2019, or 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, or CDMOs, contract research organizations, or 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 ongoing COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. The Company's financial results for the year ended December 31, 2021 and 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 2023, including the timing and enrollment of patients in its planned clinical trials and other expected milestones of its future product candidates.

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, or 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, or ASUs, of the Financial Accounting Standards Board, or 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 mast cell driven 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. These accounts are guaranteed by the Federal Deposit Insurance Corporation, or FDIC, up to $250,000 per account per institution. At December 31, 2022, we held deposits in excess of FDIC insured limits.

Restricted Cash

As of December 31, 2022, the Company was required to maintain a separate cash balance of $0.3 million and $0.2 million in the form of a letter of credit, for the benefit of the landlord in connection with the Company's Prospect Street office space lease in Cambridge, Massachusetts, or the Prospect Street Lease, and the Company's Montgomery Street office space lease in San Francisco, California, or the Montgomery Street Lease, respectively, which are each classified as restricted cash (non-current) on the consolidated balance sheets (see Note 12).

	December 31, 2021	December 31, 2022
Cash and cash equivalents	$ 128,280	$ 288,877
Restricted cash	—	441
Cash, cash equivalents and restricted cash	$ 128,280	$ 289,318

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and short term marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. The Company invests its excess cash primarily in money market funds, U.S. treasury notes, and high quality, marketable debt instruments of corporations in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. The Company has not experienced any losses related to its cash equivalents and marketable securities and management believes the Company is not exposed to significant risks of losses.

As of December 31, 2022, the Company held cash deposits at Silicon Valley Bank, or SVB, in excess of FDIC insured limits. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or FDIC, was appointed as receiver. No losses were incurred by the Company on deposits that were held at SVB. Management believes that the Company is not currently exposed to significant credit risk as the vast majority of the Company's deposits were either owned directly by the Company or held in custody at a third-party financial institution. As of March 27, 2023, the Company has approximately $3.4 million on deposit with SVB and is currently evaluating its banking relationships in light of recent events.

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 were 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 cancellable, 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.

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.

Property, Plant and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization, and comprise of furniture and equipment for use in the Company's office space, as well as leasehold improvements made by the Company to the leased office space. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, which is generally five years for furniture and equipment and three years for computer equipment. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the improvements. Depreciation and amortization begin at the time the asset is placed in service.

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, or 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 classified redeemable convertible preferred stock, or Preferred Stock, as temporary equity in the accompanying consolidated balance sheets due to terms that allowed 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, were recorded as a reduction of gross proceeds from issuance. The Company did not accrete the carrying values of the preferred stock to the redemption values since the occurrence of these events were not considered probable as of December 31, 2021. Immediately prior to the closing of the initial public offering on September 19, 2022, all outstanding shares of our redeemable convertible preferred stock were converted into common stock (see Note 7).

Preferred Stock Tranche Liability

The Company classified 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 was a freestanding financial instrument that would have required 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 were 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 was fulfilled or otherwise extinguished. As of December 31, 2021, the preferred stock tranche liability has been fulfilled or otherwise extinguished (see Note 7) in full.

Anti-Dilution Right Liability

The Company classified the anti-dilution right under its license agreement with Novartis International Pharmaceutical Ltd., or Novartis, as a derivative liability on its consolidated balance sheets as the anti-dilution right represented a freestanding financial instrument that may have required 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 was 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 were 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, or Series A-2 Preferred Stock, and the issuance and sale of the Series A-3 redeemable convertible preferred stock, or Series A-3 Preferred Stock. As of December 31, 2021, the anti-dilution liability was fulfilled (see Note 6).

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*—Prior to the Company's IPO, the Company determined that based on the stage of development and other relevant factors, it was most appropriate to prepare the common stock valuations using the option-pricing method, or OPM, which used a market approach to estimate our enterprise value. After the completion of the Company's IPO, the Company will determine the fair value of the common stock based on the quoted market price of the common stock.
- *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*—Due to our limited operating history and lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility 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.

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, or 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. 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, 2021 and 2022, 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, 2021 and 2022, there was no difference between net loss and comprehensive loss and accordingly a statement of comprehensive loss 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 included 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 entitled the holders of such shares to participate in dividends but did 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, 2021, and 2022.

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.

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

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, or 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, or 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 consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

Management evaluated other recently issued accounting pronouncements and does not believe that any of these pronouncements will have a significant impact on the consolidated financial statements and related disclosures.

3. Fair Value Measurements

The following tables present information about the Company's financial assets 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)**
Money market funds	$ 22,505	$ 22,505	$ —	$ —
Total financial assets	$ 22,505	$ 22,505	$ —	$ —

	December 31, 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)**
Money market funds	$ 286,580	$ 286,580	$ —	$ —
Total financial assets	$ 286,580	$ 286,580	$ —	$ —

As of December 31, 2021 and December 31, 2022, the Company had no financial liabilities that required fair value measurement. As of December 31, 2021 and December 31, 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 year ended December 31, 2022 there were no transfers or reclassifications between fair value measurement levels of assets or liabilities. The carrying values of prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

4. Property, Plant and Equipment

Property, plant and equipment consisted of the following (in thousands):

	December 31, 2021	December 31, 2022
Construction in progress	$ —	$ 16
Office furniture	—	—
Computer equipment	—	20
Lab equipment	—	—
Property, plant and equipment, gross	—	36
Less: Accumulated depreciation	—	(1)
Property, plant and equipment, net	$ —	$ 35

Depreciation expense was $1 for the year ended December 31, 2022, which has been recorded within general and administrative expenses.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2021	December 31, 2022
Accrued research and development expenses	$ 2,685	$ 1,444
Professional fees	450	339
Employee compensation and related benefits	752	1,165
Other	2	233
Total accrued expenses and other current liabilities	$ 3,889	$ 3,181

6. Novartis License Agreement

On June 28, 2019, the Company entered into a License Agreement, or the Novartis License Agreement, with Novartis Pharma AG, formerly known as Novartis International Pharmaceutical Ltd, or 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, or 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 year ended December 31, 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 year ended December 31, 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 December 31, 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 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.

7. Redeemable Convertible Preferred Stock

As of December 31, 2021, 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

Immediately prior to the closing of the initial public offering on September 19, 2022, all outstanding shares of our redeemable convertible preferred stock were converted into 21,967,316 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. Accordingly, there were no shares of redeemable convertible preferred stock outstanding as of December 31, 2022.

8. Stockholder's Equity (Deficit)

Common stock

As of December 31, 2021 and December 31, 2022, the Company's Amended and Restated Certificate of Incorporation authorized the Company to issue 72,731,000 and 500,000,000 shares of common stock, with a par value of $0.0001, respectively. The voting, dividend and liquidation rights of the holders of the Company's common stock were subject to and qualified by the rights, preferences and privileges of the holders of the redeemable convertible preferred stock.

The holders of the common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. There are not cumulative voting rights for the election of directors in the restated certificate of incorporation, which means that holders of a majority of the shares of the common stock will be able to elect all of the directors. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, or the Board, if any, subject to the preferential dividend rights of redeemable convertible preferred stock. Through December 31, 2022, no cash dividends had been declared or paid.

On September 19, 2022, the Company completed its IPO, at which time the Company issued 12,535,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,635,000 additional shares of common stock, at a public offering price of $17.00 per share. The Company received $198.2 million, net of underwriting discounts and commissions, but before deducting offering costs payable by the Company, which were $2.3 million. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 21,967,316 shares of common stock (see Note 6). As of December 31, 2021 and December 31, 2022, there were 4,237,290 and 39,377,222 shares of common stock issued and outstanding, respectively.

The following shares of common stock were reserved for issuance as follows:

	December 31, 2021	December 31, 2022
Conversion of outstanding shares of preferred stock	21,967,316	—
Options to purchase common stock	394,254	3,644,500
Unvested restricted common stock	1,907,102	964,992
Remaining shares reserved for future issuance	2,065,764	3,801,282
Total	26,334,436	8,410,774

Undesignated preferred stock

As of December 31, 2022, the Company’s Amended and Restated Certificate of Incorporation authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share. There were no undesignated preferred shares issued or outstanding as of December 31, 2022.

9. Stock-Based Compensation

2019 Stock Incentive Plan

The Company's 2019 Stock Incentive Plan, or the 2019 Plan, provided for the Company to grant incentive stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. The 2019 Plan was administered by the Board or, at the discretion of the Board, by a committee delegated by Board. The exercise prices, vesting and other restrictions were determined at the discretion of the Board, or its committee if so delegated. The Company’s Board valued 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 total number of shares of common stock that could have been issued under the 2019 Plan was 5,317,559 shares, of which 283,808 shares remained available for grant on September 19, 2022, the date that the Company's 2022 Equity Incentive Plan, or the 2022 Plan, became effective. Upon the effectiveness of the 2022 Plan, the 283,808 remaining shares available under the 2019 Plan were transferred and became available for issuance under the 2022 Plan. Shares of common stock underlying outstanding awards under the 2019 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added to the shares of common stock available for issuance under the 2022 Plan.

2022 Plan

The 2022 Plan was approved by the Board and stockholders in August 2022. The 2022 Plan became effective on September 14, 2022 and replaced the Company's 2019 Plan on that date. The 2022 Plan authorizes the award of incentive stock options, or ISOs, non-qualified stock options, or NQSOs, Restricted Stock Awards, or RSAs, Stock Appreciation Rights, or SARs, Restricted Stock Units, or RSUs, performance awards and stock bonus awards. Pursuant to the 2022 Plan, ISOs may be granted only to employees.

The number of shares initially reserved for issuance under the 2022 Plan is 4,710,545 shares of common stock, which includes the 283,808 shares transferred from the 2019 Plan, and shall automatically increase on January 1 of each of 2023 through 2032 by the number of shares equal of the lesser of 5% of the aggregate number of shares of all classes of the common stock, plus the total number of shares of 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 the Board.

The 2022 Plan is administered by the Board or, at the discretion of the Board, by a committee of the 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.

Shares that are expired terminated, surrendered or cancelled under the 2022 Plan without having been fully exercised will be available for future awards.

Stock Options

The assumptions that the Company used to determine the grant-date fair value of stock options awarded to employees, were as follows for the year ended December 31, 2021 and 2022:

	Year Ended December 31,	
	2021	2022
Expected term (in years)	6.06-6.53	5.19-6.53
Expected volatility	82.4 - 84.2%	72.8-83.5%
Risk-free interest rate	0.87-1.20%	1.70-4.21%
Expected dividend yield	—	—
Fair value of common stock	$ 1.90	$4.30-18.40

The following table summarizes the Company's stock option activity since December 31, 2021:

	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	$ 3,294
Granted	3,448,476	11.41		
Exercised	(13,283)	7.92		
Forfeited or cancelled	(184,947)	8.19		
Outstanding as of December 31, 2022	3,644,500	10.45	9.51	1,283
Options vested and exercisable as of December 31, 2022	173,529	6.82	8.93	581
Options unvested as of December 31, 2022	3,470,971	10.70	9.57	769

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 year ended December 31, 2022 was $8.27. As of December 31, 2022, there was $25.3 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 3.70 years.

The total fair value of options vested during the year ended December 31, 2022 was $1.9 million.

Included within the total stock options outstanding are 115,580 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 less than $0.1 million for the year ended December 31, 2021 and $0.1 million for the year ended December 31, 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, or 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, or the Promissory Note, of $1.8 million. The shares granted include both service and performance-based vesting criteria and accrued at an interest rate of 0.76% per annum, compounded annually and were accounted for as restricted stock.

On August 22, 2022, the Company forgave the entire promissory note, including principal and accrued and unpaid interest. As a result this is considered a modification to the original awards, and the Company recognized the grant date fair value plus any incremental fair value due to the modification. The incremental cost was measured as the difference between the fair value of the award at modification date and the fair value of the original award immediately prior to modification. As a result of accounting for the modification, the Company recorded an incremental stock based compensation charge of $1.0 million, which will be recognized over the remaining requisite service period of the award from the date of the modification.

The CEO was paid a one-time special bonus of $1.9 million to offset the CEO's tax liability as a result of the forgiveness of the promissory note, or the Tax Payment, which is subject to a three-year vesting schedule with six-month cliffs. The Company is allowed to claw-back the unvested portion of the Tax Payment in the event that the CEO's employment is terminated before the end of the three-year vesting period, provided that the CEO's employment is terminated by the Company other than for cause, or if the CEO resigns for a good reason (a) within 12 months following a change of control, or (b) within 3 months preceding a change in control but as to only if the separation occurs after a potential change in control. In the event the CEO's employment is terminated, the unvested portion of the Tax Payment will accelerate and will not be subject to the claw back provision. The clawback provision will be accounted for if and when the CEO leaves under the relevant circumstances and the payment amount will be capitalized and recognized over the related service period as G&A employee salary expense.

A summary of the activity of the restricted common stock since December 31, 2021:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2021	1,907,102	$ 1.17
Granted	—	—
Vested	(624,334)	1.33
Cancelled or forfeited	(317,776)	0.71
Unvested at December 31, 2022	964,992	$ 0.59

The weighted-average grant-date fair value per share of restricted common stock awards granted during the year ended December 31, 2022 was zero as no shares were granted in the period. The aggregate fair value of restricted stock awards that vested during the year ended December 31, 2022 was $0.7 million. Stock-based compensation expense recognized for the restricted stock granted was $1.1 million for the year ended December 31, 2022. As of December 31, 2022, there was unrecognized expense of $1.2 million related to the restricted stock, which is expected to be recognized over a weighted-average period of 2.29 years.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's consolidated statements of operations was as follows (in thousands):

	Year Ended December 31,	
	2021	2022
Research and development	224	1,650
General and administrative	286	3,101
Total stock-based compensation expense	510	4,751

10. Income Taxes

Income (loss) before provision for income taxes consisted of the following (in thousands):

	Year ended December 31,	
	2021	2022
Domestic	$ (29,609)	$ (35,155)
Foreign	—	—
Loss before provision for income taxes	$ (29,609)	$ (35,155)

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended December 31,	
	2021	2022
Income at US statutory rate	21.00%	21.00%
State taxes, net of federal benefit	3.43%	3.60%
Change in tranche liability	-7.04%	0.00%
Non-deductible Compensation	-0.21%	-3.31%
Tax credits	1.03%	0.50%
Valuation allowance	-18.21%	-21.78%
Other	0.00%	-0.01%
	0.00%	0.00%

The net deferred income tax asset balance related to the following (in thousands):

	Year ended December 31,	
	2021	2022
Net operating loss carryforwards	$ 7,935	$ 10,336
Research and development credits	774	1,006
Intangibles	1,613	1,422
Capitalized research and development	—	5,433
Right of use liabilities	—	1,087
Stock-based compensation	—	211
Accrued expenses & other	252	274
Total deferred tax assets	10,574	19,769
Right of use assets	—	(1,084)
Deferred compensation	—	(445)
Other	—	—
Total deferred tax liabilities	—	(1,529)
Net Deferred Tax assets	10,574	18,240
Valuation allowance	(10,574)	(18,240)
Deferred Tax Assets, Net of Valuation Allowance	$ —	$ —

As of December 31, 2021 and 2022, the Company had a federal net operating loss carryforward of $29.8 million and $38.9 million, respectively, which can be carried forward indefinitely. As of December 31, 2021 and 2022, the Company has state NOL carryforwards of $26.7 million and $34.1 million, respectively. The state net operating loss carryforwards begin to expire in 2039.

As of December 31, 2022, the Company also has federal and state tax credits of $0.8 million and $0.2 million, which begin to expire in 2039 and 2039, respectively.

The Tax Cuts and Jobs Act contained a provision which requires the capitalization of Section 174 costs incurred in years beginning on or after January 1, 2022. Section 174 costs are expenditures which represent research and development costs that are incident to the development or improvement of a product, process, formula, invention, computer software, or technique. This provision changes the treatment of Section 174 costs such that the expenditures are no longer allowed as an immediate deduction but rather must be capitalized and amortized. The Company has included the impact of this provision, which results in a deferred tax asset of approximately $5.4 million as of December 31, 2022.

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, 2021 and 2022, 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, 2021 and 2022.

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. The Company has 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 the Company's stock ownership, which may be outside of the Company's 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 the Company.

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.

The Company records 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 the Company's 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, 2021 and 2022, the Company has not recorded any uncertain tax positions in our financial statements.

The Company recognizes 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, 2021 and 2022, 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, 2019, to the present. The resolution of tax matters is not expected to have a material effect on the Company’s consolidated financial statements.

11. 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):

	Year Ended December 31,	
	2021	2022
Numerator:		
Net loss	$ 29,609	$ 35,155
Net loss attributable to common stockholders, basic and diluted	$ 29,609	$ 35,155
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	4,043,416	13,426,066
Net loss per share of common stock, basic and diluted	$ 7.32	$ 2.62

The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders during the year ended December 31, 2021 and 2022 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2021	2022
Redeemable convertible preferred stock	21,967,316	—
Options to purchase common stock	394,254	3,644,500
Unvested restricted stock	1,907,102	964,992
Total	24,268,672	4,609,492

12. Leases

Operating Leases for Office Space

In October 2022, the Company entered into an office space lease approximating 10,356 of rentable square feet, located at 130 Prospect Street in Cambridge, Massachusetts. The lease commenced on December 1, 2022 when the Company took occupancy of the space, and has an initial lease term of 63 months, expiring on February 29, 2028 with no renewal options.

Also in October 2022, the Company entered into an office space lease approximating 4,703 of rentable square feet located at 1700 Montgomery Street in San Francisco, California. The lease commenced on December 20, 2022 when the Company took occupancy of the space, and has an initial lease term of 63 months, expiring on February 20, 2028 with no renewal options.

The Company also leased various office suites on a month-to month basis from Atlas Venture Life Science Advisors, or Atlas, and other third parties during the years ended December 31, 2021 and 2022. As the Company elected to not recognize leases with a lease term of 12 months or less on the balance sheet, no operating lease right of use assets and liabilities were recognized.

During the year ended December 31, 2021 and 2022, the components of operating lease cost were as follows, and are reflected in general and administrative expenses and research and development expenses, as determined by the underlying activities:

	December 31, 2021	December 31, 2022
Lease Cost:	$ —	$ —
Operating lease cost	—	75
Variable operating lease cost	—	—
Short-term operating lease cost	97	195
Total operating lease cost	$ 97	$ 270

The following table summarizes information related to the measurement of the Company's operating leases for the years ended December 31, 2021 and 2022:

	December 31, 2021	December 31, 2022
Weighted-average remaining lease term	—	5.20
Weighted-average discount rate	—	10.5%
Cash paid for amounts included in the measurement of operating lease liabilities	$ —	$ —

Maturities of operating lease liabilities at December 31, 2022 are as follows (in thousands):

2023	$ 826
2024	1,116
2025	1,145
2026	1,176
Thereafter	1,445
Total lease payments	5,708
Less: interest	(1,369)
Total lease liability	$ 4,339

13. 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 2022, there were no litigation matters which would have a material impact on the Company’s financial results.

14. Related Party Transactions

Entities Affiliated with Atlas Venture Fund XI, L.P.

Entities affiliated with Atlas Venture Fund XI, L.P. are 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 2022. The Company leased various office space from Atlas for use in its daily operations through September 2022.

During the year ended December 31, 2021 and 2022, the Company made payments of $0.2 million and $0.1 million, 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 December 31, 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 6.

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 had a stated interest rate of 0.76%, which was compounded annually. The entire Promissory Note, including principal and accrued and unpaid interest, was forgiven on August 22, 2022. The Company has paid the CEO a one-time special bonus of $1.9 million, which was paid to offset the CEO's tax liability as a result of the forgiveness of the Promissory Note. This is subject to a three-year vesting schedule with six-month cliffs, as well as continued employment with the company on the relevant vesting dates. Refer to Note 15 Employee Benefit Plans.

15. 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, 2022 the Company has not made any contributions to the 401(k) Plan.

16. Subsequent Events

On March 6, 2023, the Board of Directors of the Company approved the reduction in exercise price of certain options that had been granted under the 2019 Plan and the 2022 Plan, that have an exercise price greater than or equal to $8.61 per share, which were each repriced at an exercise price of $4.20. There were no changes in the vesting schedule or maturity term of the options. The Company expects to record the impact of the option repricing in the quarter ending March 31, 2023.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2022, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding our internal control over financial reporting or an attestation report of our independent registered accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our independent registered accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

Management determined that, as of December 31, 2022, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report:

1. Financial Statements

See Index to Financial Statements under Part II, Item 8 of this Annual Report.

2. Financial Statement Schedules

Schedules not listed above have been omitted because they are not required, not applicable, or the required information is otherwise included.

3. Exhibits

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed herewith
3.1	Restated Certificate of Incorporation.	10-Q	001-41498	3.1	11/9/2022	
3.2	Amended and Restated Bylaws.	8-K	001-41498	3.1	12/21/2022	
4.1	Form of Common Stock Certificate.	S-1/A	333-267022	4.1	09/08/2022	
4.2	Description of Registrant's Securities.					X
4.3	Amended and Restated Investors' Rights Agreement, dated December 17, 2021 by and among the Registrant and certain of its stockholders.	S-1	333-267022	4.2	8/23/2022	
10.1+	Form of Indemnity Agreement.	S-1/A	333-267022	10.1	09/08/2022	
10.2+	2019 Stock Incentive Plan, as amended, and forms of award agreements.	S-1	333-267022	10.2	08/23/2022	
10.3+	2022 Equity Incentive Plan and forms of award agreements.	S-1/A	333-267022	10.3	09/08/2022	
10.4+	2022 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	333-267022	10.4	09/08/2022	
10.5^	Use and Occupancy Agreement, dated February 1, 2021, by and among and Registrant and Atlas Venture Life Science Advisors, LLC.	S-1	333-267022	10.5	08/23/2022	
10.6^	Use and Occupancy Agreement, dated July 1, 2021, by and between the Registrant and Atlas Venture Life Science Advisors, LLC.	S-1	333-267022	10.6	08/23/2022	
10.7†^	License Agreement, dated June 28, 2019, by and between the Registrant and Novartis International Pharmaceutical Ltd.	S-1	333-267022	10.7	08/23/2022	
10.8+	Offer Letter, dated July 2, 2021, by and between the Registrant and Natalie Holles.	S-1	333-267022	10.8	08/23/2022	
10.9+	Amended and Restated Employment Agreement, dated August 22, 2022, between the Registrant and Natalie Holles.	S-1/A	333-267022	10.9	09/08/2022	
10.10+	Offer Letter, dated February 14, 2022, by and between the Registrant and Robert Ho.					X
10.11+	Offer Letter, dated May 12, 2022, by and between the Registrant and Edward Conner.					X
10.12+	Form of Change in Control and Severance Agreement.	S-1/A	333-267022	10.10	09/08/2022	
10.13+	Consulting Agreement, dated June 14, 2019, by and between the Registrant and Mark Iwicki.	S-1	333-267022	10.11	08/23/2022	

10.14+	Consulting and Scientific Advisory Board Agreement, dated July 25, 2019, by and between the Registrant and H. Martin Seidel.	S-1	333-267022	10.10	08/23/2022	
10.15†^	Lease Agreement, dated October 21, 2022, between 130 Prospect Limited Partnership and the Registrant.					X
10.16†^	Office Lease Agreement, dated October 21, 2022, between JPPF Waterfront Plaza, L.P. and the Registrant.					X
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of Deloitte & Touche LLP.					X
24.1	Power of Attorney (reference is made to the signature page hereto).					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted in iXBRL and contained in Exhibit 101).					X

† The Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

^ The Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

+ Indicates a management contract or compensatory plan, contract or arrangement.

* This certification is deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Third Harmonic Bio, Inc.

Date: March 29, 2023	By:	/s/ Natalie Holles Natalie Holles Chief Executive Officer and Director *(Principal Executive Officer)*
Date: March 29, 2023	By:	/s/ Robert Ho Robert Ho Chief Financial Officer *(Principal Financial and Accounting Officer)*

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Natalie Holles and Robert Ho, and each of them, as her or his true and lawful attorneys-in-fact, proxies and agents, each with full power of substitution and resubstitution, for her or him and in her or his name, place and stead, in any and all capacities, to sign any and all amendments to this report and to file the same, with any exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto such attorneys-in-fact, proxies and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies and agents, or their or his or her substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Natalie Holles Natalie Holles	Chief Executive Officer and Director (*Principal Executive Officer*)	March 29, 2023
/s/ Robert Ho Robert Ho	Chief Financial Officer and Treasurer (*Principal Financial and Accounting Officer*)	March 29, 2023
/s/ Mark Iwicki Mark Iwicki	Director	March 29, 2023
/s/ David P. Bonita David P. Bonita	Director	March 29, 2023
/s/ Michael Gladstone Michael Gladstone	Director	March 29, 2023
/s/ Rob Perez Rob Perez	Director	March 29, 2023
/s/ H. Martin Seidel H. Martin Seidel	Director	March 29, 2023
/s/ Thomas M. Soloway Thomas M. Soloway	Director	March 29, 2023

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation and amended and restated bylaws, and to the applicable provisions of Delaware law.

General

Our authorized capital stock consists 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.

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.

Voting Rights

Holders of our common stock are entitled to one (1) vote for each share of common stock held on all matters submitted to a vote of stockholders. Our restated certificate of incorporation does not provide for cumulative voting for the election of directors, 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 established a classified board of directors, 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 of preferred stock.

Preferred Stock

We have no shares of preferred stock outstanding. Pursuant to our restated certificate of incorporation, our board of directors is 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.

Registration Rights

Pursuant to the terms of our amended and restated investors' rights agreement, or IRA, the holders of 25,508,705 shares of our common stock are entitled to rights with respect to the registration of these shares under the Securities Act of 1933, as amended, or 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 our initial public offering.

Demand Registration Rights

The holders of not less than a majority of the registrable securities 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 amended and restated bylaws 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 amended and restated bylaws 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 amended and restated bylaws 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 amended and restated bylaws 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.

- *Stockholder Action; Special Meetings of Stockholders*. Our restated certificate of incorporation provides 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 amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws. Further, our amended and restated bylaws 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 amended and 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 amended and restated bylaws 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 amended and restated bylaws also 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 amended and restated bylaws will not provide for cumulative voting.

- *Directors Removed Only for Cause*. Our restated certificate of incorporation provides 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 requires 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 provides 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 amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and 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

The transfer agent and registrar for our common stock is 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

Our common stock is listed on Nasdaq under the symbol "THRD."

Third Harmonic Bio, Inc.

300 Technology Square, 8th Floor, Cambridge, MA 02139

February 14, 2022

Robert K. Ho

Dear Robert:

On behalf of Third Harmonic Bio, Inc. (the "Company"), I am pleased to offer you employment with the Company on the following terms and conditions.

1.**Position.** You will be employed by the Company on a full-time basis as its Chief Financial Officer, reporting to the Chief Executive Officer. It is contemplated that you will commence employment on a date to be mutually agreed upon between you and the Company, but which in no event shall be later than March 7, 2022 (the "Start Date"). You shall work in a hybrid working arrangement as mutually agreed upon with the Chief Executive Officer. You agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. In addition, you agree that you shall not engage in any other employment, consulting or other business activity without the prior written consent of the Company.

2.**Base Salary.** You will receive a base salary at the semi-monthly rate of $16,666.67 which is equivalent to $400,000.00 on an annualized basis (the "Base Salary"). All payments will be subject to legally required tax withholdings. The Base Salary will be subject to adjustment as determined by the Company in its discretion.

3.**Annual Bonus.** Following the end of each fiscal year you will be eligible to receive an annual incentive bonus of up to forty percent (40%) of your annualized Base Salary. The actual bonus awarded for a fiscal year will be based on your performance and the Company's performance that year against criteria to be established by the Company, such bonus and such criteria as determined by the Company in its sole discretion. You must remain employed by the Company as of the last day of a fiscal year in order to be eligible for and to earn a bonus for such year. Any bonus would be pro-rated for the 2022 fiscal year.

