

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 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
(State or other jurisdiction of
incorporation or organization)

83-4553503
(I.R.S. Employer
Identification No.)

300 Technology Square, 8th Floor
Cambridge, Massachusetts,
(Address, including zip code of registrant's principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code: (617) 915-6680

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

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 1, 2022, the registrant had 40,544,756 shares of common stock, \$0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Quarterly Report”) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”), and section 27A of the Securities Act of 1933, as amended (the “Securities Act”). All statements contained in this Quarterly 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 II, Item 1A, “Risk Factors,” and elsewhere in this Quarterly 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 Quarterly 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 Quarterly 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 Quarterly Report on Form 10-Q, 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 Quarterly 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2021	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 128,280	\$ 299,516
Prepaid expenses and other current assets	884	4,053
Total current assets	129,164	303,569
Other assets	—	1,193
Total assets	<u>\$ 129,164</u>	<u>\$ 304,762</u>
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 1,797	\$ 3,337
Accrued expenses and other current liabilities	3,889	3,003
Total current liabilities	5,686	6,340
Preferred stock tranche liability	—	—
Anti-dilution liability	—	—
Total liabilities	5,686	6,340
Commitments and contingencies (Note 11)		
Series A-1 redeemable convertible preferred stock, par value \$0.0001. 13,970,000 and - shares authorized as of December 31, 2021 and September 30, 2022, respectively; 13,970,000 and - shares issued and outstanding as of December 31, 2021 and September 30, 2022 respectively; liquidation preference of \$13,970 and \$- as of December 31, 2021, and September 30, 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 September 30, 2022, respectively; 13,750,000 and - shares issued and outstanding as of December 31, 2021 and September 30, 2022, respectively; liquidation preference of \$22,000 and \$-, as of December 31, 2021, and September 30, 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 September 30, 2022, respectively; 7,812,501 and - shares issued and outstanding as of December 31, 2021 and September 30, 2022, respectively; liquidation preference of \$20,000 and \$- as of December 31, 2021 and September 30, 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 September 30, 2022 respectively; 14,091,686 and - shares issued and outstanding as of December 31, 2021, and September 30, 2022, respectively; liquidation preference of \$105,000 and \$- as of December 31, 2021, and September 30, 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 September 30, 2022; 4,237,290 and 39,270,140 shares issued and outstanding at December 31, 2021 and September 30, 2022, respectively	1	4
Preferred stock, \$0.0001 par value, - and 10,000,000 shares authorized at December 31, 2021 and September 30, 2022; - and - shares issued and outstanding at December 31, 2021 and September 30, 2022, respectively	—	—
Additional paid-in capital	1,534	370,324
Accumulated deficit	(48,241)	(71,906)
Total stockholders' (deficit) equity	(46,706)	298,422
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 129,164</u>	<u>\$ 304,762</u>

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

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Operating expenses:				
Research and development	\$ 4,917	\$ 4,757	\$ 11,463	\$ 15,150
General and administrative	780	3,831	1,790	9,008
Total operating expenses	<u>5,697</u>	<u>8,588</u>	<u>13,253</u>	<u>24,158</u>
Loss from operations	5,697	8,588	13,253	24,158
Other (income) expense, net:				
Change in fair value of anti-dilution right liability	—	—	682	—
Change in fair value of preferred stock tranche liability	1,685	—	(105)	—
Other (income)	(1)	(383)	(3)	(493)
Total other (income) expense, net	<u>1,684</u>	<u>(383)</u>	<u>574</u>	<u>(493)</u>
Net loss	<u>\$ 7,381</u>	<u>\$ 8,205</u>	<u>\$ 13,827</u>	<u>\$ 23,665</u>
Net loss per share of common stock, basic and diluted	<u>\$ 0.90</u>	<u>\$ 0.69</u>	<u>\$ 3.46</u>	<u>\$ 2.26</u>
Weighted-average common stock outstanding, basic and diluted	<u>8,159,044</u>	<u>11,827,663</u>	<u>3,994,784</u>	<u>10,451,300</u>

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

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

	Redeemable Convertible Preferred Stock						Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) and Equity	
	Series A-1		Series A-2		Series A-3						
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2020	12,746,961	\$ 11,008	6,875,000	\$ 7,691	—	\$ —	3,866,138	\$ 1	\$ 274	(18,632)	\$ (18,357)
Issuance of Series A-2 redeemable convertible preferred stock under Series A-2 Second Tranche, net of issuance costs of \$40	—	—	6,875,000	11,785	—	—	—	—	—	—	—
Gain on extinguishment of Series A-2 redeemable convertible preferred stock tranche liability	—	—	—	—	—	—	—	—	750	—	750
Issuance of Series A-1 redeemable convertible preferred stock under anti-dilution liability	1,223,039	1,566	—	—	—	—	—	—	—	—	—
Issuance of Series A-3 redeemable convertible preferred stock, net of issuance costs of \$40	—	—	—	—	1,953,125	1,982	—	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	66,837	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	73	—	73
Net loss	—	—	—	—	—	—	—	—	—	(2,247)	(2,247)
Balance at March 31, 2021	13,970,000	\$ 12,574	13,750,000	\$ 19,476	1,953,125	\$ 1,982	3,932,975	\$ 1	\$ 1,097	(20,879)	\$ (19,781)
Vesting of restricted stock	—	—	—	—	—	—	136,289	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	65	—	65
Net loss	—	—	—	—	—	—	—	—	—	(4,199)	(4,199)
Balance at June 30, 2021	13,970,000	\$ 12,574	13,750,000	\$ 19,476	1,953,125	\$ 1,982	4,069,264	\$ 1	\$ 1,162	(25,078)	\$ (23,915)
Vesting of restricted stock	—	—	—	—	—	—	84,022	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	137	—	137
Net loss	—	—	—	—	—	—	—	—	—	(7,381)	(7,381)
Balance at September 30, 2021	13,970,000	\$ 12,574	13,750,000	\$ 19,476	1,953,125	\$ 1,982	4,153,286	\$ 1	\$ 1,299	(32,459)	\$ (31,159)

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

Statement of stockholders' equity (deficit)

	Series A-1		Series A-2		Series A-3		Series B		Common Stock		Additio nal Paid-In Capital	Accumula ted Deficit	Total Stockhold ers' (Deficit) and Equity
	Shares	Amou nt	Shares	Amou nt	Shares	Amou nt	Shares	Amoun t	Shares	Amount			
Balance at December 31, 2021	13,970,000	12,574	13,750,000	19,476	7,812,501	33,288	14,091,686	104,846	4,237,290	1	1,534	(48,241)	(46,706)
Vesting of restricted stock	—	—	—	—	—	—	—	—	84,024	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	450	—	450
Net loss	—	—	—	—	—	—	—	—	—	—	—	(7,784)	(7,784)
Balance at March 31, 2022	13,970,000	12,574	13,750,000	19,476	7,812,501	33,288	14,091,686	104,846	4,321,314	1	1,984	(56,025)	(54,040)
Vesting of restricted stock	—	—	—	—	—	—	—	—	94,740	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,159	—	1,159
Net loss	—	—	—	—	—	—	—	—	—	—	—	(7,676)	(7,676)
Balance at June 30, 2022	13,970,000	12,574	13,750,000	19,476	7,812,501	33,288	14,091,686	104,846	4,416,054	1	3,143	(63,701)	(60,557)
Vesting of restricted stock	—	—	—	—	—	—	—	—	338,488	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,006	—	1,006
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	—	—	—	—	—	—	—	—	—	—	—	(8,205)	(8,205)
Balance at September 30, 2022	—	\$ —	—	\$ —	—	\$ —	—	\$ —	39,270,140	4	370,324	(71,906)	298,422

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

THIRD HARMONIC BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands, except share and per share amounts)
(Unaudited)

	Nine Months Ended September 30,	
	2021	2022
Cash flows from operating activities:		
Net loss	\$ (13,827)	\$ (23,665)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	275	2,618
Change in fair value of preferred stock tranche liability	(105)	—
Change in fair value of anti-dilution liability	682	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(345)	(3,169)
Other assets	—	(1,193)
Accounts payable	740	1,204
Accrued expenses and other current liabilities	1,175	(1,425)
Net cash used in operating activities	(11,405)	(25,630)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of issuance costs	15,922	—
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	—	(1,419)
Net cash provided by (used in) financing activities	15,922	196,866
Net increase (decrease) in cash and cash equivalents	4,517	171,236
Cash and cash equivalents at beginning of period	8,277	128,280
Cash and cash equivalents at end of period	\$ 12,794	\$ 299,516
Supplemental disclosure of cash flows:		
Conversion of preferred stock into common stock	\$ —	\$ 170,184
Offering costs in accounts payable and accrued expenses	\$ —	\$ 875
Preferred stock tranche liability established in connection with the issuance of redeemable convertible preferred stock	\$ 2,979	\$ —
Issuance of redeemable convertible preferred stock in settlement of preferred stock tranche liability	\$ 825	\$ —
Gain on extinguishment of preferred stock tranche liability record to additional paid in capital	\$ 750	\$ —
Issuance of redeemable convertible preferred stock in settlement of anti-dilution right liability	\$ 1,565	\$ —

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

THIRD HARMONIC BIO, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of the Business

Third Harmonic Bio, Inc., (the “Company”) is a clinical-stage biopharmaceutical company focused on advancing the next wave of medicine for allergy and inflammation.

The Company was incorporated in 2019 as a Delaware corporation, and its principal office is located in Cambridge, Massachusetts. In December 2021, the Company formed THB MS, Inc., a Delaware corporation and wholly-owned subsidiary of the Company, which is classified as a Security Corporation in Massachusetts.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, completion and success of clinical testing, development by competitors of new technological innovations, compliance with governmental regulations, dependence on key personnel and protection of proprietary technology and the ability to secure additional capital to fund operations. THB001 will require extensive clinical testing prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Initial public offering

On September 19, 2022, the Company closed its initial public offering (“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 6). 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 unaudited condensed 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 (“ASC”) 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the accompanying condensed consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for THB001 and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future.

Since its inception, the Company has funded its operations primarily with proceeds from sales of shares of its redeemable convertible preferred stock and most recently with proceeds from the IPO. The Company has incurred recurring losses since its inception, including net losses of \$7.4 million and \$8.2 million and for the three months ended September 30, 2021 and 2022, respectively and net losses of \$13.8 million and \$23.7 million for the nine months ended September 30, 2021 and 2022, respectively. As of September 30, 2022, the Company had an accumulated deficit of \$71.9 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 condensed consolidated financial statements, the Company expects that its existing cash and cash equivalents of \$299.5 million as of September 30, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of these condensed consolidated financial statements.

COVID-19 Pandemic

The global coronavirus disease 2019 (“COVID-19”) pandemic continues to evolve, and the Company will continue to monitor the ongoing COVID-19 pandemic. The extent of the impact of the ongoing COVID-19 pandemic on the Company’s business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company’s contract development and manufacturing organizations (“CDMOs”), contract research organizations (“CROs”), and other third parties with whom the Company does business, as well as its impact on regulatory authorities and key scientific and management personnel. The ultimate impact of the ongoing COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. The Company’s financial results for the periods ended December 31, 2021 and September 30, 2022 were not significantly impacted by the ongoing COVID-19 pandemic, however, the Company cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on its financial condition, operations, and business plans for 2022, including the timing and enrollment of patients in its planned clinical trials and other expected milestones of its lead product candidate.

2. Summary of Significant Accounting Policies

The Company’s significant accounting policies are disclosed in the audited consolidated annual financial statements for the years ended December 31, 2020 and 2021, included in our final prospectus for the IPO. Since the date of those annual financial statements, there have been no changes to the Company’s significant accounting policies, except as noted below.