4.**Equity.** Subject to the approval of the Company's Board of Directors (the "Board") and the execution by you of corresponding stock option agreements, the Company shall grant to you a stock option award to purchase an aggregate of 831,211 shares of the Company's common stock (the "Option Grant"), which represents 1.2% of the Company's fully-diluted capitalization – including all warrants, options and convertible securities – as of the date hereof. The stock option award shall vest as to twenty-five percent (25%) of the underlying shares on the first anniversary of the Start Date, and as to the balance in equal quarterly installments of 6.25% thereafter until the fourth anniversary of the Start Date. The Option Grant will be subject to the terms and conditions of the stock option agreement and the Company's 2019 Stock Incentive Plan in all respects, notwithstanding the language of this Section 4 (the "Grant Documents"), and shall have an exercise price per share equal to the fair market value of the Company's common stock at the time of grant as determined by the Company in its sole discretion. In addition, you may be entitled to additional stock option grants and/or awards of restricted shares of common stock (the "Additional Grants") that the Company may elect to grant to you in the future in its sole discretion.

5.**Benefits.** You may participate in the benefit programs offered by the Company to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion. You will also be entitled to paid vacation each year in accordance with the terms and conditions set forth in the Company's vacation policy as in effect from time to time, but for avoidance of doubt, you will accrue no less than three weeks paid vacation per year. You shall also be entitled to receive reimbursement for all reasonable business expenses incurred by you in performing your services to the Company, in accordance with the policies and procedures then in effect and established by the Company.

6.**Severance Benefits.**

a. **General.** Either party may terminate your employment relationship hereunder at any time for any reason by providing written notice to the other party; provided that if you are subject to an Involuntary Termination (as defined below), then you will be entitled to the benefits described in this Section 6. However, this Section 6 will not apply unless you: (i) have returned all Company property in your possession on or prior to your last day of employment and (ii) have entered into a separation agreement that has become enforceable and irrevocable and that includes a general release of all employment-related claims that you may have against the Company or persons affiliated with the Company (the "Separation Agreement"). Notwithstanding the foregoing, no term of this offer letter or the Separation Agreement shall impact or affect, in any way, your rights with respect to, and the Separation Agreement shall not include a waiver or release of any claims related to: (w) your status as a stockholder or equity holder of the Company or any rights you have under the terms of any Grant Document or any other equity award or agreement between you and the Company, including any claims with respect to the Option Grants, any Additional Grant or other equity owned or held by you at the time your employment is terminated, (x) any rights to indemnification from the Company, pursuant to any applicable governing documents of the Company or any applicable written agreement between you and the Company, (y) rights under ERISA or (z) rights which, as a matter of law, cannot be waived. The Separation

Agreement must be in substantially the form reasonably prescribed by the Company, and must be executed and must become enforceable and irrevocable on or before the 52nd day following your last day of employment with the Company. If you fail to execute without revocation the Separation Agreement on or before the 52nd day following your last day of employment with the Company, you shall be entitled to the accrued obligations only and no other severance payments or benefits. The continued salary provided under Section 6(b)(ii) below shall be paid in accordance with the Company's normal payroll practices and shall commence on the next payroll date falling after the date the Separation Agreement becomes enforceable and irrevocable. If, however, the 52-day period in which the Separation Agreement must become enforceable and irrevocable begins in one taxable year and ends in the following year, the Company shall commence payment of the continued salary in the second year on the first payroll date falling on the later of: (A) January 1; and (B) the date on which the Separation Agreement becomes enforceable and irrevocable. The first payroll shall include, however, all amounts that would otherwise have been paid to you between the date your employment is terminated and your receipt of the first installment.

b. **Severance.** If you are subject to an Involuntary Termination, then, subject to Section 6(a):

i. The Company shall pay you the accrued obligations earned through your last day of employment on or before the time required by law but in no event more than fifteen (15) days after your last day of employment with the Company, except to the extent such payment would accelerate compensation in a manner inconsistent with compliance with Section 409A of the Internal Revenue Code of 1986, as amended (the "Code");

ii. The Company shall continue to pay you your Base Salary as in effect on your last day of employment for a period of six (6) months;

iii. If you are participating in the Company's group health plan immediately prior to your last day of employment and you elect COBRA health continuation, then the Company shall pay you a monthly cash payment for six (6) months, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company; provided, however, that such Company-paid premiums may be recorded as additional income pursuant to Section 6041 of the Code and not entitled to any tax qualified treatment to the extent necessary to comply with or avoid the discriminatory treatment prohibited by the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010 or Section 105(h) of the Code.

iv. If the Involuntary Termination occurs on or within twelve (12 months) following a Change in Control, then: (i) one hundred percent (100%) of the unvested portion of the Option Grant and each Additional Grant will fully

vest as of the date of such Involuntary Termination; (ii) no shares may be transferred and no stock option exercised (in each case with respect to the unvested portion) until the Separation Agreement has become enforceable and irrevocable and (iii) if the Separation Agreement does not become enforceable and irrevocable in accordance with this offer letter, the portions of the Option Grants and Additional Grants that have vested as a result of this provision shall be cancelled effective as of the date of the Involuntary Termination.

The payments and benefits described in Section 6(b)(ii)-(iv) above shall hereinafter be referred to as the "Severance." If you are terminated for any reason other than as result of an Involuntary Termination, you shall be entitled to receive the accrued obligations only.

For the purposes of this Section 6, the following capitalized terms shall have the meaning set forth below.

"Cause" means (i) your material breach of the Restrictive Covenant Agreement (as defined below), (ii) your conviction of, or your plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State, (iii) your gross negligence or willful misconduct in the performance of your duties, (iv) your continuing failure to perform assigned duties after receiving written notification of the failure from the Company and you were afforded a reasonable opportunity to cure or remedy any such failure, or (v) your failure to cooperate in good faith with a governmental or internal investigation of the Company or its directors officers or employees, if the Company has requested your cooperation; provided, however, that "Cause" shall not be deemed to have occurred pursuant to subsection (iii), (iv) or (v) hereof unless you have first received written notice from the Board specifying in reasonable detail the particulars of such grounds and that the Company intends to terminate your employment hereunder for such grounds and you have failed to cure such grounds within a period of thirty (30) days from the date of such notice.

"Involuntary Termination" means either: (i) your Termination Without Cause or (ii) your Resignation for Good Reason.

"Resignation for Good Reason" means a Separation as a result of your resignation after one of the following conditions has come into existence without your consent:

i. A reduction in your base salary by more than 10% (unless such reduction is part of a broad-based salary reduction applicable to the Company's entire senior management team);

ii. A material diminution of your authority, duties or responsibilities; or

iii. A relocation of your principal workplace by more than forty (40) miles.

Notwithstanding the foregoing, a Resignation for Good Reason will not be deemed to have occurred unless (i) you give the Company written notice of the condition within ninety (90) days after the condition comes into existence, (ii) the Company fails to remedy the

condition within thirty (30) days after receiving your written notice (the "Cure Period") and (iii) you resign within thirty (30) days after the expiration of the Cure Period.

"Separation" means a "separation from service", as defined in the regulations under Section 409A of the Code.

"Termination Without Cause" means a Separation as a result of a termination of your employment by the Company without Cause, provided you are willing and able to continue performing services within the meaning of Treasury Regulation l.409A- 1(n)(l).

7.**Representation Regarding Continuing Obligations.** Your employment is contingent upon your signing and adhering to an Invention, Non-Disclosure and Non-Solicitation Agreement (the "Restrictive Covenant Agreement"), a copy of which is provided with this letter. You hereby represent to the Company that you are not a party to any agreement of any type which may impact or limit your ability to become employed by or perform your job at the Company or which is in any way inconsistent with the terms of this offer letter or the Restrictive Covenant Agreement. You represent that you will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any current or previous employer or any other party. Further, you hereby represent that (i) your employment with the Company and this offer letter does not and will not violate or conflict with any obligations you may have to or any agreements you may have with any former employer and (ii) you have provided the Company with all written agreements that describe any continuing post-employment obligations to any former employer.

8.**Proof of Legal Right to Work**. You agree to provide to the Company, within three (3) days of the Start Date, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

9.**Tax Matters.**

a. All forms of compensation referred to in this offer letter are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities and that you are solely responsible for individual tax liabilities arising from your compensation.

b. All in-kind benefits provided and expenses eligible for reimbursement hereunder shall be provided by the Company or incurred by you during your employment with the Company. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

10.**Interpretation, Amendment and Enforcement.** This offer letter and the Grant Documents along with the Restrictive Covenant Agreement constitute the complete agreement between you and the Company, contain all the terms of your employment, and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company relating to the terms of your employment. The terms of this offer letter and the resolution of any disputes as to the meaning, effect, performance or validity of this offer letter or arising out of, related to, or in any way connected with, this offer letter, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by Massachusetts law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts in connection with any Dispute or any claim related to any Dispute.

11. **Other Terms.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will as defined by applicable law, which means that you have the right to terminate your employment relationship with the Company at any time for any reason and the Company has the right to terminate its employment relationship with you at any time for any reason, with or without cause or notice. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company other than as provided in this letter.

We are excited about the prospect of having you join the Company. If this letter correctly sets forth the terms under which you will be employed by the Company, please sign this letter in the space provided below and return it to me, along with a signed copy of the Restrictive Covenant Agreement by February 18, 2022.

[*Remainder of Page Intentionally Left Blank*]

Very truly yours,

THIRD HARMONIC BIO, INC.

Signature: */s/ Natalie Holles*
Natalie Holles, CEO

The foregoing correctly sets forth the terms of my at-will employment with Third Harmonic Bio, Inc. I am not relying on any representations other than those set forth above.

Signature: */s/ Robert Ho* February 14, 2022
Robert K. Ho Date

Third Harmonic Bio, Inc.

300 Technology Square, 8th Floor, Cambridge, MA 02139

May 12, 2022

Edward Conner, MD

Dear Ed:

On behalf of Third Harmonic Bio, Inc. (the "Company"), I am pleased to offer you employment with the Company on the following terms and conditions.

1.**Position.** You will be employed by the Company on a full-time basis as its Chief Medical Officer, reporting to the Chief Executive Officer. It is contemplated that you will commence employment on a date on June 6, 2022 (the "Start Date"). You shall work in a hybrid working arrangement as mutually agreed upon with the Chief Executive Officer. You agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company. In addition, you agree that you shall not engage in any other employment, consulting or other business activity without the prior written consent of the Company.

2.**Base Salary.** You will receive a base salary at the semi-monthly rate of $19,375 which is equivalent to $465,000.00 on an annualized basis (the "Base Salary"). All payments will be subject to legally required tax withholdings. The Base Salary will be subject to adjustment as determined by the Company in its discretion.

3.**Annual Bonus.** Following the end of each fiscal year you will be eligible to receive an annual incentive bonus of up to forty percent (40%) of your annualized Base Salary. The actual bonus awarded for a fiscal year will be based on your performance and the Company's performance that year against criteria to be established by the Company, such bonus and such criteria as determined by the Company in its sole discretion. You must remain employed by the Company as of the last day of a fiscal year in order to be eligible for and to earn a bonus for such year. Any bonus would be pro-rated for the 2022 fiscal year.

4.**Equity.** Subject to the approval of the Company's Board of Directors (the "Board") and the execution by you of corresponding stock option agreements, the Company shall grant to you a stock option award to purchase an aggregate of 865,849 shares of the Company's common stock (the "Option Grant"), which represents 1.25% of the Company's fully-diluted capitalization –

including all warrants, options and convertible securities - as of the date hereof. The stock option award shall vest as to twenty-five percent (25%) of the underlying shares on the first anniversary of the Start Date, and as to the balance in equal quarterly installments of 6.25% thereafter until the fourth anniversary of the Start Date. The Option Grant will be subject to the terms and conditions of the stock option agreement and the Company's 2019 Stock Incentive Plan in all respects, notwithstanding the language of this Section 4 (the "Grant Documents"), and shall have an exercise price per share equal to the fair market value of the Company's common stock at the time of grant as determined by the Company in its sole discretion. In addition, you may be entitled to additional stock option grants and/or awards of restricted shares of common stock (the "Additional Grants") that the Company may elect to grant to you in the future in its sole discretion.

5.**Benefits.** You may participate in the benefit programs offered by the Company to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion. You will also be entitled to paid vacation each year in accordance with the terms and conditions set forth in the Company's vacation policy as in effect from time to time, but for avoidance of doubt, you will accrue no less than three weeks paid vacation per year. You shall also be entitled to receive reimbursement for all reasonable business expenses incurred by you in performing your services to the Company, in accordance with the policies and procedures then in effect and established by the Company.

6.**Severance Benefits.**

a. **General.** Either party may terminate your employment relationship hereunder at any time for any reason by providing written notice to the other party; provided that if you are subject to an Involuntary Termination (as defined below), then you will be entitled to the benefits described in this Section 6. However, this Section 6 will not apply unless you: (i) have returned all Company property in your possession on or prior to your last day of employment and (ii) have entered into a separation agreement that has become enforceable and irrevocable and that includes a general release of all employment-related claims that you may have against the Company or persons affiliated with the Company (the "Separation Agreement"). Notwithstanding the foregoing, no term of this offer letter or the Separation Agreement shall impact or affect, in any way, your rights with respect to, and the Separation Agreement shall not include a waiver or release of any claims related to: (w) your status as a stockholder or equity holder of the Company or any rights you have under the terms of any Grant Document or any other equity award or agreement between you and the Company, including any claims with respect to the Option Grants, any Additional Grant or other equity owned or held by you at the time your employment is terminated, (x) any rights to indemnification from the Company, pursuant to any applicable governing documents of the Company or any applicable written agreement between you and the Company, (y) rights under ERISA or (z) rights which, as a matter of law, cannot be waived. The Separation Agreement must be in substantially the form reasonably prescribed by the Company, and must be executed and must become enforceable and irrevocable on or before the 52nd day following your last day of employment with the Company. If you fail to execute without revocation the Separation Agreement on or before the

52nd day following your last day of employment with the Company, you shall be entitled to the accrued obligations only and no other severance payments or benefits. The continued salary provided under Section 6(b)(ii) below shall be paid in accordance with the Company's normal payroll practices and shall commence on the next payroll date falling after the date the Separation Agreement becomes enforceable and irrevocable. If, however, the 52-day period in which the Separation Agreement must become enforceable and irrevocable begins in one taxable year and ends in the following year, the Company shall commence payment of the continued salary in the second year on the first payroll date falling on the later of: (A) January 1; and (B) the date on which the Separation Agreement becomes enforceable and irrevocable. The first payroll shall include, however, all amounts that would otherwise have been paid to you between the date your employment is terminated and your receipt of the first installment.

b. **Severance.** If you are subject to an Involuntary Termination, then, subject to Section 6(a):

i. The Company shall pay you the accrued obligations earned through your last day of employment on or before the time required by law but in no event more than fifteen (15) days after your last day of employment with the Company, except to the extent such payment would accelerate compensation in a manner inconsistent with compliance with Section 409A of the Internal Revenue Code of 1986, as amended (the "Code");

ii. The Company shall continue to pay you your Base Salary as in effect on your last day of employment for a period of six (6) months;

iii. If you are participating in the Company's group health plan immediately prior to your last day of employment and you elect COBRA health continuation, then the Company shall pay you a monthly cash payment for six (6) months, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company; provided, however, that such Company-paid premiums may be recorded as additional income pursuant to Section 6041 of the Code and not entitled to any tax qualified treatment to the extent necessary to comply with or avoid the discriminatory treatment prohibited by the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010 or Section 105(h) of the Code.

iv. If the Involuntary Termination occurs on or within twelve (12 months) following a Change in Control, then: (i) one hundred percent (100%) of the unvested portion of the Option Grant and each Additional Grant will fully vest as of the date of such Involuntary Termination; (ii) no shares may be transferred and no stock option exercised (in each case with respect to the unvested portion) until the Separation Agreement has become enforceable and irrevocable and (iii) if the Separation Agreement does not become

enforceable and irrevocable in accordance with this offer letter, the portions of the Option Grants and Additional Grants that have vested as a result of this provision shall be cancelled effective as of the date of the Involuntary Termination.

The payments and benefits described in Section 6(b)(ii)-(iv) above shall hereinafter be referred to as the "Severance." If you are terminated for any reason other than as result of an Involuntary Termination, you shall be entitled to receive the accrued obligations only.

For the purposes of this Section 6, the following capitalized terms shall have the meaning set forth below.

"Cause" means (i) your material breach of the Restrictive Covenant Agreement (as defined below), (ii) your conviction of, or your plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State, (iii) your gross negligence or willful misconduct in the performance of your duties, (iv) your continuing failure to perform assigned duties after receiving written notification of the failure from the Company and you were afforded a reasonable opportunity to cure or remedy any such failure, or (v) your failure to cooperate in good faith with a governmental or internal investigation of the Company or its directors officers or employees, if the Company has requested your cooperation; provided, however, that "Cause" shall not be deemed to have occurred pursuant to subsection (iii), (iv) or (v) hereof unless you have first received written notice from the Board specifying in reasonable detail the particulars of such grounds and that the Company intends to terminate your employment hereunder for such grounds and you have failed to cure such grounds within a period of thirty (30) days from the date of such notice.

"Involuntary Termination" means either: (i) your Termination Without Cause or (ii) your Resignation for Good Reason.

"Resignation for Good Reason" means a Separation as a result of your resignation after one of the following conditions has come into existence without your consent:

i. A reduction in your base salary by more than 10% (unless such reduction is part of a broad-based salary reduction applicable to the Company's entire senior management team);

ii. A material diminution of your authority, duties or responsibilities; or

iii. A relocation of your principal workplace by more than forty (40) miles.

Notwithstanding the foregoing, a Resignation for Good Reason will not be deemed to have occurred unless (i) you give the Company written notice of the condition within ninety (90) days after the condition comes into existence, (ii) the Company fails to remedy the condition within thirty (30) days after receiving your written notice (the "Cure Period") and (iii) you resign within thirty (30) days after the expiration of the Cure Period.

"Separation" means a "separation from service", as defined in the regulations under Section 409A of the Code.

"Termination Without Cause" means a Separation as a result of a termination of your employment by the Company without Cause, provided you are willing and able to continue performing services within the meaning of Treasury Regulation l.409A- 1(n)(l).

7.**Representation Regarding Continuing Obligations.** Your employment is contingent upon your signing and adhering to an Invention, Non-Disclosure and Non-Solicitation Agreement (the "Restrictive Covenant Agreement"), a copy of which is provided with this letter. You hereby represent to the Company that you are not a party to any agreement of any type which may impact or limit your ability to become employed by or perform your job at the Company or which is in any way inconsistent with the terms of this offer letter or the Restrictive Covenant Agreement. You represent that you will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any current or previous employer or any other party. Further, you hereby represent that (i) your employment with the Company and this offer letter does not and will not violate or conflict with any obligations you may have to or any agreements you may have with any former employer and (ii) you have provided the Company with all written agreements that describe any continuing post-employment obligations to any former employer.

8.**Proof of Legal Right to Work**. You agree to provide to the Company, within three (3) days of the Start Date, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company

9.**Tax Matters.**

a. All forms of compensation referred to in this offer letter are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities and that you are solely responsible for individual tax liabilities arising from your compensation.

b. All in-kind benefits provided and expenses eligible for reimbursement hereunder shall be provided by the Company or incurred by you during your employment with the Company. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

10.**Interpretation, Amendment and Enforcement.** This offer letter and the Grant Documents along with the Restrictive Covenant Agreement constitute the complete agreement between you and the Company, contain all the terms of your employment, and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company relating to the terms of your employment. The terms of this offer letter and the resolution of any

disputes as to the meaning, effect, performance or validity of this offer letter or arising out of, related to, or in any way connected with, this offer letter, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by Massachusetts law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts in connection with any Dispute or any claim related to any Dispute.

11. **Other Terms.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will as defined by applicable law, which means that you have the right to terminate your employment relationship with the Company at any time for any reason and the Company has the right to terminate its employment relationship with you at any time for any reason, with or without cause or notice. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company other than as provided in this letter.

We are excited about the prospect of having you join the Company. If this letter correctly sets forth the terms under which you will be employed by the Company, please sign this letter in the space provided below and return it to me, along with a signed copy of the Restrictive Covenant Agreement by February 18, 2022.

[*Remainder of Page Intentionally Left Blank*]

Very truly yours,

THIRD HARMONIC BIO, INC.

Signature: */s/ Natalie Holles*
Natalie Holles, CEO

The foregoing correctly sets forth the terms of my at-will employment with Third Harmonic Bio, Inc. I am not relying on any representations other than those set forth above.

Signature: */s/Ed Conner* May 18, 2022
Edward Conner, MD Date

Exhibit 10.15

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

LEASE AGREEMENT

BETWEEN

130 PROSPECT LIMITED PARTNERSHIP,
a Massachusetts limited partnership

a n d

THIRD HARMONIC BIO, INC.
A Delaware corporation

Dated: October 20, 2022

Office No.: Suite 301
130 Prospect Street, 3rd Floor
Cambridge, MA 02139

Table of Contents

L E A S E A G R E E M E N T

This Lease Agreement ("Lease") is made and entered into as of the 20th day of October, 2022, and is by and between 130 Prospect Limited Partnership, a limited partnership duly qualified to do business in the Commonwealth of Massachusetts (hereinafter sometimes referred to as "Landlord" or "Owner") and Third Harmonic Bio, Inc., a Delaware corporation (hereinafter sometimes referred to as "Tenant").

WITNESSETH:

Article I

Grant and Term

Section 1.01.Leased Premises: In consideration of the rent, covenants and agreements hereinafter reserved and contained on the part of Tenant to be observed and performed, Landlord hereby demises and leases to Tenant, and Tenant hereby rents and takes from Landlord Suite 301 (hereinafter referred to as the "Leased Premises"), located in that certain building being a commercial office building located on 130 Prospect Street (hereinafter referred to as the "Building"), Cambridge, Massachusetts. The Leased Premises contains 10,356 net rentable square feet on the third floor of the Building and are more particularly described in Exhibit A, attached hereto. Landlord represents to Tenant that the Leased Premises and the Building were measured based on the BOMA standard for Office Buildings — Standard Measures of Management (ANSI/BOMA Z65.1 - 2010 and that the size of the Leased Premises is 10,356 net rentable square feet and the size of the Building is 30,456 net rentable square feet. The Leased Premises shall not be remeasured during the Lease Term.

Nothing herein contained shall be construed as a grant or demise by Landlord to Tenant of the roof or exterior walls of the Leased Premises, or of the space above the Leased Premises or below the underside of the floor slab thereof, or of any space within the Leased Premises used for shafts, stacks, pipes, conduits, ducts, electric or other utilities, or of the common areas of the Building.

Tenant shall have the right to use in common with Landlord and others from time to time lawfully entitled thereto such service and other common areas and facilities outside of the Leased Premises as may from time to time be established by Owner (as hereinafter defined and designated as such in respect to the Building) including means of egress and ingress and walkways, sidewalks, lobbies, stairways and other areas of the Building not occupied or intended to be occupied by any person exclusively. Owner has reserved the right to add to, subtract from, or otherwise change the common facilities from time to time as it may deem for the best interest of the Building; provided, however, it shall not thereby unreasonably interfere with Tenant use and occupancy of the Leased Premises hereunder. Tenant takes the Leased Premises subject to this reservation.

Section 1.02.Commencement and Ending Date of Term: The term of this Lease shall commence on December 1, 2022 (the "Commencement Date") and Tenant's obligation to pay rent hereunder shall commence on March 1, 2023 (the "Rent Commencement Date") and thereafter rent payments shall be made on the first day of the month following the Rent Commencement Date and shall continue until February 29, 2028.

Notwithstanding any other provision of this Lease, this Lease is subject to Nimbus Discovery, Inc., the prior tenant of the Premises (the "Prior Tenant"), entering into an agreement with Landlord for Prior Tenant to vacate and surrender the Premises on or before the Commencement Date and to amend its Lease of the Premises and of the second floor of the Building on terms that are acceptable to Landlord in its sole discretion. If the Prior Tenant does not enter into such an Agreement with the Landlord, or if it does not actually vacate and surrender the Premises on or before the Commencement Date, then the Commencement Date shall be extended until such Agreement is signed and Prior Tenant vacates and surrenders the Premises. In such event, the Rent Commencement Date and Term shall be extended for the same number of days. If the Prior Tenant does not enter into such Agreement and actually vacate and surrender the Premises on or before March 1, 2023, then either Landlord or Tenant may terminate this Lease, all rent and security deposits paid by Tenant shall be refunded to it, and neither party shall have further recourse under this Lease.

Subject to the foregoing, the Landlord shall deliver the Premises on the Commencement Date in accordance with the provisions of Section 3.01 below. In addition, Landlord shall cause the Prior Tenant to remove the moose head prior to Commencement Date.

Provided that the Prior Tenant provides its consent to the Tenant (which it shall be the responsibility of the Tenant to obtain) and without cost or expense to Prior Tenant, Tenant shall have the right to enter the Premises after the execution of this Lease and prior to the Commencement Date, at reasonable times and with prior written notice to Landlord, for the sole purpose of the installation of telephone and computer wiring and of furniture, fixtures and equipment, provided that (i) the Tenant has paid the Security Deposit and first month's rent as provided herein, (ii) Tenant and its contractor shall provide evidence of insurance naming Landlord as an additional insured in accordance with Section 6.01 below, and (iii) Tenant shall coordinate with Landlord and Prior Tenant in order that such work by Tenant not unreasonably interfere with Prior Tenant's use and enjoyment of the Premises.

The term "Lease Year" as used herein shall mean a period of twelve (12) consecutive full calendar months. The first Lease Year shall begin on the Commencement Date if the Commencement Date is the first day of a calendar month; if not, then the first Lease Year shall commence upon the first day of the calendar month next following the date of commencement of the term hereof. Each succeeding Lease Year shall commence upon the anniversary date of the first Lease Year.

Section 1.03.License for Temporary Space: From and after the execution of this Lease and the payment of all amounts due from Tenant upon such execution, Landlord grants to Tenant, upon Tenant's sole request, a revocable License to use space on the Mezzanine Level of the Building (the "Temporary Space") at a rate of $300 per day, payable monthly in arrears. Such Temporary Space shall be used solely for the Permitted Use hereunder. The Temporary Space will be delivered in its "As Is" condition. Tenant shall be solely responsible for furnishing such space and shall remove all furniture and furnishings from such Temporary Space as soon as feasible after Commencement Date but in no event more than one (1) week after the Commencement Date. Tenant shall not make any alterations to such Temporary Space. Tenant shall provide a certificate of all insurance required by this Lease to Landlord prior to commencement of occupancy of the Temporary Space. Notwithstanding its occupancy of the Temporary Space, Tenant shall have no parking rights under this Lease until the Commencement Date, however if spaces are available, at Tenant's request Landlord will provide at a daily rate of $25 per space per day. Landlord shall have the right to terminate this License at any time upon five days' written notice to Tenant if Landlord enters into a Letter of Intent to lease the Mezzanine Level to a third party tenant.

Article II

Rent

Section 2.01.Base Rent: Tenant agrees to pay Landlord at the office of Landlord, or at such other place designated by Landlord, without any prior demand therefor and without any abatement, deduction or set-off whatsoever, a fixed annual base rent per square foot for the net rentable space of the Leased Premises, as specified in Section1.01 hereof, plus any applicable sales or occupancy or rental taxes due. The fixed base rent shall be at the amounts shown on Exhibit B for the periods shown on Exhibit B (the "Fixed Base Rent"). On the Rent Commencement Date the Tenant shall pay to Landlord an amount of rent equal to 1/30th of the initial monthly Base Rent multiplied by the number of days remaining in the month in which the Rent Commencement Date occurs. Thereafter, the Tenant shall pay the Fixed Base Rent in twelve (12) equal installments each in advance on the first day of each calendar month, all of said monthly rent payments being subject to proration in the case of any partial calendar month. The annual rate of the Fixed Base Rent reserved hereinabove shall be increased by two and one-half percent (2.5%) per Lease Year and as set forth on Exhibit B which is attached hereto and made a part hereof.

Section 2.02.Past Due Rent and Additional Rent: If Tenant shall fail to pay, when the same is due and payable, any Fixed Base Rent, or any Additional Rent as hereinafter defined, or any other amounts or charges of the character, such unpaid amounts shall bear interest from the due date thereof to the date of payment at the Default Interest Rate (as defined in Section 14.04).