Unaudited Interim Financial Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”), for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated annual financial statements for the years ended December 31, 2020 and 2021 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company’s condensed consolidated balance sheet as of September 30, 2022, the condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2022, the condensed consolidated statement of stockholders’ equity (deficit) as of September 30, 2022 and condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2022. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2021 and 2022 are unaudited. The results for the nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condensed consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with certain new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

In December 2019, the FASB issued ASU No. 2019-12 ("ASU-2019-12"), *Simplifying the Accounting for Income Tax*, which contains several provisions that reduce financial statement complexity including removing the exception to the incremental approach for intra-period tax expense allocation when a company has a loss from continuing operations and income from other items not included in continuing operations. The Company adopted this accounting standard as of January 1, 2022 with no material impact on its condensed consolidated financial statements.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis (in thousands):

Description	Total	December 31, 2021		
		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	\$ —	\$ —

Description	Total	September 30, 2022		
		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	\$ 100,498	\$ 100,498	\$ —	\$ —
Total financial assets	\$ 100,498	\$ 100,498	\$ —	\$ —

As of December 31, 2021 and September 30, 2022, the Company had no financial liabilities that required fair value measurement. As of December 31, 2021 and September 30, 2022, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment.

During the year ended December 31, 2021 and nine months ended September 30, 2022 there were no transfers or reclassifications between fair value measurement levels of assets or liabilities. The carrying values of prepaid 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. Accrued Expenses and Other Current Liabilities

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

	December 31, 2021	September 30, 2022
Accrued research and development expenses	\$ 2,685	\$ 893
Professional fees	450	1,039
Employee compensation and related benefits	752	1,068
Other	2	3
Total accrued expenses and other current liabilities	<u>\$ 3,889</u>	<u>\$ 3,003</u>

5. Novartis License Agreement

On June 28, 2019, the Company entered into a License Agreement (the “Novartis License Agreement”) with Novartis Pharma AG, formerly known as Novartis International Pharmaceutical Ltd, (“Novartis”). Pursuant to the Novartis License Agreement, the Company has been granted an exclusive, worldwide, royalty-bearing, sublicensable license under specified patent rights and know-how related to two licensed compounds, to develop, make, use and sell certain products incorporating or comprising a licensed compound, including THB001, to certain intellectual property rights owned or controlled by Novartis (the “Licensed IP”), to research, develop, make, use, sell, and commercialize products containing the Licensed IP.

Under the Novartis License Agreement, the Company is solely responsible for all research, development, regulatory and commercialization activities related to the Licensed IP. The Company is required to use commercially reasonable efforts to develop and seek regulatory approval for, and commercialize, at least one licensed product in each of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

In exchange for these rights, the Company made an upfront cash payment of \$0.4 million and issued 3,449,808 shares of Series A-1 Preferred Stock with a fair value of \$3.0 million to Novartis. Upon entering into the Novartis License Agreement in 2019, the total initial consideration of \$3.4 million transferred to Novartis was charged to expenses as research and development expense. The Company determined that the Novartis License Agreement represented an asset acquisition as it did not meet the definition of a business. The Company recorded the initial consideration transferred to Novartis as research and development expense in the statement of operations because the acquired Licensed IP represented in-process research and development with no alternative future use.

In addition, under the Novartis License Agreement, an anti-dilution right was issued to Novartis, in which Novartis is entitled to receive shares of Series A-1 Preferred Stock, guaranteeing them a 15% ownership interest of the fully diluted capitalization of the Company. The Company was obligated to issue additional shares of Series A-1 Preferred Stock until the Company had (1) raised aggregate cumulative proceeds of \$30.0 million from sales of equity securities since its inception; or (2) issued and sold any securities that generate proceeds in excess of \$30.0 million. Additionally, the Company was not obligated to issue more than 6,383,142 shares of the Series A-1 Preferred Stock to Novartis under the anti-dilution right. The Company assessed the Novartis anti-dilution right and determined that the right (i) meets the definition of a freestanding financial instrument that is not indexed to the Company’s own stock and (ii) meets the definition of a derivative and does not qualify for equity classification. The initial fair value of the anti-dilution right liability of \$1.0 million was recorded as research and development expense in July 2019, as part of the initial consideration in the license agreement. The Company remeasured the liability associated with the anti-dilution right at each reporting date and at each issuance of Series A-1 Preferred Stock under the anti-dilution right. Changes in the fair value were recorded as other income and expense in the statement of operations until the anti-dilution right was satisfied in February 2021 upon the Company raising aggregate cumulative proceeds of \$30.0 million in sales of equity securities. As part of the anti-dilution right, the Company issued a total of 5,970,000 shares of Series A-1 Preferred Stock to Novartis. During the nine months ended September 30, 2021, the Company recorded an expense associated with changes in fair value of the anti-dilution right liability of \$0.7 million. No expense was recognized during the nine months ended September 30, 2022 as the anti-dilution liability was satisfied in February 2021.

Under the Novartis License Agreement, the Company is obligated to make aggregate milestone payments of up to \$231.7 million related to the achievement of specified development, commercialization, and sales milestones. The Company records the milestone payments as research and development expenses when the milestones occur and consideration is paid or becomes payable. As of September 30, 2022, the Company has made two development milestone payments under the Novartis Agreement totaling \$1.0 million, of which \$0.4 million was achieved and paid in 2019, and \$0.6 million was achieved and paid in 2020, which have been recorded as research and development expense. No other milestones have occurred or have been paid under the Novartis License Agreement.

As part of the Novartis License Agreement, the Company also agreed to pay tiered royalties based on future net sales of all products licensed under the agreement, of which the royalty percentage ranged within the single digits.

6. Redeemable Convertible Preferred Stock

As of December 31, 2021, 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	13,970,000
Series A-2 Preferred Stock	13,750,000	13,750,000	19,476	22,000	13,750,000
Series A-3 Preferred Stock	7,812,501	7,812,501	33,288	20,000	7,812,501
Series B Preferred Stock	14,091,689	14,091,686	104,846	105,000	14,091,686
Total	49,624,190	49,624,187	\$ 170,184	\$ 160,970	49,624,187

Immediately prior to the closing of the IPO 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 September 30, 2022.

7. Stockholder's Equity (Deficit)

Common stock

As of December 31, 2021 and September 30, 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 set forth in the Company's audited annual consolidated financial statements and related notes included in the registration statement on Form S-1, as amended (Registration No. 333-267022) ("Registration Statement").

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 (the "Board"), if any, subject to the preferential dividend rights of redeemable convertible preferred stock. Through September 30, 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 September 30, 2022, there were 4,237,290 and 39,270,140 shares of common stock issued and outstanding, respectively.

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

	December 31, 2021	September 30, 2022
Conversion of outstanding shares of preferred stock	21,967,316	—
Options to purchase common stock	394,254	2,542,936
Unvested restricted common stock	1,907,102	1,072,054
Remaining shares reserved for future issuance	2,065,764	4,710,545
Total	26,334,436	8,325,534

Undesignated preferred stock

As of September 30, 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 September 30, 2022.

8. Stock-Based Compensation

2019 Stock Incentive Plan

The Company's 2019 Stock Incentive Plan (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 (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 ("ISOs"), non-qualified stock options ("NQSOs"), Restricted Stock Awards ("RSAs"), Stock Appreciation Rights ("SARs"), Restricted Stock Units ("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 nine months ended September 30, 2021 and 2022:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2022</u>	<u>2021</u>	<u>2022</u>
Expected term (in years)	6.06-6.53	6.53	6.06-6.53	5.71-6.53
Expected volatility	82.4%	83.5%	82.4 - 84.2%	81.9-83.5%
Risk-free interest rate	0.87-0.92%	2.69%	0.87-1.20%	1.70-2.69%
Expected dividend yield	—	—	—	—
Fair value of common stock	\$ 1.90	\$ 8.60	\$ 1.90	\$8.61-\$9.22

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	2,348,073	9.02		
Exercised	(13,282)	7.92		
Forfeited or cancelled	(186,109)	8.15		
Outstanding as of September 30, 2022	2,542,936	\$ 7.82	9.59	\$ 28,343
Options vested and exercisable as of September 30, 2022	246,878	\$ 4.51	8.95	\$ 3,667
Options unvested as of September 30, 2022	2,296,058	\$ 8.19	9.27	\$ 26,689

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 nine months ended September 30, 2022 was \$6.53. As of September 30, 2022, there was \$12.9 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 4.21 years.

The total fair value of options vested during the nine months ended September 30, 2022 was \$0.6 million.

Included within the total stock options outstanding are 113,970 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 nine months ended September 30, 2022. No expense associated with the Performance Stock Options was recognized prior to the year ended December 31, 2021.

Restricted Common Stock Awards

The Company has granted restricted common stock awards with service and performance and service based vesting conditions to employees of the Company. Unvested shares of restricted common stock may not be sold or transferred by the holder, except for transfers for estate planning purposes in which the transferee agrees to remain bound by all restrictions set forth in the original common stock purchase agreement. These restrictions lapse over the vesting term of each award, which is typically four years. The purchase price of each share of restricted common stock was \$0.0001 per share.

On August 9, 2021, the Company's chief executive officer ("CEO") purchased 1,218,836 shares of common stock at a purchase price of \$1.44 per share, under the terms of a restricted common stock award granted under the 2019 Plan. These shares were purchased in exchange for a promissory note (the "Promissory Note") of \$1.8 million. The shares granted include both service and performance-based vesting criteria 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 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 (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	(517,252)	0.85
Cancelled or forfeited	(317,796)	0.71
Unvested at September 30, 2022	<u>1,072,054</u>	<u>\$ 0.63</u>

The weighted-average grant-date fair value per share of restricted common stock awards granted during the nine months ended September 30, 2022 was zero as no shares were granted in the period. The aggregate fair value of restricted stock awards that vested during the nine months ended September 30, 2022 was \$0.1 million. Stock-based compensation expense recognized for the restricted stock granted was \$0.9 million for the nine months ended September 30, 2022. As of September 30, 2022, there was unrecognized expense of \$2.2 million related to the restricted stock, which is expected to be recognized over a weighted-average period of 2.79 years.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Research and development	55	343	142	723
General and administrative	82	663	133	1,892
Total stock-based compensation expense	<u>137</u>	<u>1,006</u>	<u>275</u>	<u>2,615</u>

9. Income Taxes

During the three and nine months ended September 30, 2021 and 2022, the Company recorded no income tax provision or benefit.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of September 30, 2022, the Company has maintained a full valuation allowance against its remaining net deferred tax assets.

10. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Numerator:				
Net loss	\$ 7,381	\$ 8,205	\$ 13,827	\$ 23,665
Net loss attributable to common stockholders, basic and diluted	<u>\$ 7,381</u>	<u>\$ 8,205</u>	<u>\$ 13,827</u>	<u>\$ 23,665</u>
Denominator:				
Weighted-average number of common shares used in net loss per share, basic and diluted	8,159,044	11,827,663	3,994,784	10,451,300
Net loss per share of common stock, basic and diluted	<u>\$ 0.90</u>	<u>\$ 0.69</u>	<u>\$ 3.46</u>	<u>\$ 2.26</u>

The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders during the three and nine months ended September 30, 2021 and 2022 because including them would have had an anti-dilutive effect:

	Three and Nine Months Ended September 30,	
	2021	2022
Redeemable convertible preferred stock	29,673,125	—
Options to purchase common stock	394,254	2,542,936
Unvested restricted stock	1,823,080	1,072,054
Total	<u>2,217,334</u>	<u>3,614,989</u>

11. Commitments and Contingencies

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of December 31, 2021 and September 30, 2022, there were no litigation matters which would have a material impact on the Company's financial results.

Leases

The Company's operating leases comprised of month-to-month office space leases entered into with Atlas Venture Life Science Advisors ("Atlas") and other third parties for various office suites. As the Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet, no operating lease right of use asset and liability has been recognized as of December 31, 2021 and September 30, 2022. The Company incurred less than \$0.1 million and \$0.1 million of expenses during the three months ended September 30, 2021 and 2022 and \$0.1 million and \$0.1 million of expenses during the nine months ended September 30, 2021 and 2022, respectively.