Section 2.03.Operating Expense Escalation: Tenant shall be responsible to pay its Proportionate Share, as hereinafter defined, of the increase in Operating Expenses attributable to the Building that are in excess of Calendar

Year 2023 Operating Expenses (the "Operating Expense Base Year"), any such excess, which amount shall be known as the "Operating Expenses Excess". The projected Operating Expenses for the Operating Expense Base Year are depicted on Exhibit C, which is attached hereto and made a part hereof. Tenant's Proportionate Share is computed as follows: the numerator is Tenant's rentable square feet (10,356) and the denominator is the Building's total rentable square feet (30,456). Initially, Tenant's Proportionate Share is 34.00%. With respect to any Base Year or any subsequent year in which the Building is not occupied to the extent of 95% of the rentable area thereof, the Operating Expenses for such period which vary with the occupancy of the Building, for the purposes hereof, be increased to the amount which would have been incurred had the Building been occupied to the extent of 95% of the rentable area thereof, as reasonably determined by Landlord, provided, however, that in no event shall Tenant be responsible for any amount which is grossed up in excess of those amounts actually paid by Landlord. Landlord shall provide its calculations to Tenant upon Tenant's request.

Within ninety (90) days following the end of each calendar year during the term of this Lease, Landlord shall furnish to Tenant a statement of Landlord's actual Operating Expenses for the previous calendar year and a determination of the amount of Operating Expenses Excess which is due for such calendar year. Tenant shall pay such amount to Landlord within thirty (30) days of its receipt of such statement. If Landlord fails to furnish Tenant with such statement within twelve (12) months of the end of the applicable calendar year, Landlord shall be deemed to have waived all rights to any reconciliation for Operating Expenses.

Operating Expenses shall be defined as all actual costs and expenses incurred by Landlord, its agents, and/or designees in connect ion with operating, lighting, cleaning, maintaining, equipping, repairing, insuring, managing and/or replacing all or any part of the Building's common areas (and any installations therein, thereon, thereunder or thereover), and all electrical, plumbing, and other systems of the Building not exclusively serving and paid for by particular tenants, which costs and expenses shall include, but shall not be limited to, the following: all of the costs and expenses incurred in cleaning, heating, ventilating, air conditioning, maintaining, painting, repainting, repairing and replacing common toilets, lobbies, corridors, elevators, and stairways; cleaning, planting, replanting and maintaining the landscaped areas and other areas of the property not containing buildings, paving or similar improvements; the cost of all Landlord's insurance for the Building including, but not limited to, fire and other casualty, rental income, bodily injury, public liability, property damage liability, automobile parking lot liability insurance, sign insurance, workmen's compensation insurance, and any other insurance carried by Landlord for the Building in limits selected by Landlord, and the cost of any deductible carried by Landlord in the event of a casualty; assessments; repairs; repaving; line repainting; exterior repainting; rental and maintenance of signs and equipment; lighting; sanitary control; removal (including temporary storage) of snow and ice, trash, rubbish, garbage and other refuse; depreciation of machinery and equipment used in such maintenance and of all building systems; repair, maintenance and replacement of roofs; depreciation of roof and paved area; maintenance, repair and/or replacement of on-site utility systems (including, without limitation, water lines and electrical, gas, sanitary sewer, drainage and storm water systems), heating, ventilating and air conditioning systems, and alarm systems; all fuel for the Building's central heating system; all electrical, water, sewer and other utility charges not separately metered and paid for by tenants; personal property taxes; sales and use taxes on material, equipment, supplies and services for the Building; fees for required licenses and permits; fire, security and police protection (if and to the extent provided by Landlord, without implying any obligation to do so unless otherwise specified in this Lease); operation and maintenance of public address system(s) and public toilets; reasonable straight line depreciation of, and all rental charges for, movable equipment; supplies, materials and labor for the Building; and the cost of any capital improvements (other than tenant improvements for specific tenants) made by or on behalf of Landlord to the Building or common area in order to (A) comply with any amendment or other change to the enactment or interpretation of any applicable laws from its enactment or interpretation after the Commencement Date (including, without limitation, under Section 11.02), or (B) intended to reduce Operating Expenses or improve life/safety conditions, but only to the extent of the amortized amount thereof over the useful life of such capital improvements as determined in accordance with generally accepted accounting principles consistently applied. Specifically excluded from Operating Expenses, notwithstanding the foregoing, are (i) the cost of capital improvements except as expressly provided above; (ii) all costs relating to the leasing and build-out of space for other tenants of the Building or reimbursable by such other tenants or for selective services provided to any specific tenant; (iii) principal, interest and other charges payable in connection with any financing or refinancing of the Building, and all other direct costs of refinancing, selling or exchanging the Building, including broker commissions, attorney's fees and closing; (iv) real estate brokers' leasing commissions or compensation and advertising and other marketing expenses and attorneys' fees associated with the leasing of the Building; (v) legal, space planning, construction, and other

expenses incurred in procuring tenants for the Building or renewing or amending leases with existing tenants or occupants of the Building or any increase in insurance premiums to the extent that such increase is caused by the use or occupancy of another tenant; (vi) any expense for which Landlord actually receives reimbursement from insurance, condemnation awards, or other tenants (other than through the payment of additional rent under such tenants' leases); (vii) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and services to the extent the same materially exceeds the costs of such good and/or services rendered by unaffiliated third parties on a competitive basis; (viii) Landlord's charitable or political contributions; (ix) acquisition costs of sculpture, paintings or objects of art; (x) Landlord's corporate overhead and compensation for Landlord's employees and for accounting services, except to the extent relating to operation of the Building; (xi) reserves of any kind, including reserves for equipment or capital replacement and future improvements, repairs or additions; (xii) management fees in the aggregate in excess of five percent (5%) of the total rent (including Base Rent, Escalations and other additional rent hereunder) for the Building;. The operating expenses shall be accounted for using the accrual basis under generally accepted accounting principles.

Section 2.04.Security Deposit

(a) Amount of Security Deposit. Upon execution of the lease, Tenant shall pay Landlord a security deposit in the amount of Two Hundred Fifty Thousand Dollars ($250,000.00), in cash or in the form of an irrevocable standby letter of credit as described in Paragraph 2.04(d) below. Said security deposit shall be held by Landlord, as security for the faithful performance by Tenant of all the terms, covenants, and conditions of this Lease Agreement by said Tenant to be kept and performed during the term hereof. Landlord may commingle said security deposit with other funds of Landlord and shall not be required to pay Tenant interest thereon. If at any time during the term of this Lease Agreement any of the rent shall be overdue and unpaid, or any other sum payable by Tenant to Landlord hereunder shall be overdue and unpaid, or Landlord shall incur any expenses, losses or damages arising from any Tenant default, in any such case beyond applicable notice and cure periods, the Landlord, at its option, may draw from the letter of credit and apply any portion of said security deposit to the payment of any such overdue rent or other sum or other expenses, losses or damages.

(b) Use and Return of Security Deposit. In the event of the failure of Tenant to keep and perform any of the terms, covenants and conditions of this Lease Agreement to be kept and performed by Tenant, then the Landlord at its option may draw upon the letter of credit or appropriate and apply said entire security deposit, or so much thereof as may be necessary, to compensate the Landlord for loss or damage sustained or suffered by Landlord due to such breach on the part of Tenant. Should the entire security deposit, or any portion thereof, be drawn from the letter of credit, appropriated and applied by Landlord for the payment of overdue rent or other sums, loss or damage due and payable to Landlord by Tenant hereunder, then Tenant shall, upon the written demand of Landlord, forthwith remit to Landlord a sufficient amount in cash or cause the letter of credit amount to be restored, in order to restore said security deposit to the original or required sum deposited, and Tenant's failure to do so within ten (10) business days after receipt of such demand shall constitute a breach of this Lease Agreement. Should Tenant comply with all of said terms, covenants and conditions and promptly pay all of the rental herein provided for as it falls due, and all other sums payable by Tenant to Landlord hereunder, the said security deposit (or the unapplied balance thereof, if any portion shall have been applied in accordance herewith) or the original of the letter of credit shall be returned in full to Tenant after the end of the term of this Lease Agreement or upon the earlier termination of this Lease Agreement.

(c) Transfer of Security Deposit. Upon at least ten (10) days prior notice to Tenant, Landlord may deliver the security deposit funds paid hereunder by Tenant to any third party which may acquire of or succeed to Landlord's interest the Leased Premises and this Lease, and thereupon Landlord shall be discharged from any further liability with respect to such security deposit.

(d) Letter of Credit. The following provisions shall apply to the Letter of Credit for the Security Deposit:

(i) *The Letter of Credit shall be an irrevocable standby letter of credit issued by an institution satisfactory to Landlord in its sole discretion and in such form and substance as may be approved by Landlord in its sole discretion. Without limiting the generality of the foregoing, such letter of credit shall name the Landlord as the beneficiary and provide that it may be drawn against upon the furnishing of a statement to the Bank by an individual who purports to be an authorized officer or agent of the Landlord that the letter of credit is being drawn upon in accordance with the*

terms of this Lease. The Letter of Credit shall provide that it may be drawn upon by presentment in Boston, Massachusetts, and shall be subject to Massachusetts law.

(ii) *The Letter of Credit shall permit partial draws and shall remain in effect for the entire Term of this Lease and for ninety (90) days thereafter. If the letter of credit shall expire or be terminated during the Term of this Lease or within ninety days thereafter, Tenant shall replace the letter of credit with a substitute letter of credit satisfactory to Landlord no later than thirty (30) days prior to the expiration date thereof, and failure to do so shall permit Landlord to draw the entire amount of the letter of credit and hold the proceeds as a security deposit hereunder, without requirement of any notice or grace period.*

(iii) *Landlord shall have the right from time to time without prejudice to any other remedy Landlord may have upon the occurrence of any Default of Tenant as described in Paragraphs 2.04(a) and (b) above, to draw upon such letter of credit and apply such funds, or any part thereof, to Landlord's damages arising from, or to cure, any Default of Tenant. If Landlord shall draw any or all of such Letter of Credit, Tenant shall immediately deposit with the Landlord as a cash security deposit the amount so applied or restore the balance of the Letter of Credit to the full amount to be held as security hereunder.*

(iv) *If three or more Defaults of Tenant shall occur under the terms of the Lease, whether or not cured within any applicable grace period, Landlord shall have the right at its sole discretion to draw the entire amount of the Letter of Credit and hold it as a cash Security Deposit in accordance with the terms of this Section 2.04.*

(v) *If Landlord conveys Landlord's interest under this Lease, the Letter of Credit shall be fully transferable to Landlord's grantee, and Tenant shall take all necessary actions to cause the Letter of Credit to be transferred to or reissued in the name of the Grantee. Tenant agrees to pay Landlord upon demand, as Additional Rent, all costs and fees charged to Landlord to effect such transfer, if Tenant does not pay such costs and fees directly to the issuer of the Letter of Credit. No successor to Landlord or holder of any mortgage shall be responsible for the return of the Letter of Credit unless it has been duly transferred to such successor or mortgagee.*

Section 2.05.Real Estate Tax Escalations. If in any fiscal tax year (currently July 1 to June 30) during the term of this Lease, the Taxes, as herein after defined, shall exceed Fiscal Year 2023 (7/1/22 - 6/30/23) Taxes (the "Base Year Taxes"), Tenant shall pay Landlord as Additional Rent its Proportionate Share of any such excess, which amount shall be known as the "Tax Excess".

"Taxes" shall mean the real estate taxes and assessments imposed upon Owner or Landlord with respect to the Building including the parcel of land on which it stands and any and all other taxes, levies, betterment's, assessments and charges arising from the Owner's ownership of the Building and the parcel of land on which it stands which are or shall be imposed by any National, State, Municipal or other authorities which are or may become a lien upon Owner or Landlord and/or the Building and the parcel of land on which it stands, but excluding any fees or penalties levied on Owner or Landlord for late payment thereof. If, or to the extent that, due to a future change in the method of taxation any franchise, income, profit or other tax shall be levied against Owner of Landlord in substitution or in lieu of any tax which would otherwise constitute a real estate tax, such franchise, income profit or other tax shall be deemed to constitute "Taxes" for the purposes hereof. Without limitation, Taxes shall not include any federal or state income taxes, capital levy, transfer taxes, capital stock taxes, capital gains taxes, gift, estate succession or inheritance taxes and other taxes to the extent applicable to Landlord's general or net income (as opposed to rents, receipts or income attributable to operations at the Building), or taxes which are charged or levied against Landlord that are not directly a result of the operation or ownership of the Building, (i) any items included as Operating Expenses, (ii) any items paid by Tenant under this Lease, and (iii) tax penalties or interest incurred as a result of Landlord's failure or unwillingness to make payments and/or to file any tax or informational returns when due.

If the Termination Date occurs in the middle of a fiscal tax year, the Tenant shall be responsible for only that portion of the Tax Excess, in respect of such fiscal tax year represented by a fraction the numerator of which is the number of days of the herein term which falls within the fiscal tax year and the denominator of which is three hundred sixty-five (365).

In the event the first day of the fiscal tax year in the City of Cambridge should be changed after the Term Commencement date to any other date than July 1st so as to change the twelve-month period comprising the fiscal tax year, in determining the Tax Excess with respect to Taxes payable for the period between July 1st and such changed first day of the fiscal tax year, the Tax Excess shall be multiplied by a fraction, the numerator of which shall be the number of days elapsing during such period, and the denominator of which shall be three hundred sixty-five (365).

Landlord shall bill Tenant for such Tax Excess as may be due within ninety (90) days of the end of the applicable fiscal tax year, and such bills shall be paid by Tenant within thirty (30) days after receipt of the same. The failure of Landlord to bill for a Tax Excess by any specific date, shall not bar Landlord from billing for and collecting the Tax Excess for such fiscal tax year. If Landlord fails to bill Tenant for such Tax Excess within eighteen (18) months of the end of the applicable fiscal tax year, Landlord shall be deemed to have waived to rights to any payment from Tenant for such Tax Excess.

Appropriate credit against Tax Excess shall be given for any refund obtained by reason of a reduction in any Taxes by the Assessors or the Appellate Tax Board or its successor, the Courts or other governmental agency responsible therefore. The original computation as well as reimbursement or payments of additional charges, if any, or allowances, if any, under the provision of this Section 2.04 shall be based on the original assessed valuations with adjustments to be made at a later date when the tax refund, if any, shall be paid to Owner of Landlord by the taxing authority. Expenditures for legal fees and for other similar or dissimilar expenses incurred in obtaining the tax refund shall be charged against the tax refund before the adjustments are made for the fiscal tax year.

Any obligation under this Section 2.05 which shall not have been paid or refunded at the expiration or other termination of the term of this Lease shall survive and shall be paid or refunded when due and as the amount of the same shall be determined to be due. In no event shall Tenant's obligation to pay taxes extend beyond sixty (60) days after Landlord's receipt of the last tax bill due for a period of time falling within the term of this Lease.

Section 2.06.Landlord's Statements; Tenant's Audit. Within ninety (90) days following the end of each calendar year during the term of this Lease, Landlord shall furnish to Tenant a statement of Landlord's actual Operating Expenses and Taxes for the previous calendar year and fiscal tax year. Tenant shall have the right to inspect or audit (the "Audit"), at reasonable times and in a reasonable manner, during the ninety (90) day period following the delivery of Landlord's statement of the actual Operating Expenses and Taxes, such of Landlord's books of account and records as pertain to and contain information concerning such costs and expenses in order to verify the amounts thereof. Tenant agrees that any information obtained during an Audit by Tenant of Landlord's books of account and records shall be kept in confidence by Tenant and its agents and employees and shall not be disclosed to any other parties, except to Tenant's attorneys, accountants, and other consultants. Any parties retained by Tenant for an Audit shall not be compensated on a contingency fee basis. If Tenant shall not dispute any item or items included in the determination of Operating Expenses and Taxes for a particular calendar ear or fiscal tax year by delivering a written notice to Landlord generally describing in reasonable detail the basis of such dispute within the said 90-day period, Tenant shall be deemed to have approved such statement. In the event of an Audit, within thirty (30) days following the final determination of the actual Operating Expenses and Taxes, any overpayments by Tenant shall be credited or refunded by Landlord to Tenant, and any underpayments shall be paid to Landlord, it being understood that this clause shall survive the expiration of the Lease: In the event of an Audit, if, following the final determination of the actual Operating Expenses and Taxes, as applicable, Tenant has overpaid by ten percent (10%) or more, in addition to crediting or refunding such overpayment as provided above, Landlord shall also reimburse Tenant for the reasonable and actual costs of the Audit within thirty (30) days following such final determination, it being understood that this clause shall survive the expiration of the Lease.

Article III

Construction, Alterations and Relocation of Improvements and Additions Thereto

Section 3.01.Landlord's Work; "AS IS" Condition: Except as expressly provided herein, Tenant acknowledges that the Premises are being leased in its AS IS CONDITION, WITHOUT REPRESENTATION OR WARRANTY BY LANDLORD, and without any requirement of work or installations to be made by Landlord. Tenant represents that it has inspected the Premises and the Property and has, solely on the basis of such inspection, concluded that the Premises are suitable for Tenant's intended use.

Tenant acknowledges that the Premises will be delivered together with the furniture, furnishings and other personal property of the Prior Tenant listed in Exhibit E, attached hereto and made a part hereof. Tenant agrees to accept all of such furniture, furnishings and other personalty in its "as is" condition, without representation or warranty by Landlord or by Prior Tenant, and that Tenant shall have no recourse against Landlord if any of such furniture, furnishings and personalty is not delivered with the Premises.

Section 3.02.Tenant Improvement. The Tenant agrees to perform all other work or construction necessary for Tenant's permitted uses of the Leased Premises, all of which shall be performed by the Tenant at Tenant's cost and Expense, and only in accordance with Article VI of this Lease.

Article IV

Conduct of Business by Tenant

Section 4.01.Use of Premises: Tenant shall use the Leased Premises for general business and administrative offices. Tenant will not use or permit, or suffer the use of, the Leased Premises for any use other than that specified in this Section 4.01 without the written permission of the Landlord which Landlord may withhold in its sole and absolute discretion.

(a) Tenant agrees that the Leased Premises shall be used and occupied by Tenant only for permitted uses and for not for any other purpose. Landlord hereby permits the following use and no other: General Business Office.

(b) Tenant shall not perform, any act or carry on any practice which may cause damage to the Leased Premises or any other part of the Building or cause any offensive odors or loud noise or constitute a nuisance or menace to any other Tenant or other persons in the Building.

(c) Tenant shall in its use of the Leased Premises comply with the rules and regulations Owner or Landlord established for the Building, and all applicable governmental laws, rules and regulations.

(d) Tenant shall not place any sign, symbol, advertisement or the like which may be visible to public view on the exterior or interior of the Leased Premises (including both interior and exterior surfaces of doors and windows) or any other part of the Building, without the prior written consent of Landlord.

(e) Tenant shall not allow any pets to be kept on the Leased Premises during or after business hours without the prior written consent of Landlord.

(f) Tenant acknowledges that the Building is non-smoking.

Article V

Parking

Section 5.01.Parking. During the term of this Lease, the Tenant shall have the right to rent up to thirteen (13) assigned automobile parking spaces located in the parking area in the lowest level of the Building and the driveways providing access thereto under the conditions set forth herein. For clarity, Tenant shall have the option, upon notice to Landlord given not more than one time in any twelve calendar months, to increase or decrease the number of parking spaces, up to the cap of thirteen (13), Tenant rents, provided, however, that if Tenant decreases its number of parking spaces, Landlord shall have the right to allocate use of such spaces to other occupants of the Building and Tenant shall not have the right to subsequently increase its number of parking spaces unless such spaces remain available. Such spaces shall be identified on Exhibit D. Tenant shall have no right to sublease its assigned parking spaces. Tenant agrees to comply at all times with the rules and regulations as Landlord may from time to time establish for the orderly operation of said parking area and driveway. For the first Lease Year of the Lease Term, Tenant agrees to pay Landlord as additional rent $400.00 dollars per month for each space provided. Landlord reserves the right to increase this charge by an amount to bring the parking charge equal to the then market price per space for the use of such parking space from time to time, as determined by the Landlord in its sole but reasonable discretion, upon 30 days' prior written notice to Tenant, but not more than one (1) time in any twelve (12) calendar months. Landlord shall not be liable for any temporary interruption of availability of the parking area as a result of any work being done by the Landlord on the Building or the parking area provided, however, Landlord shall use commercially reasonable efforts to minimize the interference with Tenant's use and occupancy of the Leased Premises hereunder.

Article VI

Signs, Awnings, Canopies, Fixtures, Alterations

Section 6.01.Installation by Tenant: Tenant shall not make or cause to be made any alterations, additions or improvements or install or cause to be installed any trade fixture, floor covering, interior lighting, plumbing fixtures, shades or awnings or make any changes to the Leased Premises without first (i) obtaining Landlord's written approval and consent, and (ii) providing such assurance as Landlord deems necessary that any such work will be done without imposing on Landlord liability to Landlord or Owner either at the time that Tenant has work done or at the end of the Lease. Tenant shall present to the Landlord plans and specifications for such work for Landlord or Owner's approval at the time approval is sought, which such approval shall not be unreasonably withheld, delayed or conditioned. Before commencing construction of any alterations, additions or improvements permitted under this Lease ("Tenant's Work"), Tenant shall at its sole cost and expense obtain all permits, approvals and certificates required by any governmental or quasi-governmental bodies and, upon completion of Tenant's Work, certificates of final approval therefor (including final certificate of occupancy) and shall deliver promptly duplicates of all such permits, approvals and certificates to Landlord. All Tenant's Work that Tenant may undertake pursuant to this Lease shall be done in a good and workmanlike manner, using only new materials, consistent with the quality of the Building generally, and in accordance with all federal, state and local laws, rules, regulations and ordinances applicable thereto, including, if necessary, the acquisition by Tenant of a City of Cambridge Building Permit and all other required permits and approvals.

Tenant agrees to employ for any work it may do pursuant to this Lease one or more responsible contractors whose laborers will work in harmony with other laborers working in Building and with suppliers of materials for use in construction in the Building. Tenant further agrees that he will not do, or permit to be done, anything which would cause any labor difficulties in connection with any construction in said Building.

Tenant shall require all such contractors employed by Tenant to carry Workman's Compensation insurance in accordance with statutory requirements and comprehensive Public Liability Insurance and Automobile liability Insurance covering such contractors in or about the premises in amounts not less than **[***]** ($**[***]**) dollars for property damage; and **[***]** ($**[***]**) dollars for injury or death of one or more than one person in a single accident and to submit certificates of insurance evidencing such coverage to Landlord prior to commencement of such work.

Tenant shall have no power or authority to create any lien or permit any lien to the present estate, reversion or other estate of the Landlord or Owner in the Leased Premises or in the Building or the land on which it is located, and all material men, contractors, artisans, mechanics, laborers, and other parties contracting with Tenant with respect to the Leased Premises or any part thereof are hereby charged with notice that they must look solely to the Tenant to secure payment of any bill for work done or material furnished during the term of this Lease. Should any such lien so attach, Tenant shall discharge the same within five (5) business days and failure to do so will constitute a material default hereunder.

Section 6.02.Removal and Restoration by Tenant: All alterations, additions and improvements made by the Tenant, or made by the Landlord on the Tenant's behalf by agreement under this Lease Agreement, shall remain the property of the Tenant for the term of the Lease Agreement, or any extension or renewal thereof, and shall become the property of Landlord and remain in the Leased Premises at expiration or sooner termination of this Lease, unless the Landlord notifies the Tenant in writing at the time of Landlord's approval of such particular alteration, addition or improvement that it must be removed upon expiration or termination of this Lease. Tenant may at the expiration of the Lease remove its telephone, security systems, and communication systems that Tenant installed in the Leased Premises and all of Tenant's trade fixtures and equipment provided that Tenant repairs any damage to the Leased Premises arising from such removal.

Section 6.03.Signs, Awnings and Canopies: Tenant will not place or suffer to be placed or maintained on any exterior door, wall or window of the Leased Premises any sign, awning or canopy, exterior lighting, or advertising matter or other thing of any kind, and will not place or maintain any decoration, lettering or advertising matter on the glass or any window or door in or on the Leased Premises. Notwithstanding the foregoing, Tenant will be entitled to building standard signage at the common elevator in the Building's entrance lobby and at the entry intercoms at the front entrance and garage entrance of the Building. Tenant may also install a sign at the entrance to the Leased Premises on the third floor, subject to Landlord's prior written approval, not to be unreasonably withheld, conditioned or delayed as long as such sign conforms to all applicable legal requirements of the City of Cambridge and is consistent with the character of the Building.

Article VII

Maintenance of Leased Premises

Section 7.01.Maintenance of Premises. Tenant shall maintain the Leased Premises in good order, condition and repair, reasonable wear and tear and damage by casualty or condemnation excepted. Tenant will maintain with appropriate care (and replace with like items when the same become worn or damaged) the furniture, furnishings and other personal property left in place by Landlord or Prior Tenant, including without limitation the items listed on Exhibit E, the reception station outside the main conference room, the large conference table and cabinetry within the large conference room, and all other cabinetry, equipment and appliances, and all will remain with the Leased Premises at the expiration of the tenancy.

Section 7.02.Surrender of Premises: At the expiration of the tenancy hereby created, Tenant shall surrender the Leased Premises in the same condition existing upon delivery of possession thereto under this Lease and in compliance with Section 7.01 and shall surrender all keys for the Leased Premises to Landlord at the place then fixed for the payment of rent and shall inform Landlord of all combinations on locks, safes and vaults, if any, in the Leased Premises. Tenant shall remove all its trade fixtures, its telephone, security systems, and communication systems and any alterations, additions or improvements as provided in Section 6.02 above, before surrendering the Leased Premises as aforesaid and shall repair any damage to the Leased Premises caused thereby or in any other way caused by Tenant's occupancy and vacating of the Leased Premises. Tenant's obligation to observe or perform this covenant shall survive the expiration or other termination of the term of this Lease.

Section 7.03.Rules and Regulations: Landlord reserves the right to adopt and promulgate rules and regulations applicable to the Leased Premises, and from time to time to amend or supplement the same. Copies of the current Rules and Regulations are attached hereto and made a part hereof as Exhibit F. Notice of such rules and regulations, and of any such amendments and supplements, shall be given to Tenant and Tenant agrees to comply with and observe the same. Landlord agrees that in the event it modifies or supplements the Rules and Regulations, it will

exercise commercially reasonable efforts to ensure that any such modifications or supplements shall not adversely affect Tenant's business operations. Notwithstanding the matters contained herein, unless mandated by a governmental authority or agency, the Landlord agrees not to propose any new Rules and Regulations that will affect Tenant's 24 hour, 7 day access to the Leased Premises and Tenant's use and 24 hour, 7 day availability of the utilities servicing the Leased Premises. In the event of a conflict between any Rules and Regulations and the terms of this Lease, the terms of this Lease shall control. Landlord shall not knowingly enforce the Rules and Regulations against Tenant in a discriminatory manner.

Section 7.04.Miscellaneous: Tenant shall not place a load upon any floor of the Leased Premises which exceeds the load per square foot which such floor is then designed to carry and which is then allowed by law. All non-desktop business machines and equipment and all other mechanical equipment installed and used by Tenant in the Leased Premises shall be properly shielded and be so placed, installed and maintained by Tenant, at Tenant's own cost and expense, in settings of cork, rubber, or spring-type vibration-eliminators, or in such other manner as Landlord may reasonably direct, so as to be sufficient to eliminate the transmission of noise, vibration or electrical or other interference from the Leased Premises to any other area of the Building or the Property. Landlord shall include a sentence of equivalent purport to the preceding sentence in all other leases of space in the Building, and shall exercise reasonable efforts to require compliance therewith with respect to such transmissions affecting the Leased Premises.