12. 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 September 30, 2022. The Company leased various office space from Atlas for use in its daily operations.

During each of the three months ended September 30, 2021 and 2022, the Company made payments of less than \$0.1 million and \$0.1 million and during the nine months ended September 30, 2021 and 2022, the Company made payments of \$0.1 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 September 30, 2022. The Company has an in-license agreement with Novartis, which required the Company to make an upfront payment and issue shares of Series A-1 Preferred Stock to Novartis, and further includes future milestone payments upon the occurrence of certain events and royalty payments upon future sales. Refer to Note 5.

CEO Promissory Note

On August 9, 2021, the Company entered into the Promissory Note with the CEO for an amount of \$1.8 million, which was used to allow the CEO to purchase 1,218,836 shares of common stock granted in the form of a restricted stock award under the 2019 Plan. The Promissory Note 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 8.

Consulting Agreements

In June 2019, the Company entered into a consulting agreement with Mark Iwicki, the chairman of the Board, for consulting services. Pursuant to this agreement, Mr. Iwicki was granted a restricted stock award for 47,100 shares of the Company's common stock, with 1/48th of the shares subject to the award vesting in equal monthly installments. The Company recognized stock-based compensation of \$6.1 thousand and \$6.1 thousand, respectively, for the nine months ended September 30, 2021 and 2022, which was recorded within general and administrative expense.

In July 2019, the Company entered into a consulting agreement with H. Martin Seidel, in connection with his appointment to the Board and the Company's scientific advisory board, for consulting services. The Company will make payments of \$25.0 thousand per year for such consulting services, payable quarterly in arrears. In addition, Dr. Seidel was granted a restricted stock award of 75,360 shares of the Company's common stock, with 25% of the shares subject to the award vesting on July 25, 2020 and the remaining shares vesting in equal quarterly installments thereafter until July 25, 2023. The Company recognized stock-based compensation of \$9.8 thousand and \$9.8 thousand, respectively, for the nine months ended September 30, 2021 and 2022, which was recorded within general and administrative expense.

13. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 401(k) Plan for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. Since inception of the plan and through the nine months ended September 30, 2022 the Company has not made any contributions to the 401(k) Plan.

14. Subsequent Events

Cambridge and San Francisco Leases

On October 21, 2022, the Company entered into two separate lease agreements, one for office space located in Cambridge, Massachusetts (the "Cambridge Lease Agreement"), and one for office space located in San Francisco, California (the "San Francisco Lease Agreement"). The Cambridge Lease Agreement and the San Francisco Lease Agreement are expected to commence 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.

Item 2. 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 unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q.

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 II, Item 1A below.

Overview

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

Since our inception in 2019, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, acquiring or discovering product candidates, research and development activities for THB001 and other compounds, establishing arrangements with third parties for the manufacture of our product candidates and component materials, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from sales of shares of our preferred stock and our initial public offering 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 THB001 and any future product candidates. Our net losses were \$29.6 million and \$23.7 million for the year ended December 31, 2021 and nine months ended September 30, 2022, respectively. As of September 30, 2022, we had an accumulated deficit of \$71.9 million. We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will increase substantially in connection with our ongoing activities, particularly if, and as, we:

- advance THB001 through clinical development for chronic inducible urticaria, chronic spontaneous urticaria and asthma;
- conduct additional nonclinical studies and clinical trials for THB001 in additional potential indications;
- discover and develop new product candidates;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- manufacture, or have manufactured, nonclinical, clinical and potentially commercial supplies of THB001 and any future product candidates;
- seek regulatory approvals for THB001 or any future product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize THB001 or any future product candidates, if approved;

- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses;
- hire additional clinical, scientific and management personnel, as well as administrative staff to support the growth of our business;
- add operational, financial and management information systems and personnel;
- incur additional legal, accounting and other costs associated with operating as a public company;
- 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 THB001 or any future product candidates. Our ability to raise additional funds may also be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as those resulting from the ongoing COVID-19 pandemic, the hostilities in Ukraine, and increasing interest rates and rates of inflation.

Because of the numerous risks and uncertainties associated with development of treatment of allergic and inflammatory diseases, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

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

As of September 30, 2022, we had \$299.5 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 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See the subsection titled “Liquidity and Capital Resources.”

License Agreement with Novartis International Pharmaceutical Ltd.

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

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

For a more detailed description of this agreement, see Note 5 to our consolidated financial statements and our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report.

Impact of COVID-19 on Our Business

The COVID-19 pandemic continues to evolve, and we will continue to monitor any developments. The extent of the impact of the ongoing COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our CDMOs, contract research organizations, or CROs, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the ongoing COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, though it is possible we may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. Measures we have taken in response to the 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. At this point, the extent to which the ongoing COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and is subject to change. For additional details regarding the 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 clinical trials.

Results of Operations

Comparison of the three and nine months ended September 30, 2021 and 2022

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2022	\$ Change	% Change	2021	2022	\$ Change	% Change
	(unaudited)				(unaudited)			
Operating expenses:								
Research and development	\$ 4,917	\$ 4,757	\$ (160)	(3)%	\$ 11,463	\$ 15,150	\$ 3,687	32%
General and administrative	780	3,831	3,051	391%	1,790	9,008	7,218	403%
Total operating expenses	5,697	8,588	2,891	51%	13,253	24,158	10,905	82%
Loss from operations	5,697	8,588	2,891	51%	13,253	24,158	10,905	82%
Other (income) expense, net:								
Change in fair value of anti-dilution right liability	—	—	—	0%	682	—	(682)	0%
Change in fair value of preferred stock tranche liability	1,685	—	(1,685)	(100)%	(105)	—	105	(100)%
Other (income)	(1)	(383)	(382)	*	(3)	(493)	(490)	*
Total other (income) expense, net	1,684	(383)	(2,067)	(123)%	574	(493)	(1,067)	(186)%
Net loss	\$ 7,381	\$ 8,205	\$ 824	11%	\$ 13,827	\$ 23,665	\$ 9,838	71%

*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):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2022	\$ Change	% Change	2021	2022	\$ Change	% Change
	(unaudited)				(unaudited)			
Direct costs:								
THB001	\$ 3,845	\$ 1,947	\$ (1,898)	(49)%	\$ 8,474	\$ 8,116	\$ (358)	(4)%
Other discovery and development	359	1,378	1,019	284%	1,433	3,353	1,920	134%
Indirect costs:								
Personnel-related	701	1,424	723	103%	1,544	3,672	2,128	138%
Facilities and other	12	8	(4)	(33)%	12	9	(3)	(25)%
Total research and development expenses	\$ 4,917	\$ 4,757	\$ (160)	(3)%	\$ 11,463	\$ 15,150	\$ 3,687	32%

Research and development expenses decreased by \$0.2 million from \$4.9 million for the three months ended September 30, 2021 to \$4.8 million for the three months ended September 30, 2022, primarily due to the timing of our nonclinical and clinical activities. Research and development expenses increased by \$3.7 million from \$11.5 million for the nine months ended September 30, 2021 to \$15.2 million for the nine months ended September 30, 2022, primarily due to the increased clinical trial expenses related to our lead product candidate, THB001.

General and Administrative Expenses

General and administrative expenses increased by \$3.1 million from \$0.8 million for the three months ended September 30, 2021 to \$3.8 million for the three months ended September 30, 2022, primarily driven by the increases in costs associated with personnel-related expenses and the initial public offering. General and administrative expenses increased by \$7.2 million from \$1.8 million for the nine months ended September 30, 2021 to \$9.0 million for the nine months ended September 30, 2022, primarily driven by the increases in costs associated with personnel-related expenses and the initial public offering.

Total Other (Income) Expense, Net

Total other (income) expense, net increased by approximately \$2.1 million from \$1.7 million of expense for the three months ended September 30, 2021 to \$0.4 million of income for the three months ended September 30, 2022, primarily driven by a \$1.7 million expense due to the remeasurement of the fair value of the preferred stock tranche liability in 2021 and the increase in interest income received as the Company's cash balance has increased. Total other (income) expense, net increased by approximately \$1.1 million from \$0.6 million of expense for the nine months ended September 30, 2021 to \$0.5 million of income for the nine months ended September 30, 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 nine months ended September 30, 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 September 30, 2022, we had \$299.5 million in cash and cash equivalents, and we had an accumulated deficit of \$71.9 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2022
	(unaudited)	
Net cash used in operating activities	\$ (11,405)	\$ (25,630)
Net cash used in investing activities	—	—
Net cash provided by financing activities	15,922	196,866
Net increase in cash and cash equivalents	<u>\$ 4,517</u>	<u>\$ 171,236</u>

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2021 was \$11.4 million, and was primarily due to our net loss of \$13.8 million, adjusted for non-cash income of \$0.1 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, \$0.3 million non-cash stock-based compensation expense and net changes in working capital of \$1.5 million.

Net cash used in operating activities for the nine months ended September 30, 2022 was \$25.6 million, and was primarily due to our net loss of \$23.7 million, adjusted for \$2.6 million non-cash stock-based compensation expense, an increase of \$1.2 million in other assets relating to deferred compensation, and net changes in working capital of \$3.4 million.

Net Cash Provided by (Used in) Investing Activities

We had no investing activities for the nine months ended September 30, 2021 and 2022.

Net Cash Provided by Financing Activities

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

Net cash provided by financing activities for the nine months ended September 30, 2022 was \$196.9 million, resulting from the proceeds of our IPO, net of issuance costs and underwriting fees.

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. We anticipate that our expenses will increase significantly in connection with our ongoing activities.

Based on our current operating plan, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations and capital expenses through 2025. However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or licensing arrangements. We currently have no credit facility or committed sources of capital. Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. Because of the numerous risks and uncertainties associated with product development, there is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Other Commitments

Novartis Agreement

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

Lease Obligations

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

On October 21, 2022, the Company entered into two separate lease agreements, one for office space located in Cambridge, Massachusetts (the "Cambridge Lease Agreement"), and one for office space located in San Francisco, California (the "San Francisco Lease Agreement"). The Cambridge Lease Agreement and the San Francisco Lease Agreement are expected to commence 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.

Purchase and Other Obligations

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

Critical Accounting Policies

The preparation of these financial statements in accordance with U.S. generally accepted accounting principles or GAAP 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 evaluate our estimates and judgments on an ongoing basis. 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. A summary of our significant accounting policies is presented in our final prospectus for our IPO, and during the nine months ended September 30, 2022, there have been no changes to our critical accounting policies from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 15, 2022.

Internal Controls Over Financial Reporting

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

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

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

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

Emerging Growth Company and Smaller Reporting Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an “emerging growth company” can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable we have early adopted certain standards as described in Note 2 of our consolidated financial statements included elsewhere in this Quarterly 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 condensed consolidated financial statements included elsewhere in this Quarterly Report, such standards do not have a material impact on our financial statements or do not otherwise apply to our operations.

Off-Balance Sheet Arrangements

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

Item 3. 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 Quarterly Report.