The building elevator is intended for the conveyance of building occupants and visitors only. The Landlord can secure elevator pads to protect the elevator interior wall panels when necessary. Tenant shall secure Landlord's prior written consent, which consent Landlord shall not unreasonably withhold, delay or condition, before moving any equipment, furniture or bulky or sharp materials in or out of the Leased Premises that might damage entry doors or the elevator.. All such movements shall be made upon reasonable advance notice and during reasonable hours to reasonably minimize interference with the normal operations of the Building and all damage caused by such movement shall be promptly repaired by Tenant at Tenant's expense. Tenant and Tenant's employees shall park their cars only in those portions of the parking areas, if any, designated for that purpose by Landlord. The plumbing facilities shall not be used for any purpose other than that for which they were constructed, no foreign substance of any kind shall be thrown therein, and the Tenant shall not tamper with any of such facilities or in any way remove or interfere with the operation of the various devices installed to limit water consumption, and the expense of any breakage, stoppage, or damage resulting from a violation of this provision by Tenant or Tenant's employees, agents, or invitees, shall be borne by Tenant and may be billed by Landlord to Tenant as Additional Rent hereunder.

Article VIII

Insurance and Indemnity

Section 8.01.Liability and Other Insurance:

(a) Tenant shall, during the entire term hereof, keep in full force and effect (i) a policy of public liability and property damage insurance (including broad form contractual liability and independent contractor's hazard and completed operations coverage) with respect to the Leased Premises, and the business operated by Tenant and any sub-tenants of. Tenant in the Leased Premises permitted pursuant to Article X of this Lease, in which the limits of public liability shall be in such amounts as the Landlord may reasonably specify from time to time, but in no event less than $**[***]** per occurrence (combined single limit) and $**[***]** aggregate for property damage, bodily injury or death, and including not less than $**[***]** per person, and not less than $**[***]** medical payments; (ii) a policy of motor vehicle liability insurance for all owned and non-owned vehicles, including rented and leased vehicles, in an amount not less than $**[***]** per occurrence, and (iii) all such other insurance as Landlord may from time to time reasonably require consistent with customary practice for similar general office tenants in the Boston-Cambridge area. The limits of insurance provided in the preceding sentence may be satisfied through a combination of primary and excess/umbrella insurance. Each such policy shall name Landlord, Landlord's mortgagee, any managing agent of the Building, and any other person, firms or corporations designated by Landlord as additional insureds, shall be primary and noncontributory, and shall contain a clause that the insurer will not cancel or change the insurance without first giving the Landlord and such other additional insureds at least thirty (30) days prior written notice. Tenant shall also maintain in full force and effect during the entire Term of this Lease Employer's Liability Insurance in an amount of not less than $**[***]** and Workmen's Compensation insurance in the statutory amount.

Also, in addition to Landlord being included as an Additional Insured on a Primary and Non-Contributory basis on the General Liability, Automobile and Umbrella Liability coverages, a requirement for Waiver of Subrogation should be added for all lines of coverage including Workers' Compensation.

Tenant agrees to use the Leased Premises and all common areas of the Building at its own risk, and all trade fixtures, furniture, equipment, merchandise, inventory and other property of Tenant of any kind or description located in or used in connection with the Leased Premises shall be at Tenant's sole risk, as to which Tenant shall maintain "all-risk" property insurance on a full replacement cost basis (including so-called improvements and betterments.) All insurance amounts set forth herein are minimum limits only and shall not restrict any liability of Tenant. Landlord may increase the required insurance amounts hereunder from time to time based on customary practice for similar properties in the Boston-Cambridge area or any requirements of Landlord's mortgagee. All insurance shall be with an insurance company licensed to do business and in good standing in The Commonwealth of Massachusetts and having an AM Best Rating of "A" or better unless approved by Landlord. A copy of the policy or a certificate of insurance shall be delivered to Landlord and/or its designee upon the Commencement Date of this Lease and upon Landlord request. Tenant will provide, or cause Tenant's insurer to provide, notice to Landlord and/or its designee in writing not less than ten (10) days prior to any cancellation or other termination thereof.

(b) Landlord shall, during the entire term hereof, keep in full force and effect (i) a policy of insurance against loss or damage with respect to the Building on an "all risk" type insurance form in an amount equal to at least the replacement value of the Building, and (ii) commercial general liability insurance (with a contractual liability assumption provision) written on an occurrence basis for bodily injury and for property damage, insuring against liability with respect to the Building or arising out of Landlord's maintenance, use or occupancy thereof; the limit of such public liability coverage shall not be less than $**[***]** combined single limit for bodily injury and property damage per occurrence and $**[***]** annual aggregate limit per location.

Section 8.02.Increase in Fire Insurance Premium: Tenant agrees that it will not keep, use, sell or offer for sale in or upon the Leased Premises any article which may be prohibited by the standard form of fire insurance policy. In the event Tenant's occupancy causes any increase of premium for the fire, boiler or casualty rates on the Building, or any part thereof above the rate for the least hazardous type of occupancy legally permitted in the Leased Premises, the Tenant shall pay the additional premium to Landlord as Additional Rent hereunder, as well as binding the additional insurance as instructed by Landlord or Owner.

Section 8.03.Indemnification:

To the maximum extent permitted by law, Tenant agrees to indemnify Landlord, Landlord's managing agent (if any) and Landlord's mortgagee, and save them harmless from and against any and all claims, actions, injuries, damages, losses, liabilities and expenses in connection with loss of life, personal injury or damage to property to the extent arising wholly or in part from any negligent act or omission or any willful misconduct of Tenant or any officer, employee, contractor, agent, customer, business invitee, permitted sublessee, or other person entering the Premises or the Building in connection with Tenant's use and occupancy of the Premises (the "Tenant Parties"), or arising from the occupancy or use by Tenant of the Leased Premises or the breach of this Lease or the violation of any applicable legal requirement by Tenant or any of the Tenant Parties, and in any event not otherwise caused solely by the negligence or willful misconduct of Landlord, its agents (including its managing agent The Shoreline Corporation (the "Managing Agent")), contractors or employees. In case Landlord or Managing Agent shall, without fault on its part, be made a party to any litigation commenced by or against Tenant, then Tenant shall protect and hold Landlord or Managing Agent harmless and shall pay all costs, expenses and reasonable attorney's fees incurred or paid by Landlord or Managing Agent in connection with such litigation.

Article IX

Utilities

Section 9.01.Utility Charges. From and after the Commencement Date, Tenant shall be responsible and promptly pay for all charges for electricity in the Leased Premises. Tenant acknowledges that the Leased Premises are on a common meter with the second floor of the Building. Landlord shall pay all utility bills based upon such meter, and Tenant shall reimburse Landlord for its pro rata share thereof as reasonably determined by Landlord,

taking into consideration the use and equipment located on each floor. Tenant will pay one-twelfth of Landlord's estimated annual cost of such electricity together with the payment of Base Rent each month, and no less than ninety (90) days after the end of each calendar year Landlord will provide a reconciliation based on actual electricity costs for such year, together with a revised amount of the monthly estimated payment consistent with such actual usage. Tenant will pay to Landlord any additional amounts due within fifteen (15) days of receiving such reconciliation, and if Tenant has overpaid for such electricity, the amount of such overpayment shall be applied to the monthly estimated electricity costs for the current year, or if the Lease has expired, Landlord shall reimburse such amount to Tenant after all electricity bills are received for the period during the term of the Lease and a final reconciliation is made. In no event shall Landlord or Owner be liable for an interruption or failure in the supply of any utilities to the Leased Premises including but not, limited to heat, water, sewer, gas, oil, or electricity except to the extent arising from or out of the gross negligence or willful misconduct of the Landlord, its agents or employees.

Article X

Assignment and Subletting

Section 10.01.Assignment, Mortgaging and Subletting. Tenant covenants and agrees that neither this Lease nor the term and estate hereby granted, nor any interest herein or therein, will be assigned, mortgaged, pledged, encumbered or otherwise transferred, and that neither the Premises, nor any part thereof will be encumbered in any manner by reason of any act or omission on the part of Tenant, or used or occupied, or utilized for desk space or for mailing privileges, by anyone other than Tenant, or for any use or purpose other than as stated herein, or be sublet or offered or advertised for subletting, without the prior written consent of Landlord. Tenant's request for Landlord's consent to subletting or assignment shall be submitted in writing, including a detailed description of the business of and financial information and such other information as Landlord may reasonably request concerning the proposed subtenant or assignee, and, provided that no Tenant Default (or event or condition which with the giving of notice or passage of time or both would constitute a Tenant Default) is then outstanding, Landlord's consent shall not be unreasonably withheld, conditioned or delayed. However, it shall not be deemed unreasonable for Landlord to withhold his consent to any assignee or Tenant or other occupant whose financial status, character, method of doing business and/or proposed use or occupancy of the Leased Premises or any other part of the Building would, in Landlord's reasonable judgment, materially adversely affect the character or value of the Building. Notwithstanding any assignment of Tenant's interest in this Lease or any subletting of the whole or any part of the Premises consented to by Landlord, Tenant named herein shall remain fully, primarily and unconditionally liable under this Lease and shall not thereby be released from the performance and observance of all the agreements and conditions on the part of the Tenant to be performed hereunder.

If Landlord shall consent to any such assignment or subletting, Tenant shall agree to pay to Landlord, as condition of the effectiveness of any such consent, **[***]** percent (**[***]**%) of the excess of the rent (Base Rent, Escalations and other additional rent) payable by such assignee or subtenant, over the rent (Base Rent, Escalations and other additional rent) payable by Tenant to Landlord for the Premises, apportioned on a square foot of floor area basis for the Premises occupied by such subtenant. Further, it is agreed that in lieu of withholding or granting its consent Landlord may, within thirty (30) days of receipt of a request for consent to assign the Lease or subletting of all or substantially all of the Leased Premises for all or substantially all of the then remaining term of this Lease from Tenant, cancel this Lease as to so much of the Leased Premises as Tenant has proposed for assignment or subletting. If Landlord shall elect to cancel this Lease as to a portion of the Leased Premises, it shall give Tenant written notice of its election ("Cancellation Notice"), which notice shall set forth a "termination date" which shall be not less than thirty (30) or more than ninety (90) days from the receipt by Landlord of Tenant's request to assign or sublet, and on that "termination date" Tenant shall surrender the Premises for which this lease has been canceled in accordance with the provisions of this Lease relating to the surrender of the Leased Premises as the expiration of the term of this Lease. If Landlord provides its Cancellation Notice to Tenant, Tenant may rescind its proposed assignment or subletting by notifying Landlord in writing within five (5) business days following the Cancellation Notice.

It is hereby expressly understood and agreed, however, that notwithstanding the foregoing or anything to the contrary in this Lease, Tenant shall have the right, without Landlord's prior written consent but with not less than 10 business days' prior written notice to Landlord, to assign this Lease or to sublease the Leased Premises, or any portion thereof, to (i) an Affiliated Entity (hereinafter defined), or (ii) a Successor Entity (hereinafter defined) so long as such Affiliated Entity or Successor Entity, as applicable, shall have net worth at least equal to that of Tenant

immediately prior to such merger or consolidation (such corporation being hereinafter called "Assignee"), if, and upon the express condition that, Assignee and Tenant shall promptly execute, acknowledge, and deliver to Landlord an agreement in form and substance satisfactory to Landlord whereby Assignee shall agree to be personally bound and upon the covenants, agreements, terms, provisions and conditions set forth in this Lease on the part of Tenant to be performed and whereby Assignee shall expressly agree that the provisions of this Article X shall be binding upon it with respect to all future assignments and transfers.

"Affiliated Entity" shall be defined as any entity which, directly or indirectly, is controlled by, is under common control with, or which controls Tenant. "Successor Entity" shall be defined as any entity which (i) purchases all or substantially all of the assets of Tenant, (ii) purchases all or substantially all of the stock of (or other ownership or membership interests in) Tenant, or (iii) merges or combines with Tenant.

The listing of any name other than that of Tenant, whether on the doors of the Leased Premises or on a building directory, or otherwise, shall not operate to vest any right or interest in this Lease or in the Leased Premises or to be deemed to be the written consent of Landlord mentioned in this Article IX, it being expressly understood that such listing is a privilege extended by Landlord is revocable at will by written notice to Tenant.

Tenant agrees to pay to Landlord all reasonable counsel fees and disbursements and all other expenses incurred by the Landlord in connection with the consideration of any request by Tenant for approval of an assignment or sublease hereunder, whether or not such consent is granted. If this Lease be assigned, or if the Leased Premises or any part thereof be sublet or occupied by anybody other than Tenant as this Lease permits, Landlord may, after Default by Tenant, collect rent from the Assignee, Tenant or Occupant, and apply the net amount collected to the rent herein reserved, but not such assignment, subletting, occupancy or collection shall be deemed a waiver of this Article X, or the acceptance of the Assignee, Tenant or occupant as a Tenant, or a re-Lease of Tenant from the further performance by Tenant of covenants on the part of Tenant herein contained. The consent by Landlord to an assignment or subletting shall not in any way be construed to relieve Tenant from obtaining the express consent in writing of Landlord, Landlord to any further assignment or subletting. No assignment, subletting or use of the Leased Premises by any other party than Tenant shall affect the purpose for which the Leased Premises may be used as stated in Article IV.

Landlord hereby notifies the Tenant that under the terms of certain first mortgage financing of Owner, all Leases by Landlord and further by Tenant must be approved by such mortgagee(s), and Landlord has secured the required approval from such mortgagee(s). Landlord, in addition to the rights of approval granted to it hereunder, reserves the right to refuse to approve any Lease which is not approved by such mortgagee(s); and Tenant agrees that Landlord's refusal to approve a Lease based upon the lack of approval of such mortgagee(s) shall never be deemed to be unreasonable, arbitrary, capricious or unfair by Tenant.

Article XI

Waste, Governmental Regulations

Section 11.01.Waste or Nuisance: Tenant shall not commit or suffer to be committed any waste upon the Leased Premises or any nuisance or other act or thing which may disturb the quiet enjoyment of any other Tenant in the Building or the Property.

Section 11.02.Governmental Regulations: Tenant, at its sole cost and expense shall comply with all of the requirements of all county, municipal, state, federal and other applicable governmental authorities, now in force, or which may hereafter be in force, pertaining to (i) Tenant's particular manner of use of thereof the Leased Premises (as opposed to Tenant's use of the Leased Premises for general office purposes in a normal and customary manner), (ii) Tenant's particular employees or employment practices and (iii) any Tenant Work.

Article XII

Damage or Destruction of Leased Premises or Building

Section 12.01.Total or Partial Destruction: If the Leased Premises shall be damaged by fire, the elements, unavoidable accident or other casualty, but are not thereby rendered untenantable in whole or in part, Landlord shall at its own expense cause such damage to be repaired, and the then appropriate rent shall not be abated. If by reason of such occurrence, less than fifty (50%) percent of the Leased Premises shall be rendered untenantable only in part, Landlord shall at its own expense cause the damage to be repaired, and the then appropriate rent meanwhile shall be abated proportionately as to the portion of the Leased Premises rendered untenantable. If fifty (50%) percent of the Leased Premises shall be rendered untenantable, or Tenant's access to Leased Premises shall have been destroyed by reason of such occurrence the Landlord shall at its own expense cause such damage to be repaired, and the then appropriate rent meanwhile shall abate until they have been restored and rendered tenantable, or Landlord or Tenant may, at their election, terminate this Lease and the tenancy hereby created by giving to the other, within sixty (60) days following the date of said occurrence, five (5) days prior written notice of their election to do so, and in the event of such notice rent shall be adjusted as of such date. In no event, however, shall Landlord be obligated to spend more than the net proceeds available to Landlord from casualty insurance proceeds for any repairs or replacement under this Article XII.

Section 12.02.Partial Destruction of the Building: In the event that fifty percent (50%) or more of the rentable area of the Building shall be damaged or destroyed by fire or other cause, notwithstanding that the Leased Premises may be unaffected by such fire or other cause, Landlord may terminate this Lease Agreement and the tenancy hereby created by giving to Tenant five (5) days prior written notice of Landlord's election so to do, which notice shall be given, if at all, within the sixty (60) days following the date of said occurrence. Rent shall be adjusted as of the date of such termination. Landlord's obligation to restore the alterations, improvements or additions within the Leased Premises pursuant to this Article XI shall be limited to its obligations as set forth on Exhibit B hereto, in such amount not to exceed net proceeds available to Landlord from casualty insurance proceeds covering such casualty, if any. If Landlord chooses to repair and Landlord does not repair the Leased Premises within 180 days from the occurrence, Tenant has the right to terminate the Lease, provided such notice of termination is given no later than 210 days after the occurrence.

Article XIII

Eminent Domain

Section 13.01.Total Condemnation: If the whole of any part of the Leased Premises or of the access thereto shall be acquired or condemned by eminent domain for any public or quasi-public use or purpose, then the term of this Lease Agreement shall cease and terminate as of the date of title vesting in such proceeding and all rentals shall be paid up to that date and shall have no claim against Landlord nor the condemning authority for the value of any unexpired term of this Lease.

Section 13.02.Landlord's Damages: In the event of any condemnation or taking as aforesaid whether whole or partial, the Tenant shall not be entitled to any part of the award paid for such condemnation and Landlord is to receive the full amount of such award, the Tenant hereby expressly waiving any right or claim to any part thereof.

Section 13.03.Tenant's Damages: Although all damages in the event of any condemnation are to belong to the Landlord as aforesaid, Tenant shall have the right to claim and recover from the condemning authority, such compensation as may be separately awarded without any reduction in the amount payable to Landlord, such recoverable by Tenant in Tenant's own right on account of any and all damage to Tenant's business by reason of the condemnation and for or on account of any cost or loss to which Tenant might be put in removing Tenant's merchandise, furniture, fixtures, leasehold improvements and equipment, but expressly excluding any compensation for the value of Tenant's leasehold interest.

Article XIV

Defaults

Section 14.01.Tenant's Default: If (i) the Tenant shall default in the performance of any of its monetary obligations hereunder and such default shall continue for ten (10) days after written notice thereof by the Landlord to the Tenant (or, if any such notice has been given within the previous twelve months, then if any such monetary default shall continue for ten (10) days after the due date thereof); or (ii) the Tenant shall default in the performance of any of its non-monetary obligations hereunder (other than any non-monetary obligations specifically enumerated below) and such default shall continue for thirty (30) days after written notice thereof by the Landlord, hereinafter referred to as "non-monetary default grace period" (except that if the Tenant cannot reasonably cure any such default within said thirty (30) day non-monetary default grace period, this period may be extended for a reasonable time as determined by Landlord in its sole discretion, provided that the Tenant commences to cure such default within said thirty (30) day period and proceeds diligently thereafter to effect such cure, and further provided that Tenant shall be entitled to only two grace periods for non-monetary defaults in any twelve month period; or (iii) any person shall levy upon or take this leasehold interest or any part thereof upon execution, attachment or other process of law; or (iv) any bankruptcy, insolvency, or other proceeding for the benefit of creditors shall be commenced by or against Tenant or any guarantor of this Lease, or Tenant or any guarantor shall be adjudicated bankrupt or insolvent according to law, or shall make an assignment for the benefit of creditors, or a receiver, trustee or similar officer shall be appointed for the whole or any part of Tenant's or any guarantor's property, and, with regard to any of the foregoing which are involuntary (i.e., without Tenant's action or consent), the same remain in effect more than thirty (30) after the initial occurrence; or (v) Tenant shall vacate or abandon the Leased Premises for a period of at least thirty (30) days, or (vi) Tenant shall assign its interest in this Lease or sublet all or any part of the Leased Premises without the Landlord's prior written consent if the same is required in accordance with Section 10.01, or (vii) Tenant or anyone claiming through the Tenant shall use the Leased Premises for any use other than the uses permitted hereby; or (viii) Tenant shall fail to maintain any insurance coverage required by this Lease and such default shall continue for two (2) business days after written notice thereof by the Landlord; then and in any such event (each of which shall be a "Default"), Landlord may lawfully enter the Leased Premises or any part thereof in the name of the whole or mail a notice of termination addressed to Tenant at the Leased Premises and repossess the same as of the former estate of the Landlord and expel the Tenant and those claiming under the Tenant without being deemed guilty of any manner of trespass and without prejudice to any other remedies which the Landlord may have for arrears of rent or preceding breach of covenant, and upon entry or mailing as aforesaid, this Lease shall terminate and the Tenant covenants that in case of such termination, it will indemnify the Landlord against all loss of rent, re-letting expenses, and brokerage, which the Landlord may incur by reason of such termination from the date thereof until the normal expiration date of the term of this Lease.

The Landlord, at its election, shall receive as damages upon termination under this Article XIV either the amount by which, at the termination of this Lease, the aggregate of the rent and other charges (including escalations projected on the basis of experience under the Lease) projected over the period from such termination until the normal expiration date of the term of this Lease exceeds the aggregate projected rental value of the premises for such period, or amounts equal to the rent and other charges which would have been payable had the Lease not so terminated, payable upon the due dates as specified herein (subject to offset for net rents actually received from re-letting after subtraction of the expenses of re-letting).

Landlord and Tenant agree that the notice provisions provided in this Article XIV are in lieu of those provided in Massachusetts General Laws Chapter 186, Section 11.

Suit or suits for the recovery of such damages, or any installments thereof, may be brought by Landlord from time to time at its election, and nothing contained herein shall be deemed to require Landlord to postpone suit until the date when the term of this Lease would have expired if it had not been terminated hereunder.

In the event of any termination of this Lease or re-entry by Landlord under the provisions of this Article XIV, or in the event of the termination of this Lease or of reentry by or under any summary process or other proceeding or action or any provision of law by reason of default under this Lease on the Part of Tenant, then for the purposes of computing damages as shall be payable pursuant to this Article XIV, it is agreed that:

There shall be payable to Landlord as part of such damages the product of the Operating Expense Excess, Real Estate Tax Excess, Additional Rent and all other items constituting part of the Additional Rent of the immediately preceding Lease Year, times the number years then remaining for the balance of the term hereof, on the assumption that the Operating Expense Excess, Real Estate Excess Tax and all other items constituting part of the Additional Rent would have remained constant for each subsequent Lease Year of the full term hereby granted.

Section 14.02.Legal Expenses. In the event suit shall be brought for recovery of possession of the Leased Premises, for the recovery of rent or any other amount due under the provisions of this Lease Agreement, or because of any default (beyond applicable notice and cure periods) on the part of Tenant, and such a default shall be established, Tenant shall pay to Landlord all expenses incurred therefor, including but not limited to reasonable attorney's fees and actual expenses. In addition, if any action shall be instituted by either of the parties hereto for the enforcement of any of its rights in and under this Lease, the party in whose favor judgment shall be rendered shall be entitled to recover from the other party all expenses reasonably incurred by the prevailing party in such action, including but not limited to reasonable attorney's fees and actual expenses.

Section 14.03.Landlord's Default. Landlord shall in no event be in default in the performance of any of Landlord's obligations hereunder unless and until Landlord shall have failed to perform such obligations within thirty (30) days, or such additional time as is reasonably required to correct any such default as long as such cure is commenced within the thirty (30) time period unless delay is caused by conditions or events beyond Landlord's reasonable control, after written notice by Tenant to Landlord specifying wherein Landlord has failed to perform any such obligations. The obligations of Tenant to pay all rent hereunder (including Base Rent, Additional Rent, and all other payments due from Tenant to Landlord hereunder) and to perform all other obligations of Tenant hereunder are independent covenants and shall not be conditioned on, subject to, or offset by any alleged act or omission of Landlord, whether or not constituting a default by Landlord under this Lease, nor shall any breach of any obligations or covenants of Landlord hereunder give rise to any right of termination of this Lease by Tenant or any right to withhold, set-off, abate or otherwise reduce or excuse the payment and performance of the obligations of Tenant hereunder.

Section 14.04.Landlord Remedy of Tenant Defaults. Landlord shall have the right, but shall not be required, to pay such sums or do any act which requires the expenditure of monies which may be necessary or appropriate by reason of the failure or neglect of Tenant to perform such provisions of this Lease, and in the event of the exercise of such right by Landlord, Tenant agrees to pay to Landlord forthwith upon demand all such sums, together with interest thereon at a rate equal to 10% (the "Default Interest Rate") as an additional charge.

Article XV

Access by Landlord

Section 15.01.Right of Entry: Except in the event of an emergency or Tenant's default (beyond applicable notice and cure periods) hereunder, upon reasonable advance notice Landlord or Landlord's agents shall have the right to enter the Leased Premises at reasonable times to examine the same, and to show them to prospective purchasers or lessees at any time within twelve (12) months before the expiration of the Term, and to make such repairs, alterations, improvements or additions as Landlord may deem desirable, and Landlord shall be allowed to take all material into and upon said Leased Premises that may be required therefore without the same constituting an eviction of Tenant in whole or in part, and the rent reserved shall in no way abate while said repairs, alterations, improvements, or additions are being made, by reason of loss or interruption of business of Tenant or otherwise. Tenant shall permit Landlord to erect, use and maintain pipes and conduits in and through the Leased Premises, provided that the same are concealed or are painted or otherwise dealt with in a manner which does not detract from or conflict with the design and architectural treatment of the Leased Premises. Landlord shall have the right at any time without thereby creating any actual or constructive eviction or incurring any liability to Tenant therefore, and without abatement in rent, to change the arrangement or location or entrances, passageways, doors, doorways, corridors, stairs, toilets, and other like portions of the Leased Premises, but such changes shall be designed to avoid any material obstruction or reduction in Tenant's access to the Leased Premises, and other appurtenances. Nothing in this Section 15.01 shall be deemed or construed to impose upon Landlord any obligation, responsibility or liability for care, maintenance, or repair except as otherwise specifically provided in this Lease Agreement. In the

exercise of the rights reserved herein, Landlord shall use commercially reasonable efforts to minimize the disruption of Tenant's use and enjoyment of the Leased Premises and the common areas and of Tenant's business in the Leased Premises.

Article XVI

Tenant's Property

Section 16.01.Taxes on Leasehold: Tenant shall be responsible for and shall pay before delinquency all municipal, county or state taxes assessed during the term of this Lease Agreement against any leasehold interest or personal property of any kind, owned by or placed in, upon or about the Leased Premises by the Tenant or delivered to the Tenant upon the Commencement Date, including the items set forth on Exhibit E. Tenant will be responsible for occupancy taxes if applicable and pay same as additional rent.

Section 16.02.Loss and Damage: Except for damage or liability caused by the negligence of the Landlord, its employees or agents, Landlord shall not be liable for any damage to property of Tenant or of others located on the Leased Premises, nor for the loss of or damage to any property of Tenant or of others by theft or otherwise. Except to the extent caused by the gross negligence or willful misconduct of the Landlord, its employees or agents, Landlord shall not be liable for any injury or damage to persons or property, nor for any other loss or damage suffered by Tenant resulting from fire, explosion, falling plaster, steam, gas, electricity, water, rain or snow leaks from any part of the Leased Premises or the Property, or from the pipes, appliances or plumbing works or from the roof, street or sub-surface or from any other place or by dampness or by any other cause of nature whatsoever unless such loss or damage is cause by the proven negligence or the proven willful acts of the Landlord in a court of competent jurisdiction. Landlord shall not be liable for any such damage or loss caused by other tenants or persons in the Leased Premises, occupants of adjacent property, or the public, or caused by operations in construction of any private, public or quasi-public work. All property of the Tenant kept or stored on the Leased Premises shall be so kept or stored at the risk of Tenant only and Tenant shall hold Landlord and Owner harmless from any claims arising out of damage to the same, including subrogation claims by Tenant's insurance carrier.

Section 16.03.Notice by Tenant. Tenant shall give notice as soon as possible to Landlord in case of fire or accidents in the Leased Premises.

Article XVII

Holding Over, Successors

Section 17.01.Holding Over: Any holding over after the expiration of the term hereof shall be construed to be a tenancy at sufferance but shall otherwise be on the same terms and conditions herein specified except that the then applicable Fixed Base Rent shall be 150% of the rate reserved under sections 2.01 and 2.03 and Exhibit B of this Lease, and Landlord shall be entitled to avail itself of all of the rights and remedies under applicable law and hereunder and Tenant shall be subject to all of the duties and responsibilities specified in Section 14.01 in the event of default of Tenant.

Section 17.02.Successors: All rights and liabilities herein given to, or imposed upon, the respective parties hereto shall extend to and bind the several respective heirs, executors, administrators, successors, and assigns of the said parties; and if there shall be more than one tenant, they shall all be bound jointly and severally by the terms, covenants and agreements herein. No rights, however, shall insure to the benefit of any assignee of Tenant unless the assignment of such assignee has been approved by Landlord in writing to the extent required as provided in Article X hereof.