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

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in local currency. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 100 basis point increase or decrease in exchange rates during any of the periods presented would not have a material effect on our consolidated financial statements included elsewhere in this Quarterly 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 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 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 September 30, 2022, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

Management determined that, as of September 30, 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 1. 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 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q. 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.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including, among others, the following:

- We have a limited operating history, have not completed any clinical trials beyond Phase 1, and none of THB001 or any future product candidates have been approved for commercial sale. We have a history of significant net losses since our inception and expect to continue to incur significant losses for the foreseeable future.
- We will need substantial additional funds to pursue our business objectives, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.
- We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock.
- Our future performance is substantially dependent on the success of our lead product candidate, THB001, which is currently in clinical development and which has not completed a pivotal trial.
- Drug development is a lengthy and expensive process, and the outcome of clinical testing is inherently uncertain, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of THB001 or any future product candidates.
- Our future clinical trials may reveal significant adverse events not seen in our nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of THB001 or 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 THB001 or any future 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 THB001 or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

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

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

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

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

We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through private placements of preferred stock prior to the completion of our initial public offering, or IPO, as well as the net proceeds from our IPO. Our net losses were \$12.8 million and \$29.6 million for the years ended December 31, 2020 and 2021, respectively, and \$13.8 million and \$23.7 million for the nine months ended September 30, 2021 and 2022, respectively. As of September 30, 2022, we had an accumulated deficit of \$71.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of THB001 and any future product candidates. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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

- advance THB001 and any future product candidates through clinical development for chronic inducible urticaria, chronic spontaneous urticaria, and asthma;
- conduct additional nonclinical studies and clinical trials for THB001 in additional potential indications;
- discover and develop new product candidates;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- manufacture, or have manufactured, nonclinical, clinical and potentially commercial supplies of THB001 and any future product candidates;
- seek regulatory approvals for THB001 or any future product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize THB001 or any future product candidates, if approved;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses;
- hire additional clinical, scientific and management personnel, as well as administrative staff to support the growth of our business;
- add operational, financial and management information systems and personnel;

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

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

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

Identifying and developing potential product candidates and conducting nonclinical and clinical studies is a time consuming, capital-intensive and uncertain process that takes years to complete. If THB001 or any future product candidates enter and advance through nonclinical studies and clinical trials, as applicable, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial amounts of cash since inception to develop THB001 and will require significant funds to conduct further research and development and nonclinical testing and clinical trials of THB001 and any future product candidates, to seek regulatory approvals for THB001 or any future product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, 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 THB001 and any future product candidates, as applicable, will require substantial funds to complete. As of September 30, 2022 we had \$299.5 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 2025. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund continued growth of our operations, research and development of product candidates, or otherwise respond to competitive pressures, may vary significantly from what we expect and we may need to seek additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of THB001 or any future product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements for THB001, any future product candidates and our ongoing operations, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of nonclinical and clinical development activities;
- the cost of regulatory submissions and timing of regulatory approvals;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we are obligated to make under our Novartis Agreement or any future license agreements;
- the cash requirements of any future acquisitions or discovery of product candidates;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved product candidates;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing product candidates by third parties;
- the cost of commercialization activities if THB001 or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of product candidates;
- the continued effect of the 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 THB001 and any future product candidates are clinically tested, approved for commercialization and successfully marketed, if ever.

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

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for the year ended December 31, 2021, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that we identified related to the lack of segregation of duties, certain system limitations in our accounting software and the overall control environment as we had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process.

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

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

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

Risks Related to Discovery, Development and Commercialization

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

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

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

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

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

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

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

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

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

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

We or any future collaborators may experience delays in initiating or completing clinical trials. We or any future collaborators also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize THB001 or any future product candidates, including:

- regulators or institutional review boards, or IRBs, the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may halt or suspend an ongoing clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of THB001 or any future product candidates may be greater than we anticipate;
- the quality of THB001 or any future product candidates or other materials necessary to conduct clinical trials of THB001 or any future product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of THB001 or any future product candidates for use in clinical trials;
- our inability to meet drug specifications suitable for use in clinical trials and commercial applications;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about THB001 or any future product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or nonclinical data for such product candidate as well as data emerging from other molecules in the same class as THB001 or any future product candidate; and
- the FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we may in the future rely on collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of THB001 or any future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

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

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

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

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

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of THB001 or any future product candidates, the development timeline and regulatory approval and commercialization prospects for such product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

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

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

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

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

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

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

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

The 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 subjects to travel to the clinical trial sites;
- delays, difficulties or incompleteness in data collection and analysis and other related activities;
- decreased implementation of protocol required clinical trial activities and quality of source data verification at clinical trial sites;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials and our other research and development activities, including because of sickness of employees or their families or mitigation measures such as lock-downs and social distancing;
- delays due to production shortages resulting from any events affecting raw material supply or manufacturing capabilities domestically and abroad;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global and domestic shipping that may affect the transport of clinical trial materials, such as investigational drug products used in our clinical trials;
- changes in local regulations as part of a response to the 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 THB001 or any future product candidates, which would increase our costs and expenses and seriously harm our business, financial condition, results of operations and prospects. Furthermore, if either we or any third party in the supply chain for materials used in the production of THB001 are adversely impacted by restrictions resulting from the 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 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 THB001. 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. In addition, some of our competitors currently have ongoing clinical trials for product candidates that would treat the same patients as THB001, our lead clinical product candidate, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. The 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 THB001 or any future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

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

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

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

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

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

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

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

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

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of THB001 or any future product candidates as demonstrated in clinical trials;
- the prevalence and severity of any adverse side effects associated with THB001 or any future product candidates;
- limitations or warnings contained in any labeling approved by the FDA, EMA or other regulatory authority;
- relative convenience and ease of administration of THB001 or any future product candidates;
- the willingness of patients to accept any new methods of administration;
- unfavorable publicity relating to our current product candidates or any future product candidates;
- the success of our physician education programs;
- the effectiveness of sales and marketing efforts;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of THB001 or any future product candidates, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications THB001 or any future product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

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

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

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

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

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

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

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

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

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of THB001 or any future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

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

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

Risks Related to Our Business and Operations

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

As of September 30, 2022 we had 22 full-time employees. We expect to increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, late-stage regulatory affairs, finance, accounting, business operations, public company compliance, communications and other corporate development functions, and, if THB001 or any of our future product candidates receive regulatory and marketing approval, sales, marketing and distribution capabilities. If we acquire additional product candidates or enter into future collaborations, we may have to further expand our employee base beyond our current projections, which may include further nonclinical research and development or later-stage regulatory operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

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

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

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

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

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

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

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

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

Our business success depends on the security and efficient and uninterrupted operation of our information technology systems and we may be unable to adequately protect our information technology systems from cyber- attacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and sensitive personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, CDMOs, vendors and other contractors and consultants who have access to our confidential information. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the remote work environment resulting from the 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 our lead product candidate could be delayed. In addition, the loss of clinical trial data for THB001 or any other future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, CDMOs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and sensitive personal information), which could result in financial, legal, business and reputational harm to us.

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

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

We may not have adequate insurance coverage with respect to security breaches or disruptions. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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

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

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA regulations, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of THB001 or any future product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws will likely increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, EMA, or other foreign regulatory body exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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

Our research and development activities involve the use of hazardous chemicals and materials, including radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant guidelines of Middlesex County, Massachusetts. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

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

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

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

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

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

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses for any year is limited to no more than 80% of the excess, if any, of current year taxable income (without regard to certain deductions) over the amount of federal net operating losses generated in tax years beginning before January 1, 2018 that are deducted in the current year. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, if we undergo, or have undergone, an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership changes in the future. As a result, if we undergo an ownership change, our ability to use all of our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Our Reliance on Third Parties

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

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

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of THB001 or any future product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with THB001 or any future product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product, if approved, relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or, if approved, commercialization of THB001 or any future product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or, if approved, commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or, if approved, commercialization of product candidates in the most efficient manner or at all; and
- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or, if approved, commercialization program could be delayed, diminished or terminated.

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

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

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

The manufacturing process for a product candidate is subject to FDA, EMA and other foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and other foreign regulatory authorities. If our contract manufacturers are unable to maintain a compliance status acceptable to the FDA, EMA and other foreign regulatory authorities, THB001 or any future product candidates may not be approved. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of components of THB001 or any future product candidates. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are nonetheless responsible for ensuring that THB001 or any future product candidates are manufactured in accordance with applicable laws and regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture THB001 or any future product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty transferring the manufacturing of THB001 or any future product candidates to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture THB001 or any future product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

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

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

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

Risks Related to Intellectual Property

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

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

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

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

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

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

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

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

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

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

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

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

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

We may also, in the future, enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may result in termination of our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize THB001 or any future product candidates incorporating the relevant intellectual property.

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

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

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

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

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

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. In the future, we may need to collaborate with academic institutions to accelerate our research or development with respect to THB001 or any future product candidates. While we try to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot guarantee that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license intellectual property which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh Dole Act, our ability to enforce or otherwise exploit such licensed intellectual property may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual property rights of third parties could adversely affect our ability to commercialize THB001 or any future product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market THB001 or any future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

We, our licensors or collaborators, or any future strategic partners, may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries, including patent infringement lawsuits, interferences, derivations, post-grant reviews, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. There may be issued patents and pending patent applications that claim aspects of our targets or THB001 or any future product candidates and modifications that we may need to apply to THB001 or any future product candidates. There may be issued patents that claim KIT inhibitors which may be relevant to the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages and attorneys' fees if we or they are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

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

It is also possible that we have failed to identify relevant third-party patents or applications. For example, in certain situations, a U.S. patent application can remain confidential until the patent application issues as a U.S. patent. International patent applications and parallel patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of THB001 or any future product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and/or rely on our outside counsel to pay these fees due to the USPTO and non-U.S. governmental patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop and our technology, our U.S. patent or one or more U.S. patents that may issue in the future based on a patent application that we license or may own may be eligible for limited patent term extension under Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act, involved significant changes in patent legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, the decision by the *U.S. Supreme Court in Association for Molecular Pathology v. Myriad Genetics, Inc.* precludes a claim to a nucleic acid having a stated nucleotide sequence that is identical to a sequence found in nature and unmodified. Moreover, in 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to patent-ineligible subject matter. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways, particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Risks Related to Government Regulation

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

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

We have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from nonclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of nonclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of THB001 or any future product candidates. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any.

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

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

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

Even if we receive regulatory approval for THB001 or any of THB001 or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, THB001 or any future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we obtain for THB001 or any of our future product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of THB001 or any of our future product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our CDMOs, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on CDMOs, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote THB001 or any of our future product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Moreover, while we believe that THB001 or any future product candidates may provide better safety or effectiveness as compared to approved products, if we do not study THB001 or any future product candidates in head-to-head trials with those products, we will not be able to make comparative claims for our products, if approved. If we or our manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

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

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

The FDA policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of THB001 or any of our future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government such as the one that occurred from December 22, 2018 through January 25, 2019. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If any legislation, executive orders, or lapses in agency funding impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results.

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

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

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

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

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

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

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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

Existing laws and regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of THB001 or any of our future product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, or may face penalties for any approved products, and we may not achieve or sustain profitability.

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

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

These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which, among other things, will allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also, beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the “donut hole” under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. Thus, it is unclear how the IRA will be implemented but will likely have a significant impact on the pharmaceutical industry.

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

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

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

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

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

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

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

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

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of THB001 or any future product candidates to certain governments, persons, entities, countries and territories, including those that are the target of comprehensive sanctions or an embargo. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents and contractors, from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, or other partners even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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

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

Risks Related to Our Common Stock

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

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

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

The trading price of our common stock 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 THB001 or any future product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States or other countries, especially changes in laws or regulations applicable to THB001 or any future product candidates;
- the success or failure of competitive products or technologies;
- introductions and announcements of new product candidates by us, any future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to THB001 or any future product candidates, clinical studies, and, if approved, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies or product candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners if THB001 or any future product candidates are approved;

- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for THB001 or any future product candidates;
- our ability or inability to raise additional capital and the terms on which we are able to raise it, if at all;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates, development timelines or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- fluctuations of trading volume of our common stock;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- expiration of market stand-off or lock-up agreements;
- changes in accounting principles;
- actions instituted by activist shareholders or others;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities, including global pandemics such as the ongoing COVID-19 pandemic; and
- general economic, industry and market conditions, including recessions, rising interest rates and inflation.