Article XVIII

Other Covenants

Section 18.01.Quiet Enjoyment. Upon payment by the Tenant of the rents herein provided, and upon the observance and performance of all the covenants, terms and conditions of the Tenant's part to be observed and performed Tenant shall peaceably and quietly hold and enjoy the Leased Premises for the term hereby demised without hindrance or interruption by Landlord or any other person or persons lawfully or equitably claiming by, through, or under the Landlord, subject, nevertheless, to the terms and conditions of this Lease.

Article XIX

Landlord Maintenance, Services and Equipment

Section 19.01.Landlord Maintenance: Landlord shall keep and maintain in good repair and working order and perform routine and regular maintenance upon (i) the roof and structural elements of the Building and (ii) the mechanical (including HVAC), electrical, plumbing and fire/life safety systems and elevator serving the Building in general (the "Building Systems"). At the time of Commencement Date, all Building Systems shall be in good working order and repair.

Section 19.02.Landlord's Services: So long as Tenant is not in default under any of the provisions of this Lease, Landlord shall:

(a) For 24 hours per day, 7 days per week, supply heat ventilation (during the heating seasons), and air-conditioning (during the cooling seasons) from the systems installed by Owner for such purposes, except for the cost of electricity necessary to operate heat pumps that exist within the Leased Premises. The Landlord shall maintain, repair and as necessary replace such systems at the Leased Premises generally, at Landlord's own expense (to be included in Operating Expenses).

(b) Provide cleaning services and trash removal services every business day in the Leased Premises at no cost to the Tenant (but to be included in Operating Expenses).

(c) Furnish to the common areas hot and cold water for lavatory and drinking and office cleaning purposes.

(d) Provide access to the Building and parking area twenty four (24) hours a day.

Section 19.03.Landlord's Right to Suspend or Curtail Services: Landlord reserves the right to interrupt, curtail or suspend the services required to be furnished by Landlord under this Article XIX when the necessity therefore arises by reason of accident, emergency, mechanical breakdown, or when required by law, order or regulation of any federal, state, county or municipal authority, or for any other cause beyond the reasonable control of Landlord. Landlord shall use reasonable diligence to complete all required repairs or other necessary work as quickly as reasonably possible so that Tenant's inconvenience resulting therefrom may be for as short a period of time as circumstances will reasonably permit. No diminution or abatement of rent or other compensation shall or will be claimed by Tenant as a result therefrom, nor shall this Lease or any obligations of Tenant be affected or reduced by reason of such interruption, curtailment or suspension.

Section 19.04.Abatement and Termination: Subject to Section 19.03, in the event that any interruption or discontinuance of services required to be furnished by Landlord under this Article XIX continues beyond thirty (30) days after written notice to Landlord and such interruption materially and adversely affects Tenant's ability to conduct business in a substantial portion of the Leased Premises and on account of such interruption or disturbance Tenant ceases doing business in the Leased Premises, Base Rent and Tenant's Proportionate Share of Operating Expenses and Taxes shall thereafter abate proportionately for so long as Tenant remains unable to conduct its business in the Leased Premises or such portion thereof. The abatement provisions set forth above shall be inapplicable to any interruption or discontinuance of required to be furnished by Landlord under this Article XIX

that is caused by casualty or condemnation a taking (it being acknowledged that such situations shall be governed by Articles XII and XIII, respectively).

Article XX

Miscellaneous

Section 20.01.Waiver: The waiver by any party of any breach of any term, covenant, or condition herein contained shall not be deemed to be a waiver of such term, covenant or condition or any subsequent breach of the same or any other term, covenant or condition herein contained. The subsequent acceptance of rent hereunder by Landlord shall not be deemed to be a waiver of any preceding breach by Tenant of any term, covenant or condition of this Lease Agreement, other than the failure of Tenant to pay the particular rental so accepted, regardless of Landlord's knowledge of such preceding breach at the time of acceptance of such rent. No covenant, term or condition of this Lease Agreement shall be deemed to have been waived by Landlord, unless such waiver be in writing by Landlord.

Section 20.02.Accord and Satisfaction: No payment by Tenant or receipt by Landlord of a lesser amount than the then appropriate rent herein stipulated shall be deemed to be other than on account of the earliest stipulated rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such rent or pursue any other remedy in this Lease Agreement provided.

Section 20.03.Entire Agreement: This Lease Agreement and the exhibits attached hereto and forming a part hereof set forth all the covenants, promises, agreements, conditions and understandings between Landlord and Tenant concerning the Leased Premises, and there are no covenants, promises, agreements, conditions or understandings, either oral or written, between them other than as herein set forth. Except as herein otherwise provided, no subsequent alteration, amendment, change or addition to this Lease Agreement shall be binding upon Landlord or Tenant unless reduced to writing and signed by both Landlord and Tenant.

Section 20.04.Rent Control: If there shall hereafter be acted any law or ordinance which shall be of a nature commonly referred to as "rent control laws" which shall limit, reduce or suspend in whole or in part or otherwise affect the rents or revenues from the Leased Premises or which shall make it illegal to pay or prohibit or restrict the payment to, or receipt by, Landlord of the minimum base rent, additional rent, or adjustment of rent or any part or portion of any thereof, or as a result of which the Landlord may not, or may not be entitled to, receive when due the full and entire then appropriate, rent, additional rent, and adjustments or rent, or which may permit Tenant to seek the return of all or any part of the rent, additional rent, or adjustments of rent, then and in any of such events Landlord shall have the right at any time thereafter to cancel this Lease Agreement and the term hereunder upon thirty (30) days written notice to Tenant, and the Landlord may serve upon Tenant a thirty-day notice of cancellation of this Lease Agreement and upon the expiration of such thirty days this Lease Agreement and the term hereunder shall end and expire as fully and completely as if the date of expiration of such thirty-day period were the day herein definitely fixed for the end and expiration of this Lease and the term thereof, and Tenant shall then quit and surrender the Leased Premises to Landlord, and upon Tenant's failure to do so the Landlord shall be entitled to all the rights and remedies and the Tenant shall be subject to all the duties and responsibilities specified in Article XIV in the event of a default of the Tenant.

Section 20.05.Force Majeure: In the event that either party hereto shall be delayed or hindered in or prevented from the performance of any act required hereunder, by reason of strikes, lock-outs, labor troubles, inability to procure materials, failure of power, restrictive governmental laws or regulations, pandemic, riots, insurrection, war or other reason of a like nature not the fault of the party delayed in performing work or doing acts required under the terms of this Lease, then performance of such act shall be excused for the period of the delay and the period for the performance of any such act shall be extended for a period equivalent to the period of such delay. The provisions of this Section 20.05 shall not operate to excuse Tenant from prompt payment of rent or any other payments required by the terms of this Lease.

Section 20.06.Subordination: This Lease automatically and without act or deed shall be and remain subject and subordinate to any and all existing mortgage or mortgages and any and all mortgage or mortgages that may hereafter be placed against the Leased Premises, and/or the Building, and to all renewals, modifications, consolidations, replacements and extensions thereof; provided, however, that with respect to mortgages not appearing of record on the date hereof such subordination shall apply only if the Mortgagee expressly agrees, upon Tenant's written request and upon such Mortgagee's customary form of Subordination Non-Disturbance and Attornment Agreement, that, so long as the Tenant is not in default in the payment of rent or additional rent, or in the performance of any of the terms of this Lease by it to be performed, in either case beyond applicable notice and cure periods, the Tenant's possession of the Leased Premises and the Tenant's rights and privileges under this Lease shall not be interfered with or diminished by or on behalf of such Mortgagee. The recording of any such mortgage or mortgages shall have preference to and shall be superior and prior in lien to this Lease, irrespective of the recording of any notice hereof. In confirmation of such subordination, Tenant shall execute promptly any commercially reasonable certificate that Landlord may request. Notwithstanding the foregoing, Landlord will make reasonable efforts to secure an executed non-disturbance agreement from its Mortgagee upon such Mortgagee's customary form of Subordination Non-Disturbance and Attornment Agreement, immediately following the execution of the Lease Agreement. This clause shall be self-operative and no further instrument of subordination shall be required.

Section 20.07.Waiver of Jury Trial, Counterclaims. The parties hereto waive a trial by jury on any and all issues arising in any action or proceeding between them or their successors under or connected with this Lease or any of its provisions, any negotiations in connection therewith, or the Tenant's use or occupancy of the Leased Premises.

Section 20.08.Broker's Commission: Landlord is responsible for and agrees to pay in accordance with its separate agreement any and all brokerage commissions or finder's fee in connection with the execution of this Lease due to Rise 73 CRE Inc and Cushman and Wakefield. Tenant warrants and represents that it has dealt with no broker other than Rise 73 CRE Inc and Cushman and Wakefield in locating the Leased Premises and negotiating this Lease and Tenant agrees to indemnify and hold harmless Landlord against and from all liabilities arising from any claim for, brokerage fees including without limitations the cost of counsel fees in, connection therewith arising out of or on account of Tenant having dealt with any broker other than Rise 73 CRE Inc and Cushman and Wakefield in locating the Leased Premises and negotiating this Lease.

Section 20.09.Notices: Any notice to be given hereunder shall be in writing and shall be deemed given when delivered or deposited in the United States mails, postage prepaid, by registered mail or certified mail with return receipt requested, addressed as follows:

(a) If to Landlord:

130 Prospect Limited Partnership
Attn. Robert Leahy — Treasurer
130 Prospect Street
Cambridge, MA 02139

(b) If to Tenant (from and after the Commencement Date):

Third Harmonic Bio, Inc.
Attn. Natalie Holles, CEO
130 Prospect Street
Cambridge, MA 02139

Or prior to the Commencement Date at:

Third Harmonic Bio, Inc.
Attn: Natalie Holles, CEO
300 Technology Square, 8th Floor
Cambridge, MA 02139

or to such other person or address as the party entitled to notice shall have specified by written notice to the other party given in accordance with the provisions of this Section 20.12.

Section 20.10.Tenant and Landlord Defined, Use of Pronoun: The word "Tenant" shall be deemed and taken to mean each and every person or party mentioned as a tenant herein, be the same one or more, and if there shall be more than one tenant, any notice required or permitted by the terms of this Lease may be given by or to any one thereof and shall have the same force and effect as if given by or to all thereof. The term "Landlord", as used in this Lease, means only the holder of the Landlord's leasehold interest in the Property for the time being, so that, in the event of any transfer thereof, the transferor shall be and hereby is entirely freed and relieved of all covenants and obligations of the Landlord hereunder, not theretofore accrued, and it shall be deemed and construed, without further agreement between the parties or between the parties and the successor to the Landlord hereunder. The use of the neuter singular pronoun to refer to Landlord or Tenant shall be deemed a proper reference even though Landlord or Tenant may be an individual, a partnership, a corporation, or a group of two or more individuals or corporations. The necessary grammatical changes required to make the provisions of this Lease apply in the plural sense where there is more than one Landlord or Tenant and to either corporations, associations, partnerships, or individuals, males or females, shall in all instances be assumed as though in each case fully expressed.

Section 20.11.Landlord Not Personally Liable: If Landlord or any successor in interest of Landlord shall be a mortgagee, or an individual, joint venture, tenancy in common, firm or partnership, general or limited, it is specifically understood and agreed that there shall be absolutely no personal liability on the part of such mortgagee or such individual or on the part of the members of such firm, partnership or joint venture with respect to any of the terms, covenants and conditions of this Lease, and that Tenant shall look solely to the equity of Landlord or such successor in interest in the Leased Premises or the Building, or to the leasehold estate of Landlord or such successor therein, and in either case to the net rents, profits and proceeds derived therefrom, for the satisfaction of each and every remedy of Tenant in the event of any breach by Landlord or by such successor of any of the terms, covenants and conditions of this Lease to be performed by Landlord, such exculpation of personal liability to be absolute and without any exception whatsoever.

Section 20.12.Mutual Waiver of Subrogation and Release: All policies of insurance required by the terms of this Lease to be carried by the Landlord or the Tenant shall include a waiver by the insurer of all right or subrogation against Landlord or Tenant in connection with any loss or damage thereby insured against. Neither party, nor its agents, employees or guests, shall be liable to the other for loss or damage caused by any risk covered within the scope of such insurance.

Section 20.13.Notices to Mortgagees: (a) Tenant agrees to give any mortgagees and/or trust deed holders by registered mail a copy of any notice of default served by Tenant upon the Landlord provided that prior to such notice Tenant has been notified in writing (by way of notice of assignment of rents and leases or otherwise) of the address of such mortgagees and/or trust deed holders. Tenant further agrees that if Landlord shall have failed to cure such default within the time provided for in the Lease Agreement, then the mortgagees and/or trust deed holders shall have an additional 30 days within which to cure such default, or if such default cannot be cured within that time, then such additional time may be necessary if within such 30 days any mortgagee and/or trust deed holder has commenced and is diligently pursuing the remedies necessary to cure such default (including but not limited to commencement of foreclosure proceedings if necessary to effect such cure) in which event this Lease shall not be terminated while such remedies are being so diligently pursued.

(b) Tenant agrees, within ten (10) business days after request from Landlord, to provide to Landlord or any mortgagee or potential mortgagee of Landlord a statement as to the status of any matter pertaining to this Lease, including but not limited to the date to which Base Rent and Additional Rent has been paid, the amount of any security deposit held by Landlord, whether or not all improvements included in Landlord's Work have been completed, whether or not any options of Tenant under this Lease have been exercised, whether or not each party hereto is in compliance with its obligations hereunder, and such other matters as Landlord or any such mortgagee shall request. No such certificate by Tenant shall have the effect of amending this Lease or waiving any rights that Tenant may have hereunder. In the case of any conflict between the terms of this Lease and the content of any such certificate, the taints of this Lease shell control.

Section 20.14.Captions, Headings: The captions, section numbers, article numbers and table of contents appearing in this Lease are inserted only as a matter of convenience, and in no way define, limit, construe or describe the scope or intent of such sections or articles, nor in any way affect this Lease.

Section 20.15.Partial Invalidity: If any term, covenant or condition of this Lease of the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term, covenant or condition to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Lease shall be valid and be enforced to the fullest extent permitted by law.

Section 20.16.Recording: Tenant shall not record this Lease without the written consent of the Landlord, however, upon the request of either party hereto the other party shall join in the execution of a memorandum of this Lease for the purposes of recordation. Said memorandum of this Lease shall describe the parties, the Leased Premises, the term of this Lease, and such other matters required in a Notice of Lease pursuant to Massachusetts General Laws Chapter 183, Section 4. of this Lease, and shall incorporate this Lease by reference. In no event shall such document set forth the rent or other charges payable by Tenant under this Lease and any such document shall expressly state that it is executed pursuant to the provisions contained in this Lease, and is not intended to vary the terms and conditions of this Lease. If at any time Tenant abandons the Premises or this Lease is otherwise terminated or expires, Landlord may record a Notice of Termination of this Lease, including as to the non-exercise of any option to extend. The Tenant hereby grants to the Landlord an irrevocable power of attorney, which shall be deemed to be coupled with an interest, to execute, acknowledge and record any such notice on behalf of the Tenant.

Section 20.17.No Option: The submission of this Lease for examination does not constitute a reservation of or option for the Leased Premises and this Lease becomes effective as a Lease only upon the execution and delivery thereof by Landlord and Tenant.

Section 20.18.Applicable Law: This Lease shall be construed in accordance with the laws of the Commonwealth of Massachusetts.

Section 20.19.Mutual Waiver of Consequential Damages: In no event shall Landlord or Tenant ever be liable hereunder to the other for any indirect, incidental, special or consequential damages (including lost profits, even if a party has been advised of the possibility of such damages) suffered by such other from whatever cause.

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IN WITNESS WHEREOF, Landlord and Tenant have signed this Lease as of the day and year first above written.

In Presence Of:

130 PROSPECT LIMITED PARTNERSHIP
By Cambridge Development Corp.,
its General Partner

/s/ John Hopkins
John Hopkins

By: /s/ Robert J. Leahy
Name: Robert J. Leahy
Title: Treasurer
Hereunto duly authorized

THIRD HARMONIC BIO, INC.

/s/ Julie Person
Julie Person

By: /s/ Natalie Holles
Name: Natalie Holles
Title: Chief Executive Officer
Hereunto duly authorized

EXHIBIT B

FIXED BASE RENT PER YEAR

Useable Space:	9,131 square feet
Rentable Space:	10,356 square feet

3/1/23 - 11/30/23	$73.00 per rentable square foot
12/1/23 - 11/30/24	$74.83 per rentable square foot
12/1/24 - 11/30/24	$76.70 per rentable square foot
12/1/25 - 11/30/26	$78.61 per rentable square foot
12/1/26 -11/30/27	$80.58 per rentable square foot
12/1/27 - 2/29/28	$82.59 per rentable square foot

Exhibit 10.16

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

WATERFRONT PLAZA
SAN FRANCISCO, CALIFORNIA

OFFICE LEASE AGREEMENT

BETWEEN

JPPF WATERFRONT PLAZA, L.P., a Delaware limited partnership

("LANDLORD")

AND

THIRD HARMONIC BIO, INC., a Delaware corporation

("TENANT")

The following exhibits and attachments are incorporated into and made a part of this Lease:

Exhibit A - Outline and Location of Premises
Exhibit B - Expenses, Taxes and Insurance Expenses
Exhibit C - Work Agreement
Exhibit D - Commencement Letter
Exhibit E - Building Rules and Regulations
Exhibit F - Additional Provisions
Exhibit G - Parking Agreement
Exhibit H - Asbestos Notification
Exhibit I - Existing Exclusives
Exhibit J - Disability Access Notice

OFFICE LEASE AGREEMENT

THIS OFFICE LEASE AGREEMENT (this "**Lease**") is entered into as of October 19, 2022, by and between JPPF WATERFRONT PLAZA, L.P., a Delaware limited partnership ("**Landlord**"), and THIRD HARMONIC BIO, INC., a Delaware corporation ("**Tenant**").

1. Basic Lease Information.

1.01 "**Building**" means the building located at 1700 Montgomery Street, San Francisco, California, commonly known as 1700 Montgomery. "**Rentable Area of the Building**" is deemed to be 142,466 square feet.

1.02 "**Premises**" means the area shown on **Exhibit A** to this Lease. The Premises consists of a portion of the second (2nd) floor known as Suite 210. The "**Rentable Area of the Premises**" is deemed to be 4,703 square feet. All Rentable Area referred to herein is calculated in accordance with the modified guidelines of the Building Owners and Managers Association International (ANSI/BOMA Z65.1-2017 - Method A) as interpreted and applied by Landlord's measurement firm to the Building. Landlord and Tenant stipulate and agree that the Rentable Area of the Building and the Premises as set forth herein are correct and shall not be subject to remeasurement during the initial Term.

1.03 "**Base Rent**":

Period/ Months of Term	**Annual Rate Per RSF**	**Monthly Base Rent**
Month 1* - Month 12	$70.00	$27,434.17**
Month 13 - Month 24	$72.10	$28,257.19
Month 25 - Month 36	$74.26	$29,103.73
Month 37 - Month 48	$76.49	$29,977.71
Month 49 - Month 60	$78.79	$30,879.11
Month 61 - Month 63	$81.15	$31,804.04

* If the Commencement Date is other than the first (1st) day of a calendar month, "Month 1" shall be the first full calendar month of the Term plus any partial calendar month in which Commencement Date occurs, and in such event, Tenant shall pay the prorated amount of the monthly installment of Base Rent for such partial calendar month on the Commencement Date

** Subject to abatement pursuant to Section 4.02.

1.04 "**Tenant's Share**": **[***]**%.

1.05 "**Base Year**" for Taxes (defined in **Exhibit B**): 2023;
"**Base Year**" for Expenses (defined in **Exhibit B**): 2023;
"**Base Year**" for Insurance Expenses (defined in **Exhibit B**): 2023.

1.06 **"Term":** The period commencing on the Commencement Date (defined below) and, unless terminated earlier in accordance with this Lease, ending on the last day of the sixty-third (63rd) full calendar month after the Commencement Date (the "**Termination Date**"). The "**Commencement Date**" shall be the earlier of: (i) the date on which Tenant is properly and correctly notified that the Tenant Improvements (defined in Section 1.15) are Substantially Complete (defined in the Work Agreement), or (ii) the date Tenant occupies the Premises for the purpose of conducting business therein. The parties anticipate that the Tenant Improvements will be Substantially Complete on or about the date that is two (2) months following mutual execution of this Lease (the "**Target Commencement Date**").

1.07 "**Parking Rights**": Five (5) parking spaces.

1.08 "**Security Deposit**": $190,753.68, subject to possible reduction in accordance with Section 6.02.

1.09 "**Brokers**": Jones Lang LaSalle, representing Landlord, and
Evolution Real Estate, Inc. dba Faller Real Estate, representing Tenant.

1.10 "**Permitted Use**": General office and administrative use.

1.11 "**Notice Address(es)**":

Landlord:
JPPF Waterfront Plaza, L.P.
Ponce City Market
675 Ponce de Leon Avenue, NE, 7th Floor
Atlanta, Georgia 30308
Attn: General Counsel and
Asset Manager, Waterfront Plaza
and:

JPPF Waterfront Plaza, L.P.
1700 Montgomery, Suite 110
San Francisco, California 94111
Attn: Asset Manager, Waterfront Plaza

and:

Waterfront Plaza
1700 Montgomery, Suite 110
San Francisco, California 94111
Attn: Property Manager

Tenant:
Prior to the Commencement Date:

Third Harmonic Bio
300 Technology Square, 8th Floor
Cambridge, MA 02139

From and after the Commencement Date:

Third Harmonic Bio
1700 Montgomery Street, Suite 210 San Francisco, California 94111

Rent Payments: Rent shall be payable to "**JPPF WATERFRONT PLAZA, L.P.**" as follows:

If by Wire or ACH:

JPPF Waterfront Plaza, L.P.
Wire ABA Routing #:
ACH ABA Routing #:
Name of Account:
Account #:

If by US Mail:

JPPF Waterfront Plaza, L.P.
P.O. Box 31001-2173
Pasadena, California 91110-2173

If by overnight or special courier:

JPPF Waterfront Plaza, L.P.
Lockbox #912173
Pasadena Tech Center
465 N Halstead Street, Suite 160
Pasadena, California 91107

1.12 "**Business Day(s)**" are Monday through Friday of each week, exclusive of New Year's Day, Presidents Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and Christmas Day ("**Holidays**"). Landlord may designate additional Holidays that are commonly recognized by other office buildings in the area where the Building is located. "**Building Service Hours**" are 7:00 A.M. to 6:00 P.M. on Business Days (excluding weekends and Holidays).

1.13 "**Tenant Improvements**" mean the work that Landlord is obligated to perform in the Premises, pursuant to the work agreement, attached to this Lease as **Exhibit C** (the "**Work Agreement**").

1.14 "**Complex**" means Waterfront Plaza, consisting of those certain buildings and related improvements (including parking facilities) located at 50 Francisco Street, 60 Francisco Street, 1700 Montgomery Street, and 1800 Montgomery Street together with the parcel(s) of land on which the same are located.

2. Lease Grant.

The Premises are hereby leased to Tenant from Landlord for the Term, together with the right to use the Common Areas, subject to the terms and conditions of this Lease. For purposes of this Lease, "**Common Areas**" mean those certain areas and facilities of the Building and other improvements on the Complex which are, from time to time, provided by Landlord for the use in common of tenants of the Building and their employees, clients, customers, licensees and invitees or for use by the public, which facilities and improvements include any and all common corridors, elevator foyers, the lobby, vending areas, bathrooms on multi-tenant floors, electrical and telephone rooms, mechanical rooms, janitorial areas and other similar facilities of the Building and any and all grounds, landscaped areas, outside sitting areas, sidewalks, walkways and pedestrianways.

3. Possession.

3.01 Subject to Landlord's obligation to provide services as set forth in Section 7.01, to perform its maintenance obligations as set forth in this Lease, and to complete the Tenant Improvements and to perform any other obligations set forth in Exhibit C, Tenant is leasing the Premises in "as-is, where is" condition, without any obligation on the part of Landlord to make or pay for any improvements therein. Subject to the foregoing, no other representation or warranty, express or implied, has been made by Landlord with respect to any matter whatsoever, including the condition of the Premises or the Building, the suitability of the Premises or the Building for Tenant's particular use, or any other conditions that may affect Tenant's use and enjoyment of the Premises or the Building. No rights to any view or to light or air over the Building or any other property, whether belonging to Landlord or any other person, are granted to Tenant by this Lease. Landlord's failure to Substantially Complete the Tenant Improvements by the Target Commencement Date (described in Section 1.06) shall not be a Landlord Default or otherwise render Landlord liable for damages. Landlord shall not be liable for a failure to deliver possession of the Premises or any other space due to the holdover or unlawful possession of such space by another party, provided, however, Landlord shall use commercially reasonable efforts to obtain possession of any such space. Notwithstanding anything herein to the contrary, in the event Landlord has not delivered the Premises with the Tenant Improvements Substantially Complete by the date which is thirty (30) days following the Target Commencement Date as such date shall be extended by any Tenant Delay (such date, the "**Outside Delivery Date**"), then in addition to the delay of the Commencement Date, Tenant shall receive a credit against Base Rent from and after the actual Commencement Date equal to one (1) day of Base Rent for each such day of delay beyond the Outside Delivery Date. In any event, Landlord shall use commercially reasonable efforts to notify Tenant of the Commencement Date at least thirty (30) days prior to the Commencement Date. Except as otherwise provided in this Lease, including without limitation Section 3.02, Tenant shall not be permitted to take possession of or enter the Premises prior to the Commencement Date without Landlord's permission. Promptly after the determination of the Commencement Date, Landlord and Tenant shall execute and deliver a letter in the form attached hereto as **Exhibit D** (the "**Commencement Letter**"). Tenant's failure to execute and return the Commencement Letter, or to provide a good faith written objection to the statements contained in the Commencement Letter, within ten (10) days after the delivery of the Commencement Letter to Tenant, shall be deemed an approval by Tenant of the statements contained therein. Notwithstanding anything to the contrary herein, Tenant's acceptance of the Premises is subject to any punch list work to be performed by Landlord or defects not readily observable by Tenant.

3.02 Subject to the terms and conditions of this Lease including, without limitation, Section 13, and provided Landlord has received the pre-paid Base Rent required by Section 4.01 below, the Security Deposit and evidence of Tenant's procurement of all insurance coverage required hereunder, Tenant, at Tenant's sole risk, shall be permitted to enter the Premises from and after the date that is ten (10) days prior to the Commencement Date, for all permitted uses under this Lease, including installing furniture, fixtures and equipment and otherwise occupying the Premises for the conduct of business therein. Landlord may withdraw such permission for Tenant to enter the Premises, if Landlord reasonably determines that such entry is causing a dangerous situation for Landlord, Tenant, Tenant's vendors and contractors or other tenants in the Building or is delaying or interfering with the progress of any work within the Building. Tenant will have no obligation to pay Rent during such early access period, except for the cost of services requested by Tenant (e.g., after hours HVAC service, after hours security, etc.), provided, however, Landlord will not charge Tenant, and Tenant shall have no obligation to pay, for Tenant's use of the freight elevator in the Building during such early access period. If Tenant so commences business operations in the Premises, then the Commencement Date shall be deemed to have occurred on the date that Tenant commences such business operations.