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

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 before or after the lock-up and other legal restrictions on resale lapse in connection with our IPO, the market price of our stock could decline significantly. Each of our officers, directors and holders of substantially all of our outstanding equity securities have entered into lock-up agreements that restrict their ability to sell or transfer their shares. The lock-up agreements will expire on March 13, 2023. However, Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to March 14, 2023. After the lock-up agreements expire, the shares of common stock subject to these lock-up agreements will be eligible for sale in the public market, unless held by our officers, directors and their affiliated entities, in which case such shares will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

The holders of an aggregate of 25,508,705 shares of our outstanding common stock as of September 30, 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 upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above.

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 September 30, 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 Report on Form 10-K, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

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

In connection with the preparation of our financial statements for the year ended December 31, 2021, we concluded that there was a material weakness in our internal control over financial reporting. See “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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

From July 1, 2022 through September 19, 2022, we issued and sold the following securities.

1. Stock options were granted to its employees, directors, consultants, and other service providers to purchase an aggregate of 753,139 shares of common stock under the 2019 Plan, with a per share exercise price of \$8.60 per share.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act as transactions pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

Use of Proceeds from our 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, Jefferies and Cowen 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.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed herewith
3.1	Restated Certificate of Incorporation.					X
3.2	Restated Bylaws.					X
4.1	Form of Common Stock Certificate.	S-1/A	333-267022	4.1	09/08/2022	
10.1	Form of Indemnity Agreement.	S-1/A	333-267022	10.1	09/08/2022	
10.2	2022 Equity Incentive Plan and forms of award agreements.	S-1/A	333-267022	10.3	09/08/2022	
10.3	2022 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	333-267022	10.4	09/08/2022	
10.4	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	
10.5	Form of Change in Control and Severance Agreement.	S-1/A	333-267022	10.10	09/08/2022	
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 – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Third Harmonic Bio, Inc.

Date: November 9, 2022

By: /s/ Natalie Holles
Natalie Holles
Chief Executive Officer

Date: November 9, 2022

By: /s/ Robert Ho
Robert Ho
Chief Financial Officer

THIRD HARMONIC BIO, INC.

RESTATED CERTIFICATE OF INCORPORATION

Third Harmonic Bio, Inc., a Delaware corporation, hereby certifies as follows:

1. The name of this corporation is "Third Harmonic Bio, Inc." The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was April 25, 2019 under the name Project Ige, Inc.
2. The Restated Certificate of Incorporation of this corporation attached hereto as Exhibit A, which is incorporated herein by this reference, and which restates, integrates and further amends the provisions of the Certificate of Incorporation of this corporation as previously amended and/or restated, has been duly adopted by this corporation's Board of Directors and by the stockholders in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, with the approval of this corporation's stockholders having been given by written consent without a meeting in accordance with Section 228 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, this corporation has caused this Restated Certificate of Incorporation to be signed by its duly authorized officer and the foregoing facts stated herein are true and correct.

Dated: September 19, 2022

THIRD HARMONIC BIO, INC.

By: /s/ Natalie Holles

Name: Natalie Holles

Title: Chief Executive Officer

EXHIBIT A**THIRD HARMONIC BIO, INC.****RESTATED CERTIFICATE OF INCORPORATION****ARTICLE I: NAME**

The name of the corporation is Third Harmonic Bio, Inc. (the “*Corporation*”).

ARTICLE II: AGENT FOR SERVICE OF PROCESS

The address of the registered office of this Corporation in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III: PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the “*General Corporation Law*”).

ARTICLE IV: AUTHORIZED STOCK

1. Total Authorized. The total number of shares of all classes of stock that the Corporation has authority to issue is 510,000,000 shares, consisting of two classes: 500,000,000 shares of Common Stock, \$0.0001 par value per share (“*Common Stock*”), and 10,000,000 shares of Preferred Stock, \$0.0001 par value per share (“*Preferred Stock*”).

2. Designation of Additional Series.

2.1. The Board of Directors of the Corporation (the “*Board*”) is authorized, subject to any limitations prescribed by the law of the State of Delaware, to provide for the issuance of the shares of Preferred Stock in one or more series, and, by filing a Certificate of Designation pursuant to the applicable law of the State of Delaware (“*Certificate of Designation*”), to establish from time to time the number of shares to be included in each such series, to fix the designation, vesting, powers (including voting powers), preferences and relative, participating, optional or other special rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof, and, except where otherwise provided in the applicable Certificate of Designation, to thereafter increase (but not above the total number of authorized shares of the Preferred Stock) or decrease (but not below the number of shares of such series then outstanding) the number of shares of any such series. The number of authorized shares of Preferred Stock may also be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of two-thirds of the voting power of all then-outstanding shares of capital stock of the Corporation entitled to vote thereon, voting together as a single class, without a separate vote of the holders of the Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the

General Corporation Law, unless a separate vote of the holders of one or more series is required pursuant to the terms of any Certificate of Designation; *provided, however*, that if two-thirds of the Whole Board (as defined below) has approved such increase or decrease of the number of authorized shares of Preferred Stock, then only the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote thereon, voting together as a single class, without a separate vote of the holders of the Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law, unless a separate vote of the holders of one or more series is required pursuant to the terms of any Certificate of Designation, shall be required to effect such increase or decrease. For purposes of this Restated Certificate of Incorporation (as the same may be amended and/or restated from time to time, including pursuant to the terms of any Certificate of Designation designating a series of Preferred Stock, this “**Certificate of Incorporation**”), the term “**Whole Board**” shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.

2.2 Except as otherwise expressly provided in any Certificate of Designation designating any series of Preferred Stock pursuant to the foregoing provisions of this Article IV, any new series of Preferred Stock may be designated, fixed and determined as provided herein by the Board without approval of the holders of Common Stock or the holders of Preferred Stock, or any series thereof, and any such new series may have powers, preferences and rights, including, without limitation, voting powers, dividend rights, liquidation rights, redemption rights and conversion rights, senior to, junior to or pari passu with the rights of the Common Stock, any series of Preferred Stock or any future class or series of capital stock of the Corporation.

2.3 Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; *provided, that*, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock).

ARTICLE V: AMENDMENT OF BYLAWS

The Board shall have the power to adopt, amend or repeal the Bylaws of the Corporation (as the same may be amended and/or restated from time to time, the “**Bylaws**”). Any adoption, amendment or repeal of the Bylaws by the Board shall require the approval of a majority of the Whole Board. The stockholders shall also have power to adopt, amend or repeal the Bylaws; *provided, that*, notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser or no vote, but in addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Preferred Stock issued pursuant to a Certificate of Designation), the affirmative vote of the holders of at least two-thirds of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for the stockholders to

adopt, amend or repeal any provision of the Bylaws; *provided, further*, that, in the case of any proposed adoption, amendment or repeal of any provisions of the Bylaws that is approved by the Board and submitted to the stockholders for adoption thereby, if two-thirds of the Whole Board has approved such adoption, amendment or repeal of any provisions of the Bylaws, then only the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class (in addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Preferred Stock issued pursuant to a Certificate of Designation)), shall be required to adopt, amend or repeal any provision of the Bylaws.

ARTICLE VI: MATTERS RELATING TO THE BOARD OF DIRECTORS

1. **Director Powers.** Except as otherwise provided by the General Corporation Law, the Bylaws of the Corporation or this Certificate of Incorporation, the business and affairs of the Corporation shall be managed by or under the direction of the Board.

2. **Number of Directors.** Subject to the special rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the total number of directors constituting the Whole Board shall be fixed from time to time exclusively by resolution adopted by a majority of the Whole Board.

3. **Classified Board.** Subject to the special rights of the holders of one or more series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided, with respect to the time for which they severally hold office, into three classes designated as Class I, Class II and Class III, respectively (the “***Classified Board***”). The Board may assign members of the Board already in office to the Classified Board, which assignments shall become effective at the same time that the Classified Board becomes effective. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board. The number of directors in each class shall be divided as nearly equal as is practicable. The initial term of office of the Class I directors shall expire at the Corporation's first annual meeting of stockholders following the closing of the Corporation's initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, relating to the offer and sale of Common Stock to the public (the “***Initial Public Offering***”), the initial term of office of the Class II directors shall expire at the Corporation's second annual meeting of stockholders following the closing of the Initial Public Offering and the initial term of office of the Class III directors shall expire at the Corporation's third annual meeting of stockholders following the closing of the Initial Public Offering. At each annual meeting of stockholders following the closing of the Initial Public Offering, directors elected to succeed those directors of the class whose terms then expire shall be elected for a term of office expiring at the third succeeding annual meeting of stockholders after their election.

4. **Term and Removal.** Each director shall hold office until the annual meeting at which such director's term expires and until such director's successor is duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal. Any director may resign at any time by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer,

or the Secretary. Subject to the special rights of the holders of any series of Preferred Stock, no director may be removed from the Board except for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, voting together as a single class. In the event of any increase or decrease in the authorized number of directors, (a) each director then serving as such shall nevertheless continue as a director of the class of which he or she is a member and (b) the newly created or eliminated directorships resulting from such increase or decrease shall be apportioned by the Board among the classes of directors so as to make all classes as nearly equal in number as is practicable, provided that no decrease in the number of directors constituting the Board shall shorten the term of any director.

5. **Board Vacancies and Newly Created Directorships.** Subject to the special rights of the holders of any series of Preferred Stock, any vacancy occurring in the Board for any cause, and any newly created directorship resulting from any increase in the authorized number of directors, shall, unless (a) the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders or (b) as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum, or by a sole remaining director, and shall not be filled by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for a term expiring at the annual meeting of stockholders at which the term of office of the class to which the director has been assigned expires and until such director's successor shall have been duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal.

6. **Vote by Ballot.** Election of directors need not be by written ballot unless the Bylaws shall so provide.

ARTICLE VII: LIMITATION OF LIABILITY

1. **Limitation of Liability.** To the fullest extent permitted by law, neither a director of the Corporation nor an officer of the corporation shall be personally liable for monetary damages for breach of fiduciary duty as a director or officer, as applicable. Without limiting the effect of the preceding sentence, if the General Corporation Law is hereafter amended to authorize the further elimination or limitation of the liability of a director or officer, then the liability of a director or officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law, as so amended.

2. **Change in Rights.** Neither any amendment nor repeal of this Article VII, nor the adoption of any provision of this Certificate of Incorporation inconsistent with this Article VII, shall eliminate, reduce or otherwise adversely affect any limitation on the personal liability of a director or officer of the Corporation existing at the time of such amendment, repeal or adoption of such an inconsistent provision.

ARTICLE VIII: MATTERS RELATING TO STOCKHOLDERS

1. **No Action by Written Consent of Stockholders.** Subject to the rights of any series of Preferred Stock then outstanding, no action shall be taken by the stockholders of the Corporation

except at a duly called annual or special meeting of stockholders and no action shall be taken by the stockholders of the Corporation by written consent in lieu of a meeting.

2. **Special Meeting of Stockholders**. Special meetings of the stockholders of the Corporation may be called only by the Chairperson of the Board, the Chief Executive Officer, the Lead Independent Director (as defined in the Bylaws), the President, or the Board acting pursuant to a resolution adopted by a majority of the Whole Board and may not be called by the stockholders or any other person or persons.

3. **Advance Notice of Stockholder Nominations and Business Transacted at Special Meetings**. Advance notice of stockholder nominations for the election of directors of the Corporation and of business to be brought by stockholders before any meeting of stockholders of the Corporation shall be given in the manner provided in the Bylaws. Business transacted at special meetings of stockholders shall be limited to the purpose or purposes stated in the notice of meeting.