4. Rent.

4.01 From and after the Commencement Date, Tenant shall pay Landlord, without any setoff or deduction, unless expressly set forth in this Lease, all Base Rent and Additional Rent due for the Term (collectively referred to as "**Rent**"). "**Additional Rent**" means all sums (exclusive of Base Rent) that Tenant is required to pay Landlord under this Lease. Tenant shall pay and be liable for all rental, sales and use taxes (but excluding income taxes), if any, imposed upon or measured by Rent. Base Rent and recurring monthly charges of Additional Rent shall be due and payable in advance on the first day of each calendar month without notice or demand, provided that the installment of Base Rent attributable to the fourth (4th) full calendar month of the Term shall be due concurrently with the execution of this Lease by Tenant. All other items of Rent shall be due and payable on or before thirty (30) days after Tenant receives a correct billing from Landlord. Rent shall be made payable to the entity, and sent to the address, that Landlord designates and shall be made by good and sufficient check or by other means acceptable to Landlord. Landlord may return to Tenant, at any time within fifteen (15) days after receiving same, any payment of Rent (a) made following any Default (irrespective of whether Landlord has commenced the exercise of any remedy), or (b) that is less than the amount due. Each such returned payment (whether made by returning Tenant's actual check, or by issuing a refund in the event Tenant's check was deposited) shall be conclusively presumed not to have been received or approved by Landlord. If Tenant does not pay any Rent within five (5) business days after the date when the same is due hereunder, Tenant shall pay Landlord an administration fee in the amount of five percent (5%) of the past due amount. In addition, if Tenant does not pay any Rent within thirty (30) days after the date when the same is due, such past due Rent shall accrue interest at a rate equal to the lesser of (i) ten percent (10%) per annum or (ii) the maximum legal rate. To ascertain whether any interest payable exceeds the legal limits imposed, any non-principal payment (including the administration fee) shall be considered to the extent permitted by Law to be an expense or a fee, premium or penalty, rather than interest. Landlord's acceptance of less than the correct amount of Rent shall be considered a payment on account of the oldest obligation due from Tenant hereunder, then to any current Rent then due hereunder, notwithstanding any statement to the contrary contained on or accompanying any such payment from Tenant. Rent for any partial month during the Term shall be prorated. No endorsement or statement on a check or letter accompanying payment shall be considered an accord and satisfaction. Accordingly, Tenant hereby waives the provisions of California Uniform Commercial Code §3311 (and any similar Law that would permit an accord and satisfaction contrary to the provisions of this Section 4.01). Any partial payment shall be treated as a payment on account, and Landlord may accept such payment without prejudice to Landlord's right to recover any balance due or to pursue any other remedy permitted by this Lease. No payment, receipt or acceptance of Rent following (a) any Default; (b) the commencement of any action against Tenant; (c) termination of this Lease or the entry of judgment against Tenant for possession of the Premises; or (d) the exercise of any other remedy by Landlord, shall cure the Default, reinstate the Lease, grant any relief from forfeiture, continue or extend the Term, or otherwise affect or constitute a waiver of Landlord's right to or exercise of any remedy, including Landlord's right to terminate the Lease and recover possession of the Premises; provided, however, the full payment of all amounts required to cure any Monetary Default shall operate to cure said Default if paid within the time period provided in this Lease. The foregoing constitutes actual notice to Tenant of the provisions of California Code of Civil Procedure §1161.1(c).

4.02. Notwithstanding Section 4.01 above to the contrary, so long as Tenant is not in Default, Tenant shall be entitled to an abatement of Base Rent for the first three (3) full calendar months of the Term (the "**Abatement Period**"). The total amount of Base Rent abated during the Abatement Period is referred to herein as the "**Abated Rent**". If Tenant's Default at any time results in the termination of this Lease, then at Landlord's option, all then-unamortized Abated Rent credited to Tenant prior to the occurrence of the Default (assuming amortization of Abated Rent on a straight-line basis over the Term) shall become due and payable to Landlord. No such recapture by Landlord of the Abated Rent pursuant to the foregoing sentence shall constitute a waiver of any Default of Tenant or any election of remedies by Landlord.

4.03. Tenant shall pay Tenant's Share of Taxes, Insurance Expenses and Expenses in accordance with **Exhibit B** of this Lease. In addition, Tenant shall pay before delinquency any and all taxes levied or assessed and which become payable by Tenant (or directly or indirectly by Landlord) during the Term (excluding, however, state and federal personal or corporate income taxes measured by the net income of Landlord from all sources, capital stock taxes, and estate and inheritance taxes), whether or not now customary or within the contemplation of the parties hereto, which are based upon, measured by or otherwise calculated with respect to: (i) the gross or net rental income of Landlord under this Lease, including, without limitation, the San Francisco Early Care and Education Commercial Rents Tax (2018 Proposition C), any gross receipts tax levied by any taxing authority, or any other gross income tax or excise tax levied by any taxing authority with respect to the receipt of the rental payable hereunder; (ii) the value of Tenant's equipment, furniture, fixtures or other personal property located in the Premises; (iii) the possession, lease, operation, management, maintenance, alteration, repair, use or occupancy by Tenant of the Premises or any portion thereof; (iv) the value of any leasehold improvements, alterations or additions made in or to the Premises, regardless of whether title to such improvements, alterations or additions shall be in Tenant or Landlord; or (v) this transaction or any document to which Tenant is a party creating or transferring an interest or an estate in the Premises.

4.04 Tenant shall have the right to audit Landlord in accordance with Section 7 of Exhibit B of this Lease.

5. Compliance with Laws; Use.

The Premises shall be used for the Permitted Use and for no other use whatsoever. Landlord shall construct the Tenant Improvements in compliance with any and all Laws and legal requirements. From and after the Commencement Date, Tenant shall comply with all statutes, codes, ordinances, orders, rules and regulations of any municipal or governmental entity whether in effect now or later, including the Americans with Disabilities Act and the Controlled Substances Act ("**Law(s)**"), regarding the operation of Tenant's business and the use, condition, configuration and occupancy of the Premises; provided, however, Tenant shall have no obligation to make physical modifications to the Premises or the Base Building to comply with such Laws unless such obligations are triggered by Tenant's specific use of the Premises (other than for general office use) or Alterations. "**Base Building**" shall mean the structural portions of the Building, the public restrooms and the Building mechanical, electrical, fire/life-safety and plumbing systems and equipment. Tenant shall promptly provide Landlord with copies of any notices it receives regarding an alleged violation of Law in connection with the Premises. Tenant shall not exceed the standard density limit for the Building (i.e., one (1) person per every 150 square feet of Rentable Area of the Premises). (the "**Standard Density**"). Tenant may occupy the Premises at a density greater than the Standard Density, provided that such occupancy density is in compliance with applicable Law. Tenant hereby acknowledges that the Building's HVAC system and electrical systems are not designed to service space occupied at a density greater than the Standard Density, and, as a consequence, if and to the extent that Tenant desires additional HVAC services or electrical infrastructure to service any portion of the Premises and/or if any required modifications to the Premises or to the Building or Building Systems (for example, but not by way of limitation, upgrades or modifications to the fire stairways or restrooms) are required due to Tenant's occupancy of the Premises (or any portion thereof) at a density greater than the Standard Density, then Tenant will be solely responsible for the cost of providing such additional services, infrastructure or modifications (which may be carried out by Landlord for the account of Tenant). Tenant shall comply with the rules and regulations attached hereto as **Exhibit E** and such other reasonable rules and regulations adopted by Landlord from time to time, including rules and regulations for the performance of Alterations (defined in Section 9.03). Subject to Tenant's obligations set forth above, Landlord, at its sole cost and expense (except to the extent properly included in Expenses), shall be responsible for correcting any violations of Title III of the Americans with Disabilities Act with respect to the Common Areas and the Base Building. Notwithstanding the foregoing, Landlord shall have the right to contest any alleged violation in good

faith, including, without limitation, the right to apply for and obtain a waiver or deferment of compliance, the right to assert any and all defenses allowed by Law and the right to appeal any decisions, judgments or rulings to the fullest extent permitted by Law. Notwithstanding the foregoing, Tenant, not Landlord, shall be responsible for the correction of any violations that arise out of or in connection with the specific nature of Tenant's business in the Premises (other than general office use) and/or the acts or omissions of Tenant, its agents, employees or contractors, Tenant's arrangement of any furniture, equipment or other property in the Premises, any repairs, or alterations performed by or on behalf of Tenant and any design or configuration of the Premises specifically requested by Tenant. Notwithstanding anything to the contrary contained herein, in no event shall Tenant or any Permitted Tenant Parties conduct or permit any activities in the Premises that will violate the exclusive rights granted to current occupants of the Complex, as set forth on **Exhibit I** attached hereto.

6. Security for Lease.

6.01 The Security Deposit, in the form of cash or in the form of a Letter of Credit, pursuant to the provisions of **Exhibit F** attached hereto shall be delivered to Landlord concurrently with the execution of this Lease by Tenant and held by Landlord without liability for interest (unless required by Law) as security for the performance of Tenant's obligations. The Security Deposit is not an advance payment of Rent or a measure of damages. Landlord may from time to time and without prejudice to any other remedy provided in this Lease or by Law, use all or a portion of the Security Deposit to the extent necessary to satisfy past due Rent or to satisfy any other loss or damage resulting from Tenant's breach of this Lease. If Landlord uses any portion of the Security Deposit, Tenant, within five (5) days after demand, shall restore the Security Deposit to its original amount. Landlord shall return any unapplied portion of the Security Deposit to Tenant within forty-five (45) days after the later to occur of the Termination Date or the date Tenant surrenders the Premises to Landlord in compliance with Section 25. Landlord may assign the Security Deposit to a successor or transferee and, following the assignment, Landlord shall have no further liability for the return of the Security Deposit. Landlord shall not be required to keep the Security Deposit separate from its other accounts. Tenant hereby waives the provisions of Section 1950.7 of the California Civil Code, or any similar or successor Laws now or hereafter in effect.

6.02 Provided that Tenant is not in Default and has not previously been in Default, then upon written request by Tenant the Security Deposit may be reduced as of the first (1st) day of the thirty-seventh (37th) full calendar month after the Commencement Date by an amount equal to $95,376.84 (the "**Reduction Amount**"). Such reduction in the Security Deposit will be accomplished by Landlord's return to Tenant, within thirty (30) days of Tenant's reduction request, of the Reduction Amount by check. Alternatively, if the Security Deposit has been provided in the form of a Letter of Credit, then in order to effect any such reduction, Tenant shall deliver written notice to Landlord requesting such reduction in accordance with this 6.02. Within five (5) business days after receipt of such notice, provided that the conditions for reduction are satisfied, Landlord shall request that the financial institution that issues the Letter of Credit either deliver an amendment to the existing Letter of Credit or a replacement letter of credit in the new amount that otherwise complies with all other applicable requirements specified in Exhibit F.

7. Building Services.

7.01 Landlord shall furnish Tenant with the following services: (a) water for use in the Base Building lavatories; (b) customary heat and air conditioning in season during Building Service Hours, although (i) Tenant shall have the right to receive HVAC service during hours other than Building Service Hours by paying Landlord's then standard charge for additional HVAC service and providing such prior notice as is reasonably specified by Landlord (Landlord's charge for additional HVAC service shall be based on a minimum of four (4) hours of usage), and (ii) if Tenant is permitted to connect any supplemental HVAC units to the Building's condenser water loop or chilled water line, such permission shall be conditioned upon Landlord having adequate excess capacity from time to time and such connection and use shall be subject to Landlord's reasonable approval and reasonable restrictions imposed by Landlord, and Landlord shall have the right to charge Tenant a connection fee and/or a monthly usage fee, as reasonably determined by Landlord; (c) standard janitorial service on Business Days; (d) elevator service; (e) electricity in accordance with the terms and conditions in Section 7.02; (f) access to the Building for Tenant and its employees twenty-four (24) hours per day/7 days per week, subject to the terms of this Lease and such protective services or monitoring systems, if any, as Landlord may reasonably impose, including, without limitation, sign-in procedures and/or presentation of identification cards; and (g) such other services as Landlord reasonably

determines are necessary or appropriate for the Complex. If Landlord, at Tenant's request, provides any services which are not Landlord's express obligation under this Lease, including, without limitation, any repairs which are Tenant's responsibility pursuant to Section 9 below, Tenant shall pay Landlord, or such other party designated by Landlord, the cost of providing such service plus a reasonable administrative charge.

7.02 Electricity used by Tenant in the Premises shall be paid for by Tenant through inclusion in Expenses (except as provided for excess usage). Without the consent of Landlord, Tenant's use of electrical service shall not exceed Building standard usage, per square foot, as reasonably determined by Landlord, based upon the Building standard electrical design load. Landlord shall have the right to measure electrical usage by commonly accepted methods, including the installation of measuring devices such as submeters and check meters. If it is determined that Tenant is using electricity in such quantities or during such periods as to cause the total cost of Tenant's electrical usage, on a monthly, per-rentable-square-foot basis, to materially exceed that which Landlord reasonably deems to be standard for the Building, Tenant shall pay Landlord Additional Rent for the cost of such excess electrical usage and, if applicable, for the cost of purchasing and installing the measuring device(s).

7.03 Landlord's failure to furnish, or any interruption, diminishment or termination of services due to the application of Laws, the failure of any equipment, the performance of maintenance, repairs, improvements or alterations, utility interruptions or the occurrence of an event of Force Majeure (defined in Section 26.03) (collectively a "**Service Failure**") shall not render Landlord liable to Tenant, constitute a constructive eviction of Tenant, give rise to an abatement of Rent, nor relieve Tenant from the obligation to fulfill any covenant or agreement. Tenant hereby waives the provisions of California Civil Code Section 1932(1) or any other applicable existing or future law, ordinance or governmental regulation permitting the termination of this Lease due to an interruption, failure or inability to provide any services. However, if the Premises, or a material portion of the Premises, are made untenantable for a period in excess of five (5) consecutive Business Days (and the Premises are not being used by Tenant) as a result of a Service Failure that is reasonably within the control of Landlord to correct, then Tenant, as its sole remedy, shall be entitled to receive an abatement of Rent payable hereunder during the period beginning on the sixth (6th) consecutive Business Day of the Service Failure and ending on the day the service has been restored. If the entire Premises have not been rendered untenantable by the Service Failure, the amount of abatement shall be equitably prorated.

8. Leasehold Improvements.

All improvements in and to the Premises, including any Alterations (defined in Section 9.03) (collectively, "**Leasehold Improvements**") shall remain upon the Premises at the end of the Term without compensation to Tenant, provided that Tenant, at its expense, shall remove all Cable (defined in Section 9.01 below) and that Tenant may remove any Alterations, improvements, fixtures and/or equipment which have not been paid for by Landlord, provided that Tenant repair any damage caused by such removal and restore the Premises to the condition existing prior to installation of the same. Tenant shall not be required to remove the Tenant Improvements constructed by Landlord in the Work Agreement. In addition, Landlord, by written notice delivered to Tenant at least 30 days prior to the Termination Date, may require Tenant, at Tenant's expense, to remove any Alterations (the Cable and such other items collectively are referred to as "**Required Removables**"), but shall not require Tenant to remove any improvements that were part of the Tenant Improvements. Required Removables shall include, without limitation, internal stairways, raised floors, personal baths and showers, vaults, supplemental HVAC units (and associated mechanical infrastructure), rolling file systems and structural alterations and modifications and specialized non-standard office improvements (game room, bowling alley, etc.). Notwithstanding the foregoing, Tenant, at the time it requests approval for a proposed Alteration, including any initial Alterations or Tenant Improvements, may request in writing that Landlord advise Tenant whether the improvement is a Required Removable. In such event, if Landlord approves the Alteration(s) in question, Landlord shall advise Tenant concurrently with such approval as to which portions of the proposed Alterations or other improvements are Required Removables. Required Removables shall be removed by Tenant before the Termination Date. Tenant shall repair damage caused by the installation or removal of Required Removables to Landlord's satisfaction. If Tenant fails to perform its obligations in a timely manner, Landlord may perform such work at Tenant's expense.

9. Repairs and Alterations.

9.01 Tenant, at its sole cost and expense, shall perform all maintenance and repairs to the Premises that are not Landlord's express responsibility under this Lease, and keep the Premises in good condition and repair, reasonable wear and tear excepted. Tenant's repair and maintenance obligations include, without limitation, repairs to: (a) floor covering; (b) interior partitions; (c) doors; (d) the interior side of demising walls; (e) Alterations; (f) supplemental air conditioning units, kitchens, including hot water heaters, plumbing, and similar facilities exclusively serving the Premises, whether such items are installed by Tenant or are currently existing in the Premises and whether such items are located within or outside of the Premises; and (g) electronic, fiber, phone and data cabling and related equipment installed by or for the exclusive benefit of Tenant (collectively, "**Cable**"). Provided, however, if any such floor covering, interior partitions, doors, supplemental air conditioning units, kitchens, including hot water heaters, plumbing, and similar facilities installed in the Premises by Landlord as part of the Tenant Improvements fails or proves to be defective, then to the extent such failure or defect is covered by warranty or guarantee provided by a third party to Landlord, Landlord shall use commercially reasonable efforts to enforce such warranty or guaranty. All repairs and other work performed by Tenant or its contractors, including that involving Cable, shall be subject to the terms of Section 9.03 below. If Tenant fails to make any repairs to the Premises for more than fifteen (15) days after notice from Landlord (although notice shall not be required in an emergency), Landlord may make the repairs and Tenant shall pay the reasonable cost of the repairs, together with an administrative charge equal to **[***]** percent (**[***]**%) of the cost of the repairs.

9.02 Landlord shall keep and maintain in good repair and working order and perform maintenance upon the: (a) Base Building; (b) mechanical (including HVAC), electrical, plumbing and fire/life safety systems serving the Building in general (the "**Building Systems**"); (c) Common Areas; (d) roof of the Building; (e) exterior windows of the Building; and (f) elevators. Tenant hereby waives any and all rights under and benefits of subsection 1 of Section 1932, and Sections 1941 and 1942 of the California Civil Code, or any similar or successor Laws now or hereafter in effect.

9.03 Tenant shall not make alterations, repairs, additions or improvements or install any Cable (collectively referred to as "**Alterations**") without first obtaining the written consent of Landlord in each instance, which consent shall not be unreasonably withheld, conditioned, or delayed. However, Landlord's consent shall not be required for any Alteration that satisfies all of the following criteria (a "**Cosmetic Alteration**"): (a) is of a cosmetic nature such as painting, wallpapering, hanging pictures and installing carpeting; (b) is not visible from the exterior of the Premises or Building; (c) will not affect the Base Building (defined in Section 5); (d) does not require work to be performed inside the walls or above the ceiling of the Premises; (e) will not create excessive noise or result in the dispersal of odors or debris (including dust or airborne particulate matter); (f) costs less than $25,000.00; and (g) does not require the issuance of a construction permit. Cosmetic Alterations shall be subject to all the other provisions of this Section 9.03. Prior to starting any work (other than a Cosmetic Alteration), Tenant shall furnish Landlord with a proposed schedule for work and detailed plans and specifications (which shall be in CAD format if requested by Landlord) prepared by a duly licensed architect or engineer; names of contractors reasonably acceptable to Landlord (provided that Landlord may designate specific contractors with respect to Base Building, Building Systems and vertical Cable, as may be described more fully below); required permits and approvals; evidence of contractor's and subcontractor's insurance in form and amounts reasonably required by Landlord and any security for performance in amounts reasonably required by Landlord. Landlord may designate specific contractors with respect to oversight, installation, repair, connection to, and removal of vertical Cable. All Cable shall be clearly marked with adhesive plastic labels (or plastic tags attached to such Cable with wire) to show Tenant's name, suite number, and the purpose of such Cable (i) every 6 feet outside the Premises (specifically including, but not limited to, the electrical room risers and any Common Areas), and (ii) at the termination point(s) of such Cable. All changes to plans and specifications must also be submitted to Landlord for its approval which shall not be unreasonably withheld, conditioned or delayed. Alterations shall be constructed in a good and workmanlike manner using materials of a quality reasonably approved by Landlord, and Tenant shall ensure that no Alteration impairs any Building system or Landlord's ability to perform its obligations hereunder. Landlord's consent may be given or withheld in Landlord's sole discretion if the proposed Alterations would (a) affect any structural component of the Building; (b) be visible from or otherwise affect any portion of the Building other than the interior of the Premises; (c) affect the Base Building or any Building Systems; (d) result in Landlord being required under any Laws to perform any work that Landlord could otherwise avoid or defer; (e) result in an increase in the demand for utilities or services that Landlord is required to provide (whether to Tenant or to any other tenant

in the Building); (f) cause an increase in any Insurance Expenses, provided Tenant does not offer to reimburse Landlord for such increase; (g) result in the disturbance or exposure of, or damage to, any ACM or other Hazardous Material (defined below); or (h) violate or result in a violation of any Law, Rule or requirement under this Lease. Tenant shall reimburse Landlord for any sums paid by Landlord for third party examination of Tenant's plans for non-Cosmetic Alterations. In addition, Tenant shall pay Landlord a fee for Landlord's oversight and coordination of any non-Cosmetic Alterations equal to **[***]** percent (**[***]**%) of the cost of such non-Cosmetic Alterations. Neither the payment of any such fees or costs, nor the monitoring, administration or control by Landlord of any contractor or any part of the Alterations shall be deemed to constitute any express or implied warranty or representation that any Alteration was properly designed or constructed, nor shall it create any liability on the part of Landlord. Landlord's approval of an Alteration shall not be deemed a representation by Landlord that the Alteration complies with Law. Upon completion of any Alteration, Tenant shall (a) furnish Landlord with "as-built" plans (in CAD format, if requested by Landlord) for non-Cosmetic Alterations, (b) cause a timely notice of completion to be recorded in the Office of the Recorder of the county in which the Building is located, in accordance with California Civil Code §8182 or any successor statute; and (c) deliver to Landlord evidence of full payment and unconditional final lien waivers for all labor, services and materials furnished in connection therewith.

10. Entry by Landlord.

Landlord may enter the Premises at reasonable times upon reasonable advance notice to Tenant (not to be less than 24 hours, except in case of emergency) to inspect, show or clean the Premises or to perform or facilitate the performance of repairs, alterations or additions to the Premises or any portion of the Building. Except in emergencies or to provide services, Landlord shall provide Tenant with prior verbal notice of entry and shall use reasonable efforts to minimize any interference with Tenant's use of the Premises. To the extent Landlord reasonably deems necessary, Landlord may temporarily close all or a portion of the Premises to perform repairs, alterations and additions. However, except in emergencies, Landlord will not close the Premises if the work can reasonably be completed on weekends and after Building Service Hours. Entry by Landlord pursuant to this Section 10 shall not constitute a constructive eviction or entitle Tenant to an abatement or reduction of Rent.

11. Assignment and Subletting.

11.01 Tenant shall not assign, sublease, transfer or encumber any interest in this Lease or allow any third party to use any portion of the Premises (collectively or individually, a "**Transfer**") without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed if Landlord does not exercise its recapture rights under Section 11.02. Without limitation, Landlord's consent shall not be considered unreasonably withheld if the proposed transferee is a governmental entity or an occupant of the Building or if the proposed transferee, whether or not an occupant of the Building, is in discussions with Landlord regarding the leasing of space within the Building. If the entity(ies) which directly or indirectly controls the voting shares/rights of Tenant (other than through the ownership of voting securities listed on a recognized securities exchange) changes at any time, such change of ownership or control shall not constitute a Transfer. Tenant hereby waives the provisions of Section 1995.310 of the California Civil Code, or any similar or successor Laws, now or hereafter in effect, and all other remedies, including, without limitation, any right at law or equity to terminate this Lease, on its own behalf and, to the extent permitted under all applicable Laws, on behalf of the proposed transferee. Any Transfer in violation of this Section shall, at Landlord's option, be deemed a Default by Tenant, and shall be voidable by Landlord. In no event shall any Transfer, including a Permitted Transfer, release or relieve Tenant from any obligation under this Lease, and Tenant shall remain primarily liable for the performance of the Tenant's obligations under this Lease, as amended from time to time.

11.02 Tenant shall provide Landlord with financial statements (prepared in accordance with generally accepted accounting principles), a reasonably detailed calculation of excess rent (described in Section 11.03 below) and company information for the proposed transferee, a fully executed copy of the proposed assignment, sublease or other Transfer documentation and such other information as Landlord may reasonably request. Within thirty (30) days after receipt of the required information and documentation, Landlord shall either: (a) consent to the Transfer by execution of Landlord's form of consent agreement; (b) reasonably refuse to consent to the Transfer in writing; or (c) in the event of an assignment of Tenant's interest in this Lease or subletting of more than fifty percent (50%) of the Rentable Area of the Premises, recapture the portion of the Premises that Tenant is proposing to Transfer. If

Landlord exercises its right to recapture, this Lease shall automatically be amended (or terminated if the entire Premises is being assigned or sublet) to delete the applicable portion of the Premises effective on the proposed effective date of the Transfer, although Landlord may require Tenant to execute a reasonable amendment or other document reflecting such reduction or termination. Concurrently with Tenant's request for a proposed Transfer, Tenant shall pay Landlord a review fee of $500.00 for Landlord's review of any requested Transfer, regardless of whether consent is granted, and thereafter Tenant shall be obligated to pay all reasonable costs incurred by Landlord in preparing the documents for any requested Transfer, including but not limited to Landlord's attorneys' fees.

11.03 Tenant shall pay Landlord fifty percent (50%) of all rent and other consideration which Tenant receives as a result of a Transfer that is in excess of the Rent payable to Landlord for the portion of the Premises and Term covered by the Transfer. Tenant shall pay Landlord for Landlord's share of the excess within thirty (30) days after Tenant's receipt of the excess. In determining the excess due Landlord, Tenant may first deduct from the excess any commercially reasonable attorneys' fees and brokerage commissions directly incurred by Tenant and attributable to the Transfer.

11.04 Notwithstanding anything to the contrary contained in this Section 11, neither Tenant nor any other person having a right to possess, use, or occupy (for convenience, collectively referred to in this subsection as "**Use**") the Premises shall enter into any lease, sublease, license, concession or other agreement for Use of all or any portion of the Premises which provides for rental or other payment for such Use based, in whole or in part, on the net income or profits derived by any person that leases, possesses, uses, or occupies all or any portion of the Premises (other than an amount based on a fixed percentage or percentages of receipts or sales), and any such purported lease, sublease, license, concession or other agreement shall be absolutely void and ineffective as a transfer of any right or interest in the Use of all or any part of the Premises.

11.05 If Tenant's interest in this Lease is assigned, Landlord may elect to collect Rent directly from the assignee. If the Premises or any part thereof is sublet or used or occupied by anyone other than Tenant, Landlord may, after any Default(s) by Tenant (or if Tenant becomes insolvent or rejects this Lease or any relevant sublease under section 365 of the Bankruptcy Code), collect from the subtenant or occupant all amounts due from such party to Tenant. Tenant hereby authorizes and directs any assignee or subtenant (a "**Transferee**") to make payments of rent or other consideration directly to Landlord upon receipt of any notice from Landlord requesting such action. Landlord may apply all such amounts collected to Rent due or coming due hereunder, and no such collection or application shall be deemed a waiver of any of Landlord's rights or remedies hereunder, or the acceptance by Landlord of such party as a permitted Transferee, or the release of Tenant or any Guarantor from any of its obligations under or in connection with this Lease. The consent by Landlord to any Transfer shall not relieve Tenant from obtaining the express written consent of Landlord to any other Transfer. The listing of any name other than that of Tenant on any door of the Premises or on any directory or in any elevator in the Building, or otherwise, or the acceptance of Rent for the Premises from any entity other than Tenant shall not operate to vest in the person so named any right or interest in this Lease or in the Premises, or be deemed to constitute, or serve as a substitute for, or any waiver of, any consent of Landlord required under this Section 11.

11.06 So long as Tenant is not entering into the Permitted Transfer for the purpose of avoiding or otherwise circumventing the remaining terms of this Article 11, Tenant may assign its entire interest in this Lease, without the consent of Landlord, to (i) an affiliate, subsidiary, or parent of Tenant, or a corporation, partnership or other legal entity wholly owned by Tenant (collectively, an "**Affiliated Party**"), or (ii) a successor to Tenant by purchase, merger, consolidation or reorganization, provided that all of the following conditions are satisfied (each such Transfer a "**Permitted Transfer**"): (1) Tenant is not in Default; (2) Tenant gives Landlord written notice at least fifteen (15) days prior to the effective date of the proposed Permitted Transfer, provided that Landlord shall sign a commercially reasonable confidentiality agreement with respect to such financial statements or information prior to such delivery; and (3) with respect to a purchase, merger, consolidation or reorganization or any other Permitted Transfer which results in Tenant ceasing to exist as a separate legal entity, (a) Tenant's successor shall own all or substantially all of the assets of Tenant, and (b) Tenant's successor shall have a net worth which is at least equal to the net worth of Tenant immediately prior to the Permitted Transfer. Tenant's notice to Landlord shall include information and documentation showing that each of the above conditions has been satisfied. If requested by Landlord, Tenant's successor shall sign a commercially reasonable form of assumption agreement. As used herein, (A) "parent" shall mean a company which owns a majority of Tenant's voting equity; (B) "subsidiary" shall mean an entity wholly owned by Tenant or at least 51% of whose voting equity is owned by Tenant; and (C) "affiliate"

shall mean an entity controlled by, controlling or under common control with Tenant. Notwithstanding the foregoing, any parent, affiliate or subsidiary to which this Lease has been assigned or transferred must comply with this Section 11 with respect to any subsequent Transfers.

12. Liens.

Tenant shall not permit mechanics' or other liens to be placed upon or otherwise encumber the Complex, Premises or Tenant's leasehold interest in connection with any work or service done or purportedly done by or for the benefit of Tenant or its transferees, or the Premises. Tenant shall give Landlord notice at least fifteen (15) days prior to the commencement of any work in the Premises to afford Landlord the opportunity, where applicable, to post and record notices of non-responsibility. Tenant, within thirty (30) days of notice from Landlord, shall fully discharge any lien by settlement, by payment of the claim, posting a proper bond, or by insuring over the lien in the manner prescribed by the applicable lien Law and, if Tenant fails to do so, which failure is not cured within 10 business days of receipt of written notice from Landlord, Tenant shall be deemed in Default and, in addition to any other remedies available to Landlord as a result of such Default, Landlord, at its option (without any duty to investigate the validity of the lien or other encumbrance), may bond, insure over or otherwise discharge the lien. Tenant shall reimburse Landlord for any amount paid by Landlord in connection therewith, including, without limitation, reasonable attorneys' fees.

13. Indemnity and Waiver of Claims.

13.01 Except to the extent caused by the negligence or misconduct of Landlord or any Landlord Related Parties (defined below), Tenant shall indemnify, protect, defend and hold Landlord and all Landlord Related Parties harmless against and from all liabilities, obligations, losses, damages, penalties, claims, actions, costs, charges and expenses, including, without limitation, reasonable attorneys' fees and other professional fees (if and to the extent permitted by Law) (collectively referred to as "**Losses**"), which may be imposed upon, incurred by or asserted against Landlord or any Landlord Related Parties by any third party to the extent arising out of or in connection with any damage or injury occurring in the Premises or any negligent or intentionally wrongful acts or omissions (including violations of Law) of Tenant, its trustees, members, principals, beneficiaries, partners, officers, directors, employees and agents (each a "**Tenant Related Party**") or any of Tenant's transferees, contractors, invitees or licensees. Tenant hereby waives all claims against and releases Landlord and its trustees, members, principals, beneficiaries, partners, officers, directors, employees, Mortgagees (defined in Section 23) and agents (the "**Landlord Related Parties**") from all claims for any injury to or death of persons, damage to property or business loss in any manner related to (a) Force Majeure, (b) acts of third parties, (c) the bursting or leaking of any tank, water closet, drain or other pipe, (d) the inadequacy or failure of any security or protective services, personnel or equipment, or (e) any matter not within the reasonable control of Landlord; provided, however the foregoing shall in no event release Landlord from any claims arising out if its gross negligence or willful misconduct.

13.02 "**Environmental Laws**" means all Laws pertaining to (a) protection of health against environmental hazards; (b) the protection of the environment, including air, soils, wetlands, and surface and underground water, from contamination by any substance that may have any adverse health effect; (c) underground storage tank regulation or removal; (d) protection or regulation of natural resources; (e) protection of wetlands or wildlife; (f) management, regulation and disposal of solid and hazardous wastes; (g) radioactive materials; (h) biologically hazardous materials; (i) indoor air quality; (j) the manufacture, possession, presence, use, generation, storage, transportation, treatment, release, emission, discharge, disposal, abatement, cleanup, removal, remediation or handling of any Hazardous Substances. Environmental Laws include the Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. §9601 et seq. ("CERCLA"); the Resource Conservation and Recovery Act, 42 U.S.C. §6901 et seq. ("RCRA"); the Federal Water Pollution Control Act, as amended by the Clean Water Act, 33 U.S.C. §1251 et seq.; the Clean Air Act, 42 U.S.C. §7401 et seq.; and the Toxic Substances Control Act, 15 U.S.C. §2601 et seq., as well as all similar state and local Laws. "**Hazardous Material**" means any substance the release of or the exposure to which is prohibited, limited or regulated by any Environmental Law, or which poses a hazard to human health because of its toxicity or other adverse effect, including (a) any "oil," as defined by the Federal Water Pollution Control Act and regulations promulgated thereunder (including crude oil or any fraction of crude oil); (b) any radioactive material, including any source, special nuclear, or byproduct material as defined in 42 United States

Code §2011 et seq.; (c) Stacchybotris chartarum and other molds; (d) asbestos containing materials ("**ACM**") in any form or condition; and (e) polychlorinated biphenyls ("**PCBs**") and any substances or compounds containing PCBs.

(a) Tenant shall not use, store or permit Hazardous Materials to be present on or about the Premises. Notwithstanding the foregoing, Tenant may keep and use, solely for maintenance and administrative purposes, small amounts of ordinary cleaning and office supplies customarily used in business offices (such as, for example, glass cleaner, carpet spot remover, and toner for Tenant's business equipment in use on the Premises), provided that Tenant complies with all Environmental Laws relating to the use, storage or disposal of all such supplies. With respect to the presence of Hazardous Materials in or about the Premises that are stored, used or permitted by Tenant or any Tenant Related Party, Tenant shall upon request from Landlord provide Material Safety Data Sheets (MSDS) in compliance with Hazard Communication Standards of the Occupational Safety & Health Administration.

(b) If the use, storage or possession of Hazardous Materials by Tenant or any Tenant Related Party on or about the Premises results in a release, discharge or disposal of Hazardous Materials on, in, at, under, or emanating from, the Premises or the Building, Tenant agrees to investigate, clean up, remove or remediate such Hazardous Materials in full compliance with (a) the requirements of all Environmental Laws, and any Governmental Authority responsible for the enforcement of any Environmental Laws; and (b) any additional requirements of Landlord that are necessary, in Landlord's reasonable discretion, to protect the value of the Premises and the Building. Landlord shall also have the right, but not the obligation, to take whatever action with respect to any such Hazardous Materials that it deems necessary, in Landlord's reasonable discretion, to protect the value of the Premises and the Building. All costs and expenses reasonably paid or incurred by Landlord in the exercise of such right shall be payable by Tenant upon written demand, itemizing such expenses with audit worthy documentation for Tenant's review.

(c) Subject to Section 10 above, Landlord may inspect the Premises for the purpose of determining whether there exists on the Premises any Hazardous Materials or other condition or activity that is in violation of the requirements of this Lease or of any Environmental Laws. The right granted to Landlord herein to perform inspections shall not create a duty on Landlord's part to inspect the Premises, or liability on the part of Landlord for Tenant's use, storage or disposal of Hazardous Materials, it being understood that Tenant shall be solely responsible for all liability in connection therewith. Tenant shall surrender the Premises to Landlord upon the expiration or earlier termination of this Lease free of debris, waste or Hazardous Materials placed on or about the Premises by Tenant or any Tenant Related Party, and in a condition that complies with all Environmental Laws.

(d) Tenant shall indemnify, defend and hold harmless Landlord from and against any and all claims, damages, liabilities, fines, judgments, penalties, costs, losses (including loss in value of the Premises or the Building, the loss of rentable or usable space, any adverse effect on marketability of the Building or any space therein, and all sums paid for settlement of claims), costs incurred in connection with any site investigation or any cleanup, removal or restoration mandated by any Governmental Authority, and expenses (including attorneys' fees, consultant and expert fees) to the extent attributable to (i) any Hazardous Materials placed on or about the Building by Tenant or any Tenant Related Party, or on or about the Premises by any party other than Landlord or Landlord Related Party, at any time during the Term, or (ii) Tenant's failure to comply with any of its obligations under this Article 13, all of which shall survive the expiration or earlier termination of this Lease.

14. Insurance.

14.01 (a) Tenant agrees that, from and after the date on which Tenant first enters into the Premises, Tenant shall carry at its sole cost and expense the following types of insurance, in the amounts specified and in the form hereinafter provided for ("**Tenant's Insurance**"):

(i) Commercial general liability insurance covering the Premises and Tenant's use thereof against claims for contractual liability, personal injury or death, and property damage, occurring upon or about the Premises, such insurance to afford protection to the limit of not less than $**[***]** per occurrence. The foregoing may be maintained using so-called "umbrella policies" provided the stated coverages are provided;

(ii) Property damage insurance against "all-risks" of physical loss covering all Tenant Improvements and Alterations, whether paid for by Landlord or Tenant, within the core and shell of the Premises, heating, ventilating and air conditioning equipment, trade fixtures, signs and personal property from time to time upon or about the Premises, providing protection against perils included within standard forms of fire and extended coverage insurance policies, together with insurance against sprinkler damage, vandalism and malicious mischief;

(iii) Business interruption insurance for a period of at least twelve (12) months;

(iv) If alcohol or other distilled beverages are provided, or otherwise available in the Premises, Tenant shall carry host liquor liability coverage in amounts reasonably required by Landlord;

(v) Worker's compensation insurance in the minimum amounts required by the State of California, and Employers' Liability Insurance in an amount not less than $**[***]** per occurrence; and

(vi) Automobile liability insurance with a minimum combined single limit of liability of at least **[***]** dollars ($**[***]**) including coverage for owned, non-owned and hired vehicles.

(b) All such policies of insurance shall be issued in form and by issuers with a rating of "A-VIII" or higher by A.M. Best in the name of Tenant and shall name Landlord, its trustees and beneficiaries, Landlord's mortgagees, Landlord's managing agent, Landlord's advisor, and their respective officers, directors, agents and employees, and any other parties designated in writing by Landlord as additional insureds with respect to the liability insurance coverage, and shall name Landlord as the loss payee, as their interests may appear, with respect to the all-risk property insurance. Such policies shall be for the mutual and joint benefit and protection of Landlord and Tenant. All liability insurance obtained by Tenant shall be primary insurance as to all claims thereunder and provide that any insurance carried by Landlord is excess and is non-contributing with any insurance requirement of Tenant and shall contain a waiver of subrogation clause in favor of Landlord. Certificates evidencing each such policy shall be delivered to Landlord no later than the date of Tenant's access to or occupancy of the Premises, and thereafter within thirty (30) days prior to the expiration of each such policy. All such policies of insurance shall contain a provision that the company writing said policy will give Landlord at least thirty (30) days' prior written notice of any cancellation, or lapse, or the effective date of any reduction in the amounts of insurance. All such commercial general liability and property damage policies shall contain a provision that Landlord (and any other party named as an additional insured under this Article), although named as an additional insured, shall nevertheless be entitled to recover under said policies for any loss occasioned to it, its servants, agents and employees by reason of the negligence of Tenant. The minimum limits of such insurance policies shall be subject to increase if Landlord shall reasonably deem it necessary for adequate protection.

(c) All of Tenant's contractors shall maintain worker's compensation, liability insurance, and property insurance and such other insurance in force and effect as may be reasonably requested by Landlord or as required by applicable law and shall provide copies of applicable insurance certificates to Landlord for review and approval prior to the commencement of any work in the Premises. Any such insurance certificate for liability coverage shall name Landlord as additional insured.

14.02 Landlord shall maintain so called All Risk property insurance on the Building in coverage terms and amounts consistent with industry standards and reasonably determined by Landlord to be necessary, together with such other insurance coverage as Landlord, in its reasonable judgment, may elect to maintain; Landlord may elect to self-insure with respect to any such coverage.

15. Subrogation.

Landlord and Tenant hereby waive any rights they may have against each other on account of any loss or damage occasioned to Landlord or Tenant, their property, the Demised Premises or, its contents, arising from any risk covered by fire and extended coverage insurance maintained by Landlord or Tenant, as the case may be. The parties hereto each, on behalf of their respective insurance companies insuring the property of either Landlord or Tenant against any such loss, waive any right of subrogation that it may have against Landlord or Tenant, and covenant to use commercially reasonable efforts to cause such insurance companies to waive any such rights of subrogation.

16. Casualty Damage.

16.01 If, as a result of fire or other casualty (each, a "**Casualty**"), all or any portion of the Premises becomes untenantable or inaccessible, Landlord, with reasonable promptness, shall cause a general contractor selected by Landlord to provide Landlord with a written estimate of the amount of time required, using standard working methods, to substantially complete the repair and restoration of the Premises and any Common Areas necessary to provide access to the Premises ("**Completion Estimate**"). Landlord shall promptly forward a copy of the Completion Estimate to Tenant. If the Completion Estimate indicates that the Premises or any Common Areas necessary to provide access to the Premises cannot be made tenantable within 270 days from the date the repair is started (when such repairs are made without the payment of overtime or other premiums), then either party shall have the right to terminate this Lease upon written notice to the other within thirty (30) days after Landlord's delivery of the Completion Estimate. Tenant, however, shall not have the right to terminate this Lease if the Casualty was caused by the negligence or intentional misconduct of Tenant or any Tenant Related Parties. In addition, Landlord, by notice delivered to Tenant within ninety (90) days after the date of the Casualty, shall have the right to terminate this Lease if the Building or Complex shall be damaged by Casualty, whether or not the Premises are affected, and one or more of the following conditions is present: (1) in Landlord's reasonable judgment, repairs cannot reasonably be completed within two hundred seventy (270) days from the date the repairs are started (when such repairs are made without the payment of overtime or other premiums); (2) any Mortgagee requires that the insurance proceeds or a substantial portion thereof be applied to the payment of the mortgage debt; (3) the material damage is not fully covered by Landlord's insurance policies provided Landlord maintained the insurance required by this Lease; or (4) the damage occurs during the last twelve (12) months of the Term.

16.02 If this Lease is not terminated, Landlord shall promptly and diligently, subject to reasonable delays for insurance adjustment or other matters beyond Landlord's reasonable control, restore the Premises and Common Areas. Such restoration shall be to substantially the same condition that existed prior to the Casualty, except for modifications required by Law or any other modifications to the Common Areas reasonably deemed desirable by Landlord. Upon notice from Landlord, Tenant shall assign or endorse over to Landlord (or to any party designated by Landlord) all property insurance proceeds payable to Tenant under Tenant's Insurance with respect to any Leasehold Improvements performed by or for the benefit of Tenant; provided if the estimated cost to repair such Leasehold Improvements exceeds the amount of insurance proceeds received by Landlord from Tenant's insurance carrier, the excess cost of such repairs shall be paid by Tenant to Landlord prior to Landlord's commencement of repairs. Within 15 days of demand, Tenant shall also pay Landlord for any additional excess costs that are determined during the performance of the repairs to such Leasehold Improvements. In no event shall Landlord be required to spend more for the restoration of the Premises and Common Areas than the proceeds received by Landlord, whether insurance proceeds under Landlord's insurance or insurance proceeds or other amounts received from Tenant, unless such shortfall is a result of Landlord's noncompliance with any obligation under this Lease. Landlord shall not be liable for any inconvenience to Tenant, or injury to Tenant's business resulting in any way from the Casualty or the repair thereof. Provided that Tenant is not in Default, during any period of time that all or a material portion of the Premises is rendered untenantable as a result of a Casualty, the Rent shall abate for the portion of the Premises that is untenantable.

16.03 The provisions of this Section 16 constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises or the Complex, and any Laws, including, without limitation, Sections 1932(2) and 1933(4) of the California Civil Code, with respect to any rights or obligations concerning damage or destruction in the absence of an express agreement between the parties, and

any similar or successor Laws now or hereafter in effect, shall have no application to this Lease or any damage or destruction to all or any part of the Premises or the Complex.

17. Condemnation.

Either party may terminate this Lease if any material part of the Premises is taken or condemned for any public or quasi-public use under Law, by eminent domain or private purchase in lieu thereof (a "**Taking**"). Landlord shall also have the right to terminate this Lease if there is a Taking of any portion of the Building or Complex which would have a material adverse effect on Landlord's ability to profitably operate the remainder of the Building. The terminating party shall provide written notice of termination to the other party within thirty (30) days after it first receives notice of the Taking. The termination shall be effective as of the effective date of any order granting possession to, or vesting legal title in, the condemning authority. If this Lease is not terminated, Base Rent and Tenant's Share shall be appropriately adjusted to account for any reduction in the square footage of the Building or Premises. All compensation awarded for a Taking shall be the property of Landlord. The right to receive compensation or proceeds are expressly waived by Tenant, provided, however, Tenant may file a separate claim for Tenant's Property and Tenant's reasonable relocation expenses, provided the filing of the claim does not diminish the amount of Landlord's award. If only a part of the Premises is subject to a Taking and this Lease is not terminated, Landlord, with reasonable diligence, will restore the remaining portion of the Premises as nearly as practicable to the condition immediately prior to the Taking. Tenant hereby waives any and all rights it might otherwise have pursuant to Section 1265.130 of the California Code of Civil Procedure, and any similar or successor Laws.

18. Events of Default.

In addition to any other default specifically described in this Lease, each of the following occurrences shall be a "**Default**": (a) Tenant's failure to pay any portion of Rent when due, if the failure continues for five (5) days after written notice to Tenant ("**Monetary Default**"); (b) Tenant's failure (other than a Monetary Default) to comply with any term, provision, condition or covenant of this Lease, if the failure is not cured within thirty (30) days after written notice to Tenant; provided, however, if Tenant's failure to comply cannot reasonably be cured within thirty (30) days, Tenant shall be allowed additional time (not to exceed sixty (60) days) as is reasonably necessary to cure the failure so long as Tenant begins the cure within thirty (30) days and diligently pursues the cure to completion; (c) Tenant permits a Transfer without Landlord's required approval or otherwise in violation of Section 11 of this Lease; (d) Tenant becomes insolvent, makes a transfer in fraud of creditors, makes an assignment for the benefit of creditors, admits in writing its inability to pay its debts when due or forfeits or loses its right to conduct business; (e) the leasehold estate is taken by process or operation of Law; or (f) in the case of any ground floor or retail Tenant, Tenant does not take possession of or abandons or vacates all or any portion of the Premises. If Landlord provides Tenant with notice of Tenant's failure to comply with any specific provision of this Lease on three (3) or more occasions during any twelve (12) month period, Tenant may, as Landlord's option, lose any renewal and/or expansion options. All notices sent under this Section shall be in satisfaction of, and not in addition to, notice required by Law. Tenant acknowledges that its obligation to pay Rent hereunder is a condition as well as a covenant, and that such obligation is independent of any and all covenants of Landlord hereunder except as otherwise specifically provided in this Lease. Tenant waives any rights of redemption or relief from forfeiture under California Code of Civil Procedure sections 1174 and 1179, or under any other applicable present or future Law, if Tenant is evicted or Landlord takes possession of the Premises by reason of any Default.

19. Remedies.

19.01 Upon the occurrence of any Default under this Lease, whether enumerated in Section 18 or not, Landlord shall have the option to pursue any one or more of the following remedies without any notice (except as expressly prescribed herein) or demand whatsoever (and without limiting the generality of the foregoing, Tenant hereby specifically waives notice and demand for payment of Rent or other obligations, except for those notices specifically required pursuant to the terms of Section 18 or this Section 19, and waives any and all other notices or demand requirements imposed by applicable Law):

(a) Terminate this Lease and Tenant's right to possession of the Premises and recover from Tenant an award of damages in accordance with section 1951.2 of the California Civil Code or any successor statute as well as any such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time under applicable law.

(b) Employ the remedy described in California Civil Code § 1951.4 (Landlord may continue this Lease in effect after Tenant's breach and abandonment and recover Rent as it becomes due, if Tenant has the right to sublet or assign, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease on account of any Default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies under this Lease, including the right to recover all Rent as it becomes due; or

(c) Notwithstanding Landlord's exercise of the remedy described in California Civil Code § 1951.4 in respect of an event or events of default, at such time thereafter as Landlord may elect in writing, to terminate this Lease and Tenant's right to possession of the Premises and recover an award of damages as provided above in Paragraph 19.01(a).

19.02 The subsequent acceptance of Rent hereunder by Landlord shall not be deemed to be a waiver of any preceding breach by Tenant of any term, covenant or condition of this Lease, other than the failure of Tenant to pay the particular Rent so accepted, regardless of Landlord's knowledge of such preceding breach at the time of acceptance of such Rent. No waiver by either party of any breach hereof shall be effective unless such waiver is in writing and signed by the waiving party.

19.03 TENANT HEREBY WAIVES ANY AND ALL RIGHTS CONFERRED BY SECTION 3275 OF THE CIVIL CODE OF CALIFORNIA AND BY SECTIONS 1174 (c) AND 1179 OF THE CODE OF CIVIL PROCEDURE OF CALIFORNIA AND ANY AND ALL OTHER LAWS AND RULES OF LAW FROM TIME TO TIME IN EFFECT DURING THE LEASE TERM OR THEREAFTER PROVIDING THAT TENANT SHALL HAVE ANY RIGHT TO REDEEM, REINSTATE OR RESTORE THIS LEASE FOLLOWING ITS TERMINATION BY REASON OF TENANT'S BREACH.

THE PARTIES HEREBY WAIVE, TO THE FULLEST EXTENT PERMITTED BY LAW, THE RIGHT TO TRIAL BY JURY IN ANY LITIGATION ARISING OUT OF OR RELATING TO THIS LEASE. IF THE JURY WAIVER PROVISIONS OF THIS SECTION 19.03 ARE NOT ENFORCEABLE UNDER CALIFORNIA LAW, THEN THE FOLLOWING PROVISIONS SHALL APPLY. It is the desire and intention of the parties to agree upon a mechanism and procedure under which controversies and disputes arising out of this Lease or related to the Premises will be resolved in a prompt and expeditious manner. Accordingly, except with respect to actions for unlawful or forcible detainer or with respect to the prejudgment remedy of attachment, any action, proceeding or counterclaim brought by either party hereto against the other (and/or against its officers, directors, employees, agents or subsidiaries or affiliated entities) on any matters whatsoever arising out of or in any way connected with this Lease, Tenant's use or occupancy of the Premises and/or any claim of injury or damage, whether sounding in contract, tort, or otherwise, shall be heard and resolved by a referee under the provisions of the California Code of Civil Procedure, Sections 638 — 645.1, inclusive (as same may be amended, or any successor statute(s) thereto) (the "**Referee Sections**"). Any fee to initiate the judicial reference proceedings and all fees charged and costs incurred by the referee shall be paid by the party initiating such procedure (except that if a reporter is requested by either party, then a reporter shall be present at all proceedings where requested and the fees of such reporter – except for copies ordered by the other parties – shall be borne by the party requesting the reporter); provided however, that allocation of the costs and fees, including any initiation fee, of such proceeding shall be ultimately determined in accordance with Section 26.02 below. The venue of the proceedings shall be in the county in which the Premises are located. Within 10 days of receipt by any party of a written request to resolve any dispute or controversy pursuant to this Section 19.03, the parties shall agree upon a single referee who shall try all issues, whether of fact or law, and report a finding and judgment on such issues as required by the Referee Sections. If the parties are unable to agree upon a referee within such 10 day period, then any party may thereafter file a lawsuit in the county in which the Premises are located for the purpose of appointment of a referee under the Referee Sections. If the referee is appointed by the court, the referee shall be a neutral and impartial retired judge with substantial experience in the relevant matters to be determined, from Jams/Endispute, Inc., the American Arbitration Association or similar mediation/arbitration entity. The proposed referee may be challenged by any party for any of the grounds listed in

the Referee Sections. The referee shall have the power to decide all issues of fact and law and report his or her decision on such issues, and to issue all recognized remedies available at Law or in equity for any cause of action that is before the referee, including an award of attorneys' fees and costs in accordance with this Lease. The referee shall not, however, have the power to award punitive damages, nor any other damages which are not permitted by the express provisions of this Lease, and the parties hereby waive any right to recover any such damages. The parties shall be entitled to conduct all discovery as provided in the California Code of Civil Procedure, and the referee shall oversee discovery and may enforce all discovery orders in the same manner as any trial court judge, with rights to regulate discovery and to issue and enforce subpoenas, protective orders and other limitations on discovery available under California law. The reference proceeding shall be conducted in accordance with California law (including the rules of evidence), and in all regards, the referee shall follow California law applicable at the time of the reference proceeding. The parties shall promptly and diligently cooperate with one another and the referee, and shall perform such acts as may be necessary to obtain a prompt and expeditious resolution of the dispute or controversy in accordance with the terms of this Section 19.03. In this regard, the parties agree that the parties and the referee shall use best efforts to ensure that (a) discovery be conducted for a period no longer than 6 months from the date the referee is appointed, excluding motions regarding discovery, and (b) a trial or arbitration date be set within 9 months of the date the referee is appointed. In accordance with Section 644 of the California Code of Civil Procedure, the decision of the referee upon the whole issue must stand as the decision of the court, and upon the filing of the statement of decision with the clerk of the court, or with the judge if there is no clerk, judgment may be entered thereon in the same manner as if the action had been tried by the court. Any decision of the referee and/or judgment or other order entered thereon shall be appealable to the same extent and in the same manner that such decision, judgment, or order would be appealable if rendered by a judge of the superior court in which venue is proper hereunder. The referee shall in his/her statement of decision set forth his/her findings of fact and conclusions of law. The parties intend this general reference agreement to be specifically enforceable in accordance with the Code of Civil Procedure. Nothing in this Section 19.03 shall prejudice the right of any party to obtain provisional relief or other equitable remedies from a court of competent jurisdiction as shall otherwise be available under the Code of Civil Procedure and/or applicable court rules.

19.04 No right or remedy herein conferred upon or reserved to either party is intended to be exclusive of any other right or remedy unless expressly stated otherwise, and each and every right and remedy shall be cumulative and in addition to any other right or remedy given hereunder or now or hereafter existing by agreement, applicable Law or in equity. In addition to other remedies provided in this Lease, Landlord may be entitled, to the extent permitted by applicable Law, to seek injunctive relief, or to seek a decree compelling performance of any of the covenants, agreements, conditions or provisions of this Lease, or to seek any other remedy allowed to Landlord at law or in equity. Forbearance by Landlord to enforce one or more of the remedies herein provided upon any Default shall not be deemed or construed to constitute a waiver of such Default.

19.05 If Tenant is in Default of any of its non-monetary obligations under the Lease beyond applicable notice and cure periods, Landlord shall have the right to perform such obligations. Tenant shall reimburse Landlord for the cost of such performance upon demand together with an administrative charge equal to **[***]** percent (**[***]**%) of the cost of the work performed by Landlord.

19.06 No act of Landlord or of any Landlord Related Party, including Landlord's acceptance of the keys to the Premises, shall constitute Landlord's acceptance of a surrender or abandonment of the Premises by Tenant prior to the expiration of the Term unless such acceptance is expressly acknowledged by Landlord in a written agreement executed by both parties.

19.07 This Section 19 shall be enforceable to the maximum extent such enforcement is not prohibited by applicable Law, and the unenforceability of any portion thereof shall not thereby render unenforceable any other portion.

20. Landlord Default; Limitation of Liability.

20.1 Landlord shall be in default hereunder (a "**Landlord Default**") if Landlord has not commenced and pursued with reasonable diligence the cure of any failure of Landlord to meet its obligations hereunder within thirty (30) days after the receipt by Landlord of written notice from Tenant of the alleged failure to perform, which notice

must be delivered by Tenant in accordance with the notice provisions of Section 24, provided that notice will be deemed to have been given, even if not delivered in accordance with Section 24, if Landlord acknowledges in writing the receipt of such notice. In no event shall Tenant have the right to terminate or rescind this Lease as a result of any Landlord Default as to any covenant or agreement contained in this Lease. Tenant hereby waives such remedies of termination and rescission and hereby agrees that Tenant's remedies for any Landlord Default hereunder and for breach of any promise or inducement shall be limited to a suit for damages and/or injunction. In addition, Tenant hereby covenants that, prior to the exercise of any such remedies, it will use reasonable efforts to mitigate its damages and losses arising from any Landlord Default.