ARTICLE IX: CHOICE OF FORUM

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the Corporation; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any director, officer, stockholder, employee or agent of the Corporation to the Corporation or the Corporation's stockholders; (c) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation arising pursuant to any provision of the General Corporation Law, this Certificate of Incorporation or the Bylaws or as to which the General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; (d) any action to interpret, apply, enforce or determine the validity of this Certificate of Incorporation or the Bylaws; or (e) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation governed by the internal affairs doctrine, provided that, for the avoidance of doubt, nothing in this Article IX shall preclude the filing of claims in the federal district courts of the United States of America under the Exchange Act, or any successor thereto. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and to have consented to the provisions of this Article IX.

ARTICLE X: AMENDMENT OF CERTIFICATE OF INCORPORATION

If any provision of this Certificate of Incorporation shall be held to be invalid, illegal, or unenforceable, then such provision shall nonetheless be enforced to the maximum extent possible consistent with such holding and the remaining provisions of this Certificate of Incorporation (including, without limitation, all portions of any section of this Certificate of Incorporation containing any such provision held to be invalid, illegal, or unenforceable, which is not invalid, illegal, or unenforceable) shall remain in full force and effect.

The Corporation reserves the right to amend or repeal any provision contained in this Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all

rights conferred upon stockholders are granted subject to this reservation: provided, however, that, notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote (but subject to the rights of any series of Preferred Stock set forth in any Certificate of Designation), but in addition to any vote of the holders of any class or series of the stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least two-thirds of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend or repeal this Article X or Article V, Article VI, Article VII or Article VIII; provided, further, that if two-thirds of the Whole Board has approved such amendment or repeal of any provisions of this Certificate of Incorporation, then only the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class (in addition to any other vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation or any Certificate of Designation), shall be required to amend or repeal such provisions of this Certificate of Incorporation.

THIRD HARMONIC BIO, INC.

(a Delaware corporation)

RESTATED BYLAWS

As Adopted August 22, 2022, and

As Effective September 19, 2022

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THIRD HARMONIC BIO, INC.

(a Delaware corporation)

RESTATED BYLAWS

As Adopted August 22, 2022 and
As Effective September 19, 2022

ARTICLE I: STOCKHOLDERS

Section 1.1: Annual Meetings. If required by applicable law, an annual meeting of stockholders shall be held for the election of directors at such date and time as the Board of Directors (the “**Board**”) of Third Harmonic Bio, Inc. (the “**Corporation**”) shall each year fix. The meeting may be held either at a place, within or without the State of Delaware as permitted by the Delaware General Corporation Law (the “**DGCL**”), or by means of remote communication as the Board in its sole discretion may determine. Any proper business may be transacted at the annual meeting.

Section 1.2: Special Meetings. Special meetings of stockholders for any purpose or purposes shall be called in the manner set forth in the Restated Certificate of Incorporation of the Corporation (as the same may be amended and/or restated from time to time, the “**Certificate of Incorporation**”). The special meeting may be held either at a place, within or without the State of Delaware, or by means of remote communication as the Board in its sole discretion may determine. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of the meeting.

Section 1.3: Notice of Meetings. Notice of all meetings of stockholders shall be given in writing or by electronic transmission in the manner provided by applicable law (including, without limitation, as set forth in Section 7.1.1 of these Bylaws) stating the date, time and place, if any, of the meeting, the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting). In the case of a special meeting, such notice shall also set forth the purpose or purposes for which the meeting is called. Unless otherwise required by applicable law or the Certificate of Incorporation, notice of any meeting of stockholders shall be given not less than ten (10), nor more than sixty (60), days before the date of the meeting to each stockholder of record entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

Section 1.4: Adjournments. Notwithstanding Section 1.5 of these Bylaws, the chairperson of the meeting shall have the power to adjourn the meeting to another time, date and place (if any), regardless of whether a quorum is present, at any time and for any reason. Any meeting of stockholders, annual or special, may be adjourned from time to time, and notice need not be given of any such adjourned meeting if the time, date and place (if any) thereof and the means of remote communication (if any) by which stockholders and proxy holders may be deemed

to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; *provided, however*, that if the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If, after the adjournment, a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record as of the record date so fixed for notice of such adjourned meeting. At the adjourned meeting, the Corporation may transact any business that might have been transacted at the original meeting. If a quorum is present at the original meeting, it shall also be deemed present at the adjourned meeting. To the fullest extent permitted by law, the Board may postpone, reschedule or cancel at any time and for any reason any previously scheduled special or annual meeting of stockholders before it is to be held, regardless of whether any notice or public disclosure with respect to any such meeting has been sent or made pursuant to Section 1.3 hereof or otherwise, in which case notice shall be provided to the stockholders of the new date, time and place, if any, of the meeting as provided in Section 1.3 above.

Section 1.5: Quorum. Except as otherwise provided by applicable law, the Certificate of Incorporation or these Bylaws, at each meeting of stockholders the holders of a majority of the voting power of the shares of stock issued and outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business; *provided, however*, that where a separate vote by a class or classes or series of stock is required by applicable law or the Certificate of Incorporation, the holders of a majority of the voting power of the shares of such class or classes or series of the stock issued and outstanding and entitled to vote on such matter, present in person or represented by proxy at the meeting, shall constitute a quorum entitled to take action with respect to the vote on such matter. If a quorum shall fail to attend any meeting, the chairperson of the meeting or, if directed to be voted on by the chairperson of the meeting, the holders of a majority of the voting power of the shares entitled to vote who are present in person or represented by proxy at the meeting may adjourn the meeting. Shares of the Corporation's stock belonging to the Corporation (or to another corporation, if a majority of the shares entitled to vote in the election of directors of such other corporation are held, directly or indirectly, by the Corporation), shall neither be entitled to vote nor be counted for quorum purposes; *provided, however*, that the foregoing shall not limit the right of the Corporation or any other corporation to vote any shares of the Corporation's stock held by it in a fiduciary capacity and to count such shares for purposes of determining a quorum. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

Section 1.6: Organization. Meetings of stockholders shall be presided over by (a) such person as the Board may designate, or (b) in the absence of such a person, the Chairperson of the Board, or (c) in the absence of such person, the Lead Independent Director, or (d) in the absence of such person, the Chief Executive Officer of the Corporation, or (e) in the absence of such person, the President of the Corporation, or (f) in the absence of such person, by a Vice President of the Corporation. The Secretary of the Corporation shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 1.7: Voting; Proxies. Each stockholder of record entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy. Such a proxy may be prepared, transmitted and delivered in any manner permitted by applicable law. Except as may be required in the Certificate of Incorporation, directors shall be elected by a plurality of the votes cast by the holders of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. At all meetings of stockholders at which a quorum is present, unless a different or minimum vote is required by applicable law, rule or regulation applicable to the Corporation or its securities, the rules or regulations of any stock exchange applicable to the Corporation, the Certificate of Incorporation or these Bylaws, in which case such different or minimum vote shall be the applicable vote on the matter, every matter other than the election of directors shall be decided by the affirmative vote of the holders of a majority of the voting power of the shares of stock entitled to vote on such matter that are present in person or represented by proxy at the meeting and are voted for or against the matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each class or series, the holders of a majority of the voting power of the shares of stock of that class or series present in person or represented by proxy at the meeting voting for or against such matter).

Section 1.8: Fixing Date for Determination of Stockholders of Record. In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at 5:00 p.m. Eastern Time on the day next preceding the day on which notice is given, or, if notice is waived, at 5:00 p.m. Eastern Time on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix, in advance, a record date, which shall not precede the date upon which the resolution fixing the record date is adopted by the Board and which shall not be more than sixty (60) days prior to such action. If no such record date is fixed by the Board, then the record date for determining stockholders for any such purpose shall be at 5:00 p.m. Eastern Time on the day on which the Board adopts the resolution relating thereto.

Section 1.9: List of Stockholders Entitled to Vote. The Corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of stockholders entitled

to vote at the meeting (*provided, however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth (10th) day before the meeting date), arranged in alphabetical order and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least ten (10) days prior to the meeting, either (a) on a reasonably accessible electronic network as permitted by applicable law (*provided* that the information required to gain access to the list is provided with the notice of the meeting), or (b) during ordinary business hours, at the principal place of business of the Corporation. If the meeting is held at a location where stockholders may attend in person, a list of stockholders entitled to vote at the meeting shall also be produced and kept at the time and place of the meeting during the whole time thereof and may be inspected by any stockholder who is present at the meeting. If the meeting is held solely by means of remote communication, then the list shall be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access the list shall be provided with the notice of the meeting. Except as otherwise provided by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 1.9 or to vote in person or by proxy at any meeting of stockholders.

Section 1.10: Inspectors of Elections.

1.10.1 Applicability. Unless otherwise required by the Certificate of Incorporation or by applicable law, the following provisions of this Section 1.10 shall apply only if and when the Corporation has a class of voting stock that is: (a) listed on a national securities exchange, (b) authorized for quotation on an interdealer quotation system of a registered national securities association, or (c) held of record by more than two thousand (2,000) stockholders. In all other cases, observance of the provisions of this Section 1.10 shall be optional, and at the discretion of the Board.

1.10.2 Appointment. The Corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors of election to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting.

1.10.3 Inspector's Oath. Each inspector of election, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability.

1.10.4 Duties of Inspectors. At a meeting of stockholders, the inspectors of election shall (a) ascertain the number of shares outstanding and the voting power of each share, (b) determine the shares represented at a meeting and the validity of proxies and ballots, (c) count all votes and ballots, (d) determine and retain for a reasonable period of time a record of the disposition of any challenges made to any determination by the inspectors, and (e) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

1.10.5 Opening and Closing of Polls. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced by the chairperson of the meeting at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless the Court of Chancery upon application by a stockholder shall determine otherwise.

1.10.6 Determinations. In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in connection with proxies pursuant to Section 211(a)(2)b.(i) of the DGCL, or in accordance with Sections 211(e) or 212(c)(2) of the DGCL, ballots and the regular books and records of the Corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted herein, the inspectors at the time they make their certification of their determinations pursuant to this Section 1.10 shall specify the precise information considered by them, including the person or persons from whom they obtained the information, when the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

Section 1.11: Conduct of Meetings. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting, (b) rules and procedures for maintaining order at the meeting and the safety of those present, (c) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine, (d) restrictions on entry to the meeting after the time fixed for the commencement thereof, (e) limitations on the time allotted to questions or comments by participants, (f) restricting the use of audio/video recording devices and cell phones, and (g) complying with any state and local laws and regulations concerning safety and security. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

Section 1.12: Notice of Stockholder Business; Nominations.

1.12.1 Annual Meeting of Stockholders.

(a) Nominations of persons for election to the Board and the proposal of other business to be considered by the stockholders may be made at an annual meeting of stockholders only: (i) pursuant to the Corporation's notice of such meeting (or any supplement thereto), (ii) by or at the direction of the Board or any committee thereof or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving of the notice provided for in this Section 1.12 (the "**Record Stockholder**"), who is entitled to vote at such meeting and who complies with the notice and other procedures set forth in this Section 1.12 in all applicable respects. For the avoidance of doubt, the foregoing clause (iii) shall be the exclusive means for a stockholder to make nominations or propose business (other than business included in the Corporation's proxy materials pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (such act, and the rules and regulations promulgated thereunder, the "**Exchange Act**")), at an annual meeting of stockholders, and such stockholder must fully comply with the notice and other procedures set forth in this Section 1.12 to make such nominations or propose business before an annual meeting.