20.2 NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS LEASE, THE LIABILITY OF LANDLORD (AND OF ANY SUCCESSOR LANDLORD) SHALL BE LIMITED TO THE LESSER OF (A) THE INTEREST OF LANDLORD IN THE PROPERTY, OR (B) THE EQUITY INTEREST LANDLORD WOULD HAVE IN THE PROPERTY IF THE PROPERTY WERE ENCUMBERED BY THIRD PARTY DEBT IN AN AMOUNT EQUAL TO 50% OF THE VALUE OF THE PROPERTY. TENANT SHALL LOOK SOLELY TO LANDLORD'S INTEREST IN THE PROPERTY FOR THE RECOVERY OF ANY JUDGMENT OR AWARD AGAINST LANDLORD OR ANY LANDLORD RELATED PARTY. NEITHER ANY LIMITED PARTNER OF LANDLORD NOR ANY LANDLORD RELATED PARTY SHALL BE PERSONALLY LIABLE FOR ANY JUDGMENT OR DEFICIENCY, AND IN NO EVENT SHALL LANDLORD OR ANY LANDLORD RELATED PARTY BE LIABLE TO TENANT FOR ANY LOST PROFIT, DAMAGE TO OR LOSS OF BUSINESS OR ANY FORM OF SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGE. BEFORE FILING SUIT FOR AN ALLEGED DEFAULT BY LANDLORD, TENANT SHALL GIVE LANDLORD AND THE MORTGAGEE(S) WHOM TENANT HAS BEEN NOTIFIED HOLD MORTGAGES (DEFINED IN SECTION 23 BELOW), WRITTEN NOTICE AND THIRTY (30) DAYS TO CURE THE ALLEGED DEFAULT, AND LANDLORD SHALL NOT BE IN DEFAULT UNDER THIS LEASE UNLESS LANDLORD AND THE MORTGAGEE(S) HAVE FAILED TO CURE OR COMMENCE TO CURE OF SUCH ALLEGED DEFAULT WITHIN THE PERIOD SET FORTH IN SECTION 20.1 ABOVE.

21. Relocation.

Landlord, at its expense, once during the Term upon not less than sixty (60) days' prior written notice to Tenant (a "**Relocation Notice**"), may relocate Tenant from the Premises to space that (i) is the same or larger size, (ii) has equal or superior finishes, and (iii) has a substantially similar configuration and layout with at least the same number of offices and space for the same number of non-office stations (such that Tenant's furniture may be utilized in such space) ("**Relocation Space**") within the Complex. Notwithstanding the foregoing sentence, Landlord may not relocate Tenant during the final twenty-four months of the Term; provided, however, that Landlord may relocate Tenant in accordance with this Section 21 during the final twenty-four months of the Term if Tenant and Landlord have agreed in principle to (1) extend the Term at least thirty-six (36) months after the Termination Date, or (2) execute a separate lease agreement governing Tenant's occupancy of the Relocation Space for at least thirty-six (36) months after the Termination Date. Tenant shall not be obligated to pay any additional Base Rent or Additional Rent regardless of whether the Relocation Space is larger. Landlord shall pay all of Tenant's reasonable costs of relocation which amount shall include, without limitation all costs for moving and installing Tenant's furniture, equipment, supplies and other personal property, the installation of computer systems and telecommunication systems, internal costs due to the relocation, including notifying customers of the change of address and data entry, the cost of printing and distributing change of address notices to Tenant's customers and one month's supply of stationery showing the new address. Notwithstanding the forgoing, if Tenant in its good faith discretion finds the Relocated Space unacceptable or the move would unduly burden Tenant's business operations, then Tenant shall have the right, exercisable by delivery of written notice to Landlord (a "**Relocation Termination Notice**") within fifteen (15) days following delivery to Tenant of a Relocation Notice, to terminate this Lease, in which event Tenant shall vacate and surrender the Premises to Landlord in accordance with this Lease on or before effective date of such relocation, and this Lease shall terminate upon such relocation date; provided, further, upon receipt of a Relocation Termination Notice from Tenant, Landlord shall have the right, exercisable upon delivery of written notice to Tenant to rescind its Relocation Notice and Tenant's right to terminate this Lease.

22. Holding Over.

If Tenant fails to surrender all or any part of the Premises at the termination of this Lease, occupancy of the Premises after termination shall be that of a tenancy at sufferance. Tenant's occupancy shall be subject to all the terms and provisions of this Lease, and Tenant shall pay an amount (on a per month basis without reduction for partial months during the holdover) equal to 150% of the sum of the Base Rent and Additional Rent in effect immediately preceding such termination for the first thirty (30) days of such holding over and 200% for any such holding over which exceeds thirty (30) days. No holdover by Tenant or payment by Tenant after the termination of this Lease shall be construed to extend the Term or prevent Landlord from immediate recovery of possession of the Premises by summary proceedings or otherwise. If Landlord is unable to deliver possession of the Premises to a new tenant or to perform improvements for a new tenant as a result of Tenant's holdover beyond thirty (30) days, then Tenant shall be liable for any and all damages, fees, and/or costs incurred or to be incurred (including consequential damages) that Landlord suffers from the holdover.

23. Subordination to Mortgages; Estoppel Certificate.

Tenant accepts this Lease subject and subordinate to any mortgage(s), deed(s) of trust, ground lease(s) or other lien(s) now or subsequently arising upon the Premises, the Building or the Complex, and to renewals, modifications, refinancings and extensions thereof (collectively referred to as a "**Mortgage**"). The party having the benefit of a Mortgage shall be referred to as a "**Mortgagee**". This clause shall be self-operative, but upon request from a Mortgagee, Tenant shall execute Mortgagee's standard form subordination agreement in favor of the Mortgagee. As an alternative, a Mortgagee shall have the right at any time to subordinate its Mortgage to this Lease. Upon request, Tenant, without charge, shall attorn to any successor to Landlord's interest in this Lease. Tenant shall, within ten (10) Business Days after receipt of a written request from Landlord, execute and deliver a subordination agreement and/or estoppel certificate to those parties as are reasonably requested by the other (including a Mortgagee or prospective purchaser). Without limitation, such estoppel certificate may include a certification as to the status of this Lease, the existence of any defaults and the amount of Rent that is due and payable. Tenant acknowledges its obligation to pay an administration fee at a daily rate of $50.00 for each day that Tenant is late in providing any such subordination agreement or estoppel certificate (or a daily rate of $100.00 for both), commencing on the eleventh (11th) day following Landlord's request therefor. If Tenant has not provided any such subordination agreement or estoppel certificate within twenty (20) days following Tenant's receipt of Landlord's written request therefor, Tenant hereby appoints Landlord as Tenant's attorney-in-fact, which appointment is coupled with an interest, to execute, acknowledge and deliver any such subordination agreement or estoppel certificate for and on behalf of Tenant, without any liability on the part of Landlord for the accuracy of any information contained therein, and Tenant shall thereupon be deemed to have acknowledged the accuracy of all information set forth therein for the benefit of Landlord, any current or prospective Mortgagee, or any prospective purchaser of any interest of Landlord in the Building. However, if any such party is unwilling to rely on such subordination agreement or estoppel certificate from Landlord (or if Landlord is unwilling for any reason to execute such subordination agreement or estoppel certificate as attorney-in-fact for Tenant), the daily administration fee described herein shall continue until such time as Tenant has provided the subordination agreement or estoppel certificate as originally requested.

24. Notice.

All demands, approvals, consents or notices (collectively referred to as a "**notice**") shall be in writing and delivered by hand or sent by registered, express, or certified mail, with return receipt requested or with delivery confirmation requested from the U.S. postal service, or sent by overnight or same day courier service at the party's respective Notice Address(es) set forth in Section 1; provided, however, notices sent by Landlord regarding general Building operational matters may be posted in the Building mailroom or the general Building newsletter or sent via e-mail to the e-mail address provided by Tenant to Landlord for such purpose. In addition, if the Building is closed (whether due to emergency, governmental order or any other reason), then any notice address at the Building shall not be deemed a required notice address during such closure, and, unless Tenant has provided an alternative valid notice address to Landlord for use during such closure, any notices sent during such closure may be sent via e-mail or in any other practical manner reasonably designed to ensure receipt by the intended recipient. Each notice shall be deemed to have been received on the earlier to occur of actual delivery or the date on which delivery is refused, or, if Tenant has vacated the Premises or any other Notice Address of Tenant without providing a new Notice

Address, 3 days after notice is deposited in the U.S. mail or with a courier service in the manner described above. Either party may, at any time, change its Notice Address (other than to a post office box address) by giving the other party written notice of the new address.

25. Surrender of Premises.

At the termination of this Lease or Tenant's right of possession, Tenant shall remove Tenant's Property and any and all Required Removables from the Premises, and quit and surrender the Premises to Landlord, broom clean, and in good order, condition and repair, ordinary wear and tear and damage which Landlord is obligated to repair hereunder excepted. If Tenant fails to remove any of Tenant's Property or Required Removables, or to restore the Premises to the required condition as of the date of termination of this Lease or Tenant's right to possession of the Premises, Landlord, at Tenant's sole cost and expense, shall be entitled (but not obligated) to remove and/or store Tenant's Property and Required Removables, as the case may be, and/or perform such restoration of the Premises. Landlord shall not be responsible for the value, preservation or safekeeping of Tenant's Property. Tenant shall pay Landlord the reasonable expenses and storage charges incurred. If Tenant fails to remove Tenant's Property from the Premises or storage, within thirty (30) days after notice, Landlord may deem all or any part of Tenant's Property to be abandoned and, at Landlord's option, title to Tenant's Property shall vest in Landlord or Landlord may dispose of Tenant's Property in any manner Landlord deems appropriate.

26. Miscellaneous.

26.01 This Lease shall be interpreted and enforced in accordance with the Laws of the State of California and Landlord and Tenant hereby irrevocably consent to the jurisdiction and proper venue of California. In addition to any methods of service of process provided for under applicable law, all service of process in any proceeding in any California state or United States court sitting in the county where the Premises are located, may be made by certified or registered mail, return receipt requested, to the Tenant's Notice Address, and service so made shall be complete upon receipt; except that if Tenant shall refuse to accept delivery, service shall be deemed complete on the date such delivery was attempted and refused.

26.02 If Landlord utilizes the services of an attorney due to Tenant's failure to pay Rent when due or otherwise comply with the provisions of this Lease, then Tenant shall be required to pay Additional Rent in an amount equal to the actual attorneys' fees and costs actually incurred by Landlord in connection therewith irrespective of whether any legal action or proceeding may be commenced or filed by Landlord. Notwithstanding the foregoing, in any action or proceeding between Landlord and Tenant, including any appellate or alternative dispute resolution proceeding, the prevailing party shall be entitled to recover from the non-prevailing party all of its costs and expenses in connection therewith, including, but not limited to, reasonable attorneys' fees actually incurred. Any such fees and other expenses incurred by either party in enforcing a judgment in its favor under this Lease shall be recoverable separately from and in addition to any other amount included in such judgment, and such obligation is intended to be severable from the other provisions of this Lease and to survive and not be merged into any such judgment.

26.03 No failure by either party to declare a default immediately upon its occurrence, nor any delay by either party in taking action for a default, nor Landlord's acceptance of Rent with knowledge of a Default by Tenant, shall constitute a waiver of the Default, nor shall it constitute an estoppel.

26.04 Whenever a period of time is prescribed for the taking of an action by Landlord or Tenant, the period of time for the performance of such action shall be extended by the number of days that the performance is actually delayed due to strikes, acts of God, shortages of labor or materials, war, terrorist acts, pandemics, civil disturbances and other causes beyond the reasonable control of Landlord or Tenant, as the case may be, except with respect to the obligations imposed with regard to Rent and other charges to be paid by Tenant pursuant to this Lease ("**Force Majeure**").

26.05 Landlord shall have the right to transfer and assign its rights and obligations under this Lease and in the Building and Complex. Upon transfer, Landlord shall be released from any further obligations hereunder and Tenant agrees to look solely to the successor in interest of Landlord for the performance of such obligations,

provided that any successor pursuant to a voluntary, third party transfer (but not as part of an involuntary transfer resulting from a foreclosure or deed in lieu thereof) shall have assumed Landlord's obligations under this Lease.

26.06 Landlord has delivered a copy of this lease to Tenant for Tenant's review only and the delivery of it does not constitute an offer to Tenant or an option. Tenant represents that it has dealt directly with and only with Tenant's Broker as a broker in connection with this Lease. Tenant shall defend, indemnify and hold Landlord and the Landlord Related Parties harmless from all claims of any other brokers claiming to have represented Tenant in connection with this Lease. Landlord shall defend, indemnify and hold Tenant and the Tenant Related Parties harmless from all claims of any brokers claiming to have represented Landlord in connection with this Lease.

26.07 Landlord, at Landlord's cost, shall provide initial "Building Standard" signage at the main lobby directory and at the entrance to the Premises identifying Tenant; any replacements of or changes to such signage shall be at Tenant's sole cost and expense. Tenant shall not place or permit to be placed any lights, decorations, banners, signs, window or door lettering, advertising media, or any other item that can be viewed from the exterior of the Premises without obtaining Landlord's prior written consent, which may be withheld in Landlord's sole discretion. Subject to the foregoing, Tenant shall have the right to install custom signage in the Premises; any such signage shall be a Required Removable. By no later than the Termination Date (or earlier the date of any earlier termination of this Lease), Tenant shall repair any damage to the Premises or the Building caused by any installation, maintenance or removal of signage, all at Tenant's expense. If any such items are installed without Landlord's consent, or are not timely removed, or repairs are not timely made, Landlord shall have the right (but not the obligation) to remove any or all of such items and/or repair any such damage or injury, all at Tenant's sole cost and expense.

26.08 Time is of the essence of each and every term, condition and provision of this Lease in which time of performance is a factor. The parties agree that notwithstanding any Law to the contrary, Landlord has no duty to notify Tenant that Tenant has failed to give any notice that Tenant has the right to give under the Lease, including notice of the exercise of any option.

26.09 Tenant may peacefully have, hold and enjoy the Premises, subject to the terms of this Lease, provided Tenant pays the Rent and fully performs all of its covenants and agreements. This covenant shall be binding upon Landlord and its successors only during its or their respective periods of ownership of the Building.

26.10 This Lease does not grant any rights to light or air over or about the Building. Landlord excepts and reserves exclusively to itself any and all rights not specifically granted to Tenant under this Lease. Landlord reserves the right to make changes to the Complex, Building and Common Areas as Landlord deems appropriate.

26.11 If Tenant comprises more than one person, all such persons shall be jointly and severally liable for payment of Rent and the performance of Tenant's obligations hereunder. If Tenant is a partnership, all current and future general partners of Tenant shall be jointly and severally liable for such obligations. No individual partner or other person shall be deemed to be released from its obligations hereunder except to the extent any such release is expressly set forth in a written agreement executed by Landlord in the exercise of its sole discretion. If there is more than one Tenant or if Tenant is comprised of more than one party or entity, requests or demands from any one person or entity comprising Tenant shall be deemed to have been made by all such persons or entities. Notices to any one person or entity shall be deemed to have been given to all persons and entities.

26.12 Tenant represents, warrants and covenants that:

(a) Tenant and its principals are not acting, and will not act, directly or indirectly, for or on behalf of any person, group, entity, or nation named by any Executive Order or the United States Treasury Department as a terrorist, "Specially Designated and Blocked Person," or other banned or blocked person, entity, nation, or transaction pursuant to any law, order, rule, or regulation that is enforced or administered by the Office of Foreign Assets Control;

(b) Tenant and its principals are not engaged, and will not engage, in this transaction, directly or indirectly, on behalf of, or instigating or facilitating, and will not instigate or facilitate, this transaction, directly or indirectly, on behalf of, any such person, group, entity, or nation; and

(c) Tenant acknowledges that the breach of this representation, warranty and covenant by Tenant shall be an immediate Default under the Lease.

26.13 If any term or provision of this Lease shall to any extent be void or unenforceable, the remainder of this Lease shall not be affected. Tenant represents and warrants to Landlord, and agrees, that each individual executing this Lease on behalf of Tenant is authorized to do so on behalf of Tenant and that the entity(ies) or individual(s) constituting Tenant or Tenant's guarantor, if any, or which may own or control Tenant or Tenant's guarantor or which may be owned or controlled by Tenant or Tenant's guarantor are not and at no time will be (i) in violation of any Laws relating to terrorism or money laundering, or (ii) among the individuals or entities identified on any list compiled pursuant to Executive Order 13224 for the purpose of identifying suspected terrorists or on the most current list published by the U.S. Treasury Department Office of Foreign Assets Control at its official website or other replacement official publication of such list.

26.14 This Lease has been negotiated at arms' length between persons knowledgeable in business and real estate matters who have had the opportunity to confer with counsel in the negotiation hereof. Accordingly, any rule of law or legal decision that would require interpretation of this Lease against the party that drafted it is not applicable and is waived, and this Lease shall be given a fair and reasonable interpretation in accordance with the meaning of its terms. References in this Lease to articles, sections, paragraphs or exhibits pertain to articles, sections, paragraphs and exhibits of this Lease unless otherwise specified. The word "including" means "including, without limitation." The word "or" means "and/or" unless the context clearly indicates an obligation to choose one of two or more alternatives. The word "person" includes legal entities as well as natural persons. The word "may" means "may, but shall not be required to." Unless otherwise expressly specified in the applicable provisions, the phrase "at any time" means "at any time and from time to time." The article, section and paragraph headings in this Lease are solely for convenience of reference and shall not constitute a part of this Lease, nor shall they affect the meaning, construction or effect hereof. All terms and words used in this Lease, regardless of the number or gender in which they are used, shall be deemed to include the appropriate number and gender, as the context may require. Any reference to any specific statute, ordinance or other Law shall be deemed to include any amendments thereto, or any successor or similar Law addressing the same subject matter.

26.15 Neither this Lease, nor any memorandum, affidavit or other writing with respect thereto, shall be recorded by Tenant, by any Tenant Related Party, or by any other person except Landlord. Any such recording in violation of this Section 26.16 shall constitute a Default.

26.16 Within ten (10) days after written request from Landlord from time to time during the Term, but not more frequently than once per calendar year unless in connection with any financing, refinancing or sale of the Building, Tenant shall provide Landlord with current financial statements and a statement of Tenant's cash flow setting forth Tenant's financial condition and net worth for the most recent quarter, including balance sheets and statements of profits and losses. Such statements shall be prepared in accordance with generally accepted accounting principles certified by Tenant's president, chief executive officer or chief financial officer. Landlord shall keep such financial information confidential and shall only disclose such information to Landlord's lenders, consultants, purchasers or investors, or other agents (who shall be subject to the same confidentiality obligations) on a need to know basis in connection with the administration of this Lease.

26.17 This Lease shall only become effective and binding upon full execution hereof by both parties and delivery of a signed copy to both parties. This Lease may be executed in one or more counterparts, and each of which, so executed, shall be deemed to be an original, and all such counterparts together shall constitute one and the same instrument. This Lease may be executed in so-called "pdf" format and each party has the right to rely upon a pdf counterpart of this Lease signed by the other party to the same extent as if such party had received an original counterpart.

26.18 This Lease constitutes the final, complete and exclusive statement among the parties hereto, supersedes all prior and contemporaneous understandings or agreements of the parties, and is binding on and, subject to the provisions herein, inures to the benefit of their respective heirs, representatives, successors and assigns. No party has been induced to enter into this Lease by, nor is any party relying on, any representation or warranty outside those expressly set forth in this Lease. Any agreement made after the date of this Lease is ineffective to modify,

waive, or terminate this Lease, in whole or in part, unless such agreement is in writing, signed by the parties to this Lease, and specifically states that such agreement modifies this Lease.

26.19 Tenant acknowledges that Tenant has received the asbestos notification letter attached to this Lease as **Exhibit H** hereto, disclosing the existence of asbestos in the Building. As part of Tenant's obligations under this Lease, Tenant agrees to comply with the California "Connelly Act" and other applicable laws, including providing copies of Landlord's asbestos notification letter to all of Tenant's "employees" and "owners," as those terms are defined in the Connelly Act and other applicable laws.

26.20 The Premises have not been issued a disability access inspection certificate or undergone inspection by a Certified Access Specialist ("CASp"). The following notice is given pursuant to California Civil Code Section 1938: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." Landlord and Tenant hereby agree that if Tenant elects to perform a CASp inspection of the Premises, Tenant will provide written notice to Landlord, and Landlord may elect, in Landlord's sole discretion, to retain a CASp to perform the inspection. If Landlord does not so elect, the time and manner of the CASp inspection is subject to the prior written approval of Landlord. In either event, the payment of the fee for the CASp inspection shall be borne by Tenant. The cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises shall be allocated as provided in Section 5 of this Lease.

26.21 In the performance of this Lease, Tenant covenants and agrees not to discriminate on the basis of the fact or perception of a person's race, color, creed, religion, national origin, ancestry, age, sex, sexual orientation, gender identity, domestic partner status, marital status, disability or Acquired Immune Deficiency Syndrome or HIV status (AIDS/HIV status), weight, height, association with members of classes protected under this chapter or in retaliation for opposition to any practices forbidden under Chapter 12 of the San Francisco Administrative Code against any employee of Tenant, any City and County employee working with Tenant, any applicant for employment with Tenant, or any person seeking accommodations, advantages, facilities, privileges, services, or membership in all business, social, or other establishments or organizations operated by Tenant in the City and County of San Francisco. Tenant must comply with the provisions of Sections 12B.2(a), 12B.2(c)-(k), and 12C.3 of the San Francisco Administrative Code which are incorporated herein by reference. Where the term "contractor is used therein it shall be deemed to mean "tenant".

26.22 The State of California, pursuant to Section 2 of Chapter 1333 of the Statutes of 1968, as amended, has reserved all subsurface mineral deposits, including oil and gas deposits, on or underlying the leased premises under the Ground Lease. In accordance with the provisions of the Statute, the Ground Lessor granted to the State of California the right to explore and drill for and extract said subsurface minerals, including oil and gas deposits, from an area of 2,500 square feet located by the California Grid System, Zone 3, at a point where x = 1,452,333 and y = 401,666 which area was not improved on June 1, 1972.

26.23 Tenant's estate hereunder shall in all respects be limited to, and be construed in a fashion consistent with, the estate granted to Landlord under the Ground Lease by Ground Lessor. In the event Landlord is prevented from performing any of its obligations under this Lease by reason of a breach by Ground Lessor of its obligations under the Ground Lease, then Landlord's sole obligation to Tenant in respect thereto shall be to use reasonable efforts in diligently pursuing the correction or cure by Ground Lessor of Ground Lessor's breach. Any condition resulting from a breach by Ground Lessor shall not constitute as between Landlord and Tenant an eviction, actual or constructive, of Tenant and no such breach shall excuse Tenant from the performance or observance of any of its obligations to be performed or observed under this Lease, or entitle Tenant to receive any reduction in or abatement of any Rent. If for any reason the term of the Ground Lease shall terminate prior to the Expiration Date, this Lease shall automatically be terminated, and Landlord shall not be liable to Tenant by reason thereof unless said termination shall have been caused by the default of Landlord, and said Landlord default was not a result of a default by Tenant hereunder. As used in this Lease, the term "**Ground Lease**" shall mean that certain Lease Agreement

dated June 28, 1974, between the City and County of San Francisco, a municipal corporation operating through the San Francisco Port Commission ("Ground Lessor"), and Francisco Bay Office Park, a limited partnership (Landlord's predecessor-in-title), respecting Seawall Lots 315, 316 and 317, San Francisco, California, as the same has been and may from time to time in the future be supplemented, amended, modified, extended or replaced.

26.24 The City and County of San Francisco adopted a City-wide "First Source Hiring Program" on August 3, 1998 by Ordinance No. 264-98, codified at San Francisco Administrative Code Sections 83.1-83.18. The First Source Hiring Program ("FSHP") is designed to identify entry level positions associated with commercial activities and provide first interview opportunities to graduates of City-sponsored training programs. Tenant acknowledges that its activities on the Premises are or may be subject to FSHP. Although Landlord makes no representation or warranty as to the interpretation or application of FSHP to the Premises, or to Tenant's activities thereon, Tenant acknowledges that (a) FSHP may impose obligations on Tenant, including good faith efforts to meet requirements and goals regarding interviewing, recruiting, hiring and retention of individuals for entry level positions; (b) FSHP requirements could also apply to certain contracts and subcontracts entered into by Tenant regarding the Premises, including construction contracts; and (c) FSHP requirements, if applicable, may be imposed as a condition of permits, including building permits, issued for construction or occupancy of the Premises.

26.25 In accordance with Chapter 38 of the San Francisco Administrative Code, the Disability Access Obligations Notice attached hereto as **Exhibit J** (the "**Access Notice**") is incorporated herein by this reference. **Execution of this Lease by the parties hereto shall be deemed to constitute and represent the parties' acknowledgement and execution of the Access Notice, notwithstanding that such Access Notice may not be separately executed**. Section 5 of this Lease sets forth the parties' respective obligations regarding the performance of and payment for disability access improvements. Further, each party shall use reasonable efforts to notify the other of alterations the notifying party may make to or affecting the Premises or Building that might impact accessibility under federal and state disability access laws. Such notification regarding alterations shall in no event be construed to limit Tenant's obligations or to expand Tenant's rights under this Lease (including, without limitation, Section 9 of this Lease, and, without limiting the generality of the foregoing, in no event shall such notification be deemed to constitute any notice required to be given by Tenant to Landlord under any other provision of this Lease. Pursuant to San Francisco Ordinance No. 51-16 (3/23/16), Landlord hereby provides, and Tenant acknowledges receipt of, written notice of the mandatory requirements of Chapter 11D of the San Francisco Building Code that are applicable to all places of public accommodation, provided, however, such notice shall not be deemed to be an expression of opinion by Landlord as to whether the Premises is or may be a "place of public accommodation" as that term has meaning under California and United States law.

SIGNATURE PAGE FOLLOWS

Landlord and Tenant have executed this Lease as of the day and year first above written.

LANDLORD:

JPPF WATERFRONT PLAZA, L.P.,
a Delaware limited partnership

By: JPPF Waterfront Plaza GP, LLC,
a Delaware limited liability company
Its: General Partner

By: */s/ Kyle Snyder*
Name: Kyle Snyder
Its: Authorized Signatory

TENANT:

Third Harmonic Bio, Inc.,
a Delaware corporation

By: */s/ Natalie Holles*
Name: Natalie Holles
Its: Chief Executive Officer

EXHIBIT A

OUTLINE AND LOCATION OF PREMISES

EXHIBIT B

EXPENSES, TAXES AND INSURANCE EXPENSES

EXHIBIT C

WORK AGREEMENT

EXHIBIT C-1

SPACE PLAN

EXHIBIT D

COMMENCEMENT LETTER

EXHIBIT E

BUILDING RULES AND REGULATIONS

EXHIBIT F

ADDITIONAL PROVISIONS

EXHIBIT G

PARKING AGREEMENT

EXHIBIT H

ASBESTOS NOTIFICATION

EXHIBIT I

EXISTING EXCLUSIVES

EXHIBIT J

DISABILITY ACCESS OBLIGATIONS UNDER
SAN FRANCISCO ADMINISTRATIVE CODE CHAPTER 38

Exhibit 21.1

Subsidiaries of Third Harmonic Bio, Inc.

Name of Subsidiary	Jurisdiction
THB MS, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-267445 on Form S-8 of our report dated March 29, 2023 relating to the financial statements of Third Harmonic Bio, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Deloitte & Touche LLP

Morristown, NJ
March 29, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Natalie Holles, certify that:

1. I have reviewed this Annual Report on Form 10-K of Third Harmonic Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2023

/s/ Natalie Holles
Natalie Holles
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Ho, certify that:

1. I have reviewed this Annual Report on Form 10-K of Third Harmonic Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2023

/s/ Robert Ho
Robert Ho
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Natalie Holles, Chief Executive Officer of Third Harmonic Bio, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2023

/s/ Natalie Holles
Natalie Holles
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Ho, Chief Financial Officer of Third Harmonic Bio, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2023

/s/ Robert Ho
Robert Ho
Chief Financial Officer (Principal Financial and Accounting Officer)