(b) For nominations or other business to be properly brought before an annual meeting by a Record Stockholder pursuant to Section 1.12.1(a) of these Bylaws:

(i) the Record Stockholder must have given timely notice thereof in writing to the Secretary of the Corporation and provide any updates or supplements to such notice at the times and in the forms required by this Section 1.12;

(ii) such other business (other than the nomination of persons for election to the Board) must otherwise be a proper matter for stockholder action;

(iii) if the Proposing Person (as defined below) has provided the Corporation with a Solicitation Notice (as defined below), such Proposing Person must, in the case of a proposal other than the nomination of persons for election to the Board, have delivered a proxy statement and form of proxy to holders of at least the percentage of the Corporation's voting shares required under applicable law to carry any such proposal, or, in the case of a nomination or nominations, have delivered a proxy statement and form of proxy to holders of a percentage of the Corporation's voting shares reasonably believed by such Proposing Person to be sufficient to elect the nominee or nominees proposed to be nominated by such Record Stockholder, and must, in either case, have included in such materials the Solicitation Notice; and

(iv) if no Solicitation Notice relating thereto has been timely provided pursuant to this Section 1.12, the Proposing Person proposing such business or nomination must not have solicited a number of proxies sufficient to have required the delivery of such a Solicitation Notice under this Section 1.12.

To be timely, a Record Stockholder's notice must be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not later than 5:00 p.m. Eastern Time on the seventy-fifth (75th) day nor earlier than 5:00 p.m. Eastern Time on the one hundred and fifth (105th) day prior to the first anniversary of the preceding year's annual meeting (except in the case of the Corporation's first annual meeting following its initial public offering,

for which such notice shall be timely if delivered in the same time period as if such meeting were a special meeting governed by Section 1.12.3 of these Bylaws); *provided, however*, that in the event that the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the Record Stockholder to be timely must be so delivered (A) no earlier than 5:00 p.m. Eastern Time on the one hundred and fifth (105th) day prior to such annual meeting and (B) no later than 5:00 p.m. Eastern Time on the later of the ninetieth (90th) day prior to such annual meeting or 5:00 p.m. Eastern Time on the tenth (10th) day following the day on which Public Announcement (as defined below) of the date of such meeting is first made by the Corporation. In no event shall an adjournment or postponement of an annual meeting commence a new time period (or extend any time period) for providing the Record Stockholder's notice.

(c) As to each person whom the Record Stockholder proposes to nominate for election or reelection as a director, in addition to the matters set forth in paragraph (e) below, such Record Stockholder's notice shall set forth:

(i) the name, age, business address and residence address of such person;

(ii) the principal occupation or employment of such nominee;

(iii) the class, series and number of any shares of stock of the Corporation that are beneficially owned or owned of record by such person or any Associated Person (as defined in Section 1.12.4(c));

(iv) the date or dates such shares were acquired and the investment intent of such acquisition;

(v) all other information relating to such person that would be required to be disclosed in solicitations of proxies for election of directors in an election contest (even if an election contest is not involved), or would be otherwise required, in each case pursuant to and in accordance with Section 14(a) (or any successor provision) under the Exchange Act and the rules and regulations thereunder;

(vi) such person's written consent to being named in the Corporation's proxy statement as a nominee, to the public disclosure of information regarding or related to such person provided to the Corporation by such person or otherwise pursuant to this Section 1.12 and to serving as a director if elected;

(vii) whether such person meets the independence requirements of the stock exchange upon which the Corporation's Common Stock is primarily traded;

(viii) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three (3) years, and any other material relationships, between or among such Proposing Person or any of its respective affiliates and associates, on the one hand, and each proposed nominee, and his or her respective affiliates and associates, on the other hand, including all information that would be required to be disclosed pursuant to Rule 404 promulgated under Regulation S-K if the Proposing Person or any

of its respective affiliates and associates were the “registrant” for purposes of such rule and the nominee were a director or executive officer of such registrant; and

(ix) a completed and signed questionnaire, representation and agreement required by Section 1.12.2 of these Bylaws.

(d) As to any business other than the nomination of a director or directors that the Record Stockholder proposes to bring before the meeting, in addition to the matters set forth in paragraph (e) below, such Record Stockholder’s notice shall set forth:

(i) a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the Bylaws, the text of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such Proposing Person, including any anticipated benefit to any Proposing Person therefrom; and

(ii) a description of all agreements, arrangements and understandings between or among any such Proposing Person and any of its respective affiliates or associates, on the one hand, and any other person or persons, on the other hand, (including their names) in connection with the proposal of such business by such Proposing Person.

(e) As to each Proposing Person giving the notice, such Record Stockholder’s notice shall set forth:

(i) the current name and address of such Proposing Person, including, if applicable, their name and address as they appear on the Corporation’s stock ledger, if different;

(ii) the class or series and number of shares of stock of the Corporation that are directly or indirectly owned of record or beneficially owned by such Proposing Person, including any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future;

(iii) whether and the extent to which any derivative interest in the Corporation’s equity securities (including without limitation any option, warrant, convertible security, stock appreciation right or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of shares of the Corporation or otherwise, and any cash-settled equity swap, total return swap, synthetic equity position or similar derivative arrangement (any of the foregoing, a “**Derivative Instrument**”), as well as any rights to dividends on the shares of any class or series of shares of the Corporation that are separated or separable from the underlying shares of the Corporation) or any short interest in any security of the Corporation (for purposes of this Bylaw a person shall be deemed to have a short interest in a security if such person directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has the opportunity to profit or share in any profit derived from any increase or decrease in the value of the subject security, including through performance-related fees) is held directly or indirectly by or for the

benefit of such Proposing Person, including without limitation whether and the extent to which any ongoing hedging or other transaction or series of transactions has been entered into by or on behalf of, or any other agreement, arrangement or understanding (including without limitation any short position or any borrowing or lending of shares) has been made, the effect or intent of which is to mitigate loss to or manage risk or benefit of share price changes for, or to increase or decrease the voting power of, such Proposing Person with respect to any share of stock of the Corporation (any of the foregoing, a “**Short Interest**”);

(iv) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such Proposing Person or any of its respective affiliates or associates is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership;

(v) any direct or indirect material interest in any material contract or agreement with the Corporation, any affiliate of the Corporation or any Competitor (as defined below) (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement);

(vi) any significant equity interests or any Derivative Instruments or Short Interests in any Competitor held by such Proposing Person and/or any of its respective affiliates or associates;

(vii) any other material relationship between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation or any Competitor, on the other hand;

(viii) all information that would be required to be set forth in a Schedule 13D filed pursuant to Rule 13d-1(a) or an amendment pursuant to Rule 13d-2(a) if such a statement were required to be filed under the Exchange Act and the rules and regulations promulgated thereunder by such Proposing Person and/or any of its respective affiliates or associates;

(ix) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) (or any successor provision) under the Exchange Act and the rules and regulations thereunder;

(x) such Proposing Person’s written consent to the public disclosure of information provided to the Corporation pursuant to this Section 1.12;

(xi) a complete written description of any agreement, arrangement or understanding (whether oral or in writing) (including any knowledge that another person or entity is Acting in Concert (as defined in Section 1.12.4(c)) with such Proposing Person) between or among such Proposing Person, any of its respective affiliates or associates and any other person Acting in Concert with any of the foregoing persons;

(xii) a representation that the Record Stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business or nomination;

(xiii) a representation whether such Proposing Person intends (or is part of a group that intends) to deliver a proxy statement or form of proxy to holders of, in the case of a proposal, at least the percentage of the Corporation's voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Corporation's voting shares to elect such nominee or nominees (an affirmative statement of such intent being a "**Solicitation Notice**"); and

(xiv) any proxy, contract, arrangement, or relationship pursuant to which the Proposing Person has a right to vote, directly or indirectly, any shares of any security of the Corporation.

The disclosures to be made pursuant to the foregoing clauses (ii), (iii), (iv) and (vi) shall not include any information with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these Bylaws on behalf of a beneficial owner.

(f) A stockholder providing written notice required by this Section 1.12 shall update such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (i) the record date for determining the stockholders entitled to notice of the meeting and (ii) 5:00 p.m. Eastern Time on the tenth (10th) business day prior to the meeting or any adjournment or postponement thereof. In the case of an update pursuant to clause (i) of the foregoing sentence, such update shall be received by the Secretary of the Corporation at the principal executive office of the Corporation not later than five (5) business days after the record date for determining the stockholders entitled to notice of the meeting, and in the case of an update and supplement pursuant to clause (ii) of the foregoing sentence, such update and supplement shall be received by the Secretary of the Corporation at the principal executive office of the Corporation not later than eight (8) business days prior to the date for the meeting and, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed). For the avoidance of doubt, the obligation to update as set forth in this paragraph shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or nomination or to submit any new proposal, including by changing or adding nominees, matters, business and/or resolutions proposed to be brought before a meeting of the stockholders.

(g) Notwithstanding anything in Section 1.12 or any other provision of these Bylaws to the contrary, any person who has been determined by a majority of the Whole Board to have violated Section 2.11 of these Bylaws or a Board Confidentiality Policy (as defined below) while serving as a director of the Corporation in the preceding five (5) years shall be ineligible to be nominated or be qualified to serve as a member of the Board, absent a prior waiver for such nomination or qualification approved by two-thirds of the Whole Board.

1.12.2 Submission of Questionnaire, Representation and Agreement. To be eligible to be a nominee of any stockholder for election or reelection as a director of the Corporation, the person proposed to be nominated must deliver (in accordance with the time periods prescribed for delivery

of notice under Section 1.12 of these Bylaws) to the Secretary of the Corporation at the principal executive offices of the Corporation a completed and signed questionnaire in the form required by the Corporation (which form the stockholder shall request in writing from the Secretary of the Corporation and which the Secretary of the Corporation shall provide to such stockholder within ten days of receiving such request) with respect to the background and qualification of such person to serve as a director of the Corporation and the background of any other person or entity on whose behalf, directly or indirectly, the nomination is being made and a signed representation and agreement (in the form available from the Secretary of the Corporation upon written request) that such person: (a) is not and will not become a party to (i) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the Corporation, will act or vote on any issue or question (a **“Voting Commitment”**) that has not been disclosed to the Corporation or (ii) any Voting Commitment that could limit or interfere with such person’s ability to comply, if elected as a director of the Corporation, with such person’s fiduciary duties under applicable law, (b) is not and will not become a party to any Compensation Arrangement (as defined below) that has not been disclosed therein, (c) if elected as a director of the Corporation, will comply with all informational and similar requirements of applicable insurance policies and laws and regulations in connection with service or action as a director of the Corporation, (d) if elected as a director of the Corporation, will comply with all corporate governance, conflict of interest, stock ownership requirements, confidentiality and trading policies and guidelines of the Corporation publicly disclosed from time to time, (e) if elected as a director of the Corporation, will act in the best interests of the Corporation and its stockholders and not in the interests of individual constituencies, (f) consents to being named as a nominee in the Corporation’s proxy statement pursuant to Rule 14a-4(d) under the Exchange Act and any associated proxy card of the Corporation and agrees to serve if elected as a director and (g) intends to serve as a director for the full term for which such individual is to stand for election.

1.12.3 Special Meetings of Stockholders. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation’s notice of such meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation’s notice of such meeting (a) by or at the direction of the Board or any committee thereof or (b) provided that the Board has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice of the special meeting, who shall be entitled to vote at the meeting and who complies with the notice and other procedures set forth in this Section 1.12 in all applicable respects. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder may nominate a person or persons (as the case may be), for election to such position(s) as specified in the Corporation’s notice of meeting, if the stockholder’s notice required by Section 1.12.l(b) of these Bylaws shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation (i) no earlier than the one hundred and fifth (105th) day prior to such special meeting and (ii) no later than 5:00 p.m. Eastern Time on the later of the seventy-fifth (75th) day prior to such special meeting or the tenth (10th) day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. In no event shall an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for providing such notice.

1.12.4 General.

(a) Except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act, only such persons who are nominated in accordance with the procedures set forth in this Section 1.12 shall be eligible to be elected at a meeting of stockholders and serve as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 1.12. Except as otherwise provided by law or these Bylaws, the chairperson of the meeting shall have the power and duty to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 1.12 and, if any proposed nomination or business is not in compliance herewith, to declare that such defective proposal or nomination shall be disregarded. Notwithstanding the foregoing provisions of this Section 1.12, unless otherwise required by law, if the stockholder (or a Qualified Representative of the stockholder (as defined below)) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or proposed business, such nomination shall be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation.

(b) Notwithstanding the foregoing provisions of this Section 1.12, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth herein. Nothing in this Section 1.12 shall be deemed to affect any rights of (a) stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act or (b) the holders of any series of the Corporation's Preferred Stock to elect directors pursuant to any applicable provisions of the Certificate of Incorporation.

(c) For purposes of these Bylaws the following definitions shall apply:

(A) a person shall be deemed to be "*Acting in Concert*" with another person if such person knowingly acts (whether or not pursuant to an express agreement, arrangement or understanding) in concert with, or toward a common goal relating to the management, governance or control of the Corporation in substantial parallel with, such other person where (1) each person is conscious of the other person's conduct or intent and this awareness is an element in their decision-making processes and (2) at least one additional factor suggests that such persons intend to act in concert or in substantial parallel, which such additional factors may include, without limitation, exchanging information (whether publicly or privately), attending meetings, conducting discussions or making or soliciting invitations to act in concert or in substantial parallel; provided that a person shall not be deemed to be Acting in Concert with any other person solely as a result of the solicitation or receipt of revocable proxies or consents from such other person in response to a solicitation made pursuant to, and in accordance with, Section 14(a) (or any successor provision) of the Exchange Act by way of a proxy or consent solicitation statement filed on Schedule 14A. A person Acting in Concert with another person shall be deemed to be Acting in Concert with any third party who is also Acting in Concert with such other person;

(B) “*affiliate*” and “*associate*” shall have the meanings ascribed thereto in Rule 405 under the Securities Act of 1933, as amended (the “*Securities Act*”); provided, however, that the term “partner” as used in the definition of “associate” shall not include any limited partner that is not involved in the management of the relevant partnership;

(C) “*Associated Person*” shall mean with respect to any subject stockholder or other person (including any proposed nominee) (1) any person directly or indirectly controlling, controlled by or under common control with such stockholder or other person, (2) any beneficial owner of shares of stock of the Corporation owned of record or beneficially by such stockholder or other person, (3) any associate of such stockholder or other person, and (4) any person directly or indirectly controlling, controlled by or under common control or Acting in Concert with any such Associated Person;

(D) “*Compensation Arrangement*” shall mean any direct or indirect compensatory payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation, including any agreement, arrangement or understanding with respect to any direct or indirect compensation, reimbursement or indemnification in connection with candidacy, nomination, service or action as a nominee or as a director of the Corporation;

(E) “*Competitor*” shall mean any entity that provides products or services that compete with or are alternatives to the principal products produced or services provided by the Corporation or its affiliates;

(F) “*Proposing Person*” shall mean (1) the Record Stockholder providing the notice of business proposed to be brought before an annual meeting or nomination of persons for election to the Board at a stockholder meeting, (2) the beneficial owner or beneficial owners, if different, on whose behalf the notice of business proposed to be brought before the annual meeting or nomination of persons for election to the Board at a stockholder meeting is made, and (3) any Associated Person on whose behalf the notice of business proposed to be brought before the annual meeting or nomination of persons for election to the Board at a stockholder meeting is made;

(G) “*Public Announcement*” shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act; and

(H) to be considered a “*Qualified Representative*” of a stockholder, a person must be a duly authorized officer, manager, trustee or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as a proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction thereof, at the meeting.

The Secretary of the Corporation, or any other person who shall be appointed to serve as secretary of the meeting, may require, on behalf of the Corporation, reasonable and appropriate documentation to verify the status of a person purporting to be a “Qualified Representative” for purposes hereof.

ARTICLE II: BOARD OF DIRECTORS

Section 2.1: Number; Qualifications. The total number of directors constituting the Whole Board shall be fixed from time to time in the manner set forth in the Certificate of Incorporation and the term “**Whole Board**” shall have the meaning specified in the Certificate of Incorporation. No decrease in the authorized number of directors constituting the Whole Board shall shorten the term of any incumbent director. Directors need not be stockholders of the Corporation.

Section 2.2: Election; Resignation; Removal; Vacancies. Election of directors need not be by written ballot. Each director shall hold office until the annual meeting at which such director’s term expires and until such director’s successor is elected and qualified or until such director’s earlier death, resignation, disqualification or removal. Any director may resign by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer, or the Secretary of the Corporation. Such resignation shall be effective upon delivery unless it is specified to be effective at a later time or upon the happening of an event. Subject to the special rights of holders of any series of the Corporation’s Preferred Stock to elect directors, directors may be removed only as provided by the Certificate of Incorporation and applicable law. All vacancies occurring in the Board and any newly created directorships resulting from any increase in the authorized number of directors shall be filled in the manner set forth in the Certificate of Incorporation.

Section 2.3: Regular Meetings. Regular meetings of the Board may be held at such places, within or without the State of Delaware, and at such times as the Board may from time to time determine. Notice of regular meetings need not be given if the date, times and places thereof are fixed by resolution of the Board.

Section 2.4: Special Meetings. Special meetings of the Board may be called by the Chairperson of the Board, the Chief Executive Officer, the Lead Independent Director or a majority of the members of the Board then in office and may be held at any time, date or place, within or without the State of Delaware, as the person or persons calling the meeting shall fix. Notice of the time, date and place of such meeting shall be given, orally, in writing or by electronic transmission (including electronic mail), by the person or persons calling the meeting to all directors at least four (4) days before the meeting if the notice is mailed, or at least twenty-four (24) hours before the meeting if such notice is given by telephone, hand delivery, telegram, telex, mailgram, facsimile, electronic mail or other means of electronic transmission; *provided, however,* that if, under the circumstances, the Chairperson of the Board, the Lead Independent Director or the Chief Executive Officer calling a special meeting deems that more immediate action is necessary or appropriate, notice may be delivered on the day of such special meeting. Unless otherwise indicated in the notice, any and all business may be transacted at a special meeting.

Section 2.5: Remote Meetings Permitted. Members of the Board, or any committee of the Board, may participate in a meeting of the Board or such committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting pursuant to conference telephone or other communications equipment shall constitute presence in person at such meeting.

Section 2.6: Quorum; Vote Required for Action. At all meetings of the Board, a majority of the Whole Board shall constitute a quorum for the transaction of business. If a quorum shall fail to attend any meeting, a majority of those present may adjourn the meeting to another place, date or time. Except as otherwise provided herein or in the Certificate of Incorporation, or required by law, the vote of a majority of the directors present at a meeting at which a quorum is present shall be the act of the Board.

Section 2.7: Organization. Meetings of the Board shall be presided over by (a) the Chairperson of the Board, or (b) in the absence of such person, the Lead Independent Director, or (c) in such person's absence, by the Chief Executive Officer, or (d) in such person's absence, by a chairperson chosen by the Board at the meeting. The Secretary of the Corporation shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 2.8: Unanimous Action by Directors in Lieu of a Meeting. Any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee, as applicable. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 2.9: Powers. Except as otherwise provided by the Certificate of Incorporation or the DGCL, the business and affairs of the Corporation shall be managed by or under the direction of the Board.

Section 2.10: Compensation of Directors. Members of the Board, as such, may receive, pursuant to a resolution of the Board, fees and other compensation for their services as directors, including without limitation their services as members of committees of the Board.

Section 2.11: Confidentiality. Each director shall maintain the confidentiality of, and shall not share with any third party person or entity (including third parties that originally sponsored, nominated or designated such director (the "**Sponsoring Party**")), any non-public information learned in their capacities as directors, including communications among Board members in their capacities as directors. The Board may adopt a board confidentiality policy further implementing and interpreting this Section 2.11 (a "**Board Confidentiality Policy**"). All directors are required to comply with this Section 2.11 and any Board Confidentiality Policy unless such director or the Sponsoring Party for such director has entered into a specific written agreement with the Corporation, in either case as approved by the Board, providing otherwise with respect to such confidential information.

ARTICLE III: COMMITTEES

Section 3.1: Committees. The Board may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of the committee, the member or members thereof present at any meeting of such committee who are not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in place of any such absent or disqualified member. Any such committee, to the extent provided in a resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving, adopting, or recommending to the stockholders any action or matter (other than the election or removal of members of the Board) expressly required by the DGCL to be submitted to stockholders for approval or (b) adopting, amending or repealing any bylaw of the Corporation.

Section 3.2: Committee Rules. Each committee shall keep records of its proceedings and make such reports as the Board may from time to time request. Unless the Board otherwise provides, each committee designated by the Board may make, alter and repeal rules for the conduct of its business. In the absence of such rules, each committee shall conduct its business in the same manner as the Board conducts its business pursuant to Article II of these Bylaws. Except as otherwise provided in the Certificate of Incorporation, these Bylaws or the resolution of the Board designating the committee, any committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and may delegate to any such subcommittee any or all of the powers and authority of the committee.

ARTICLE IV: OFFICERS; CHAIRPERSON; LEAD INDEPENDENT DIRECTOR

Section 4.1: Generally. The officers of the Corporation shall consist of a Chief Executive Officer (who may be the Chairperson of the Board or the President), a President, a Secretary and a Treasurer and may consist of such other officers, including, without limitation, a Chief Financial Officer, and one or more Vice Presidents, as may from time to time be appointed by the Board. All officers shall be elected by the Board; *provided, however*, that the Board may empower the Chief Executive Officer of the Corporation to appoint any officer other than the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer. Except as otherwise provided by law, by the Certificate of Incorporation or these Bylaws, each officer shall hold office until such officer's successor is duly elected and qualified or until such officer's earlier resignation, death, disqualification or removal. Any number of offices may be held by the same person. Any officer may resign by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer, or the Secretary of the Corporation. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event. Any vacancy occurring in any office of the Corporation by death, resignation, removal or otherwise may be filled by the Board and the Board may, in its discretion, leave unfilled, for such period as it may

determine, any offices. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is duly elected and qualified or until such officer's earlier resignation, death, disqualification or removal.

Section 4.2: Chief Executive Officer. Subject to the control of the Board and such supervisory powers, if any, as may be given by the Board, the powers and duties of the Chief Executive Officer of the Corporation are:

(a) to act as the general manager and, subject to the control of the Board, to have general supervision, direction and control of the business and affairs of the Corporation;

(b) subject to Section 1.6 of these Bylaws, to preside at all meetings of the stockholders;

(c) subject to Section 1.2 of these Bylaws, to call special meetings of the stockholders to be held at such times and, subject to the limitations prescribed by law or by these Bylaws, at such places as he or she shall deem proper; and

(d) to affix the signature of the Corporation to all deeds, conveyances, mortgages, guarantees, leases, obligations, bonds, certificates and other papers and instruments in writing which have been authorized by the Board or which, in the judgment of the Chief Executive Officer, should be executed on behalf of the Corporation; to sign certificates for shares of stock of the Corporation (if any); and, subject to the direction of the Board, to have general charge of the property of the Corporation and to supervise and control all officers, agents and employees of the Corporation.

The person holding the office of President shall be the Chief Executive Officer of the Corporation unless the Board shall designate another officer to be the Chief Executive Officer.

Section 4.3: Chairperson of the Board. Subject to the provisions of Section 2.7 of these Bylaws, the Chairperson of the Board shall have the power to preside at all meetings of the Board and shall have such other powers and duties as provided in these Bylaws and as the Board may from time to time prescribe. The Chairperson of the Board may or may not be an officer of the Corporation.

Section 4.4: Lead Independent Director. The Board may, in its discretion, elect a lead independent director from among its members that are Independent Directors (as defined below) (such director, the "***Lead Independent Director***"). The Lead Independent Director shall preside at all meetings at which the Chairperson of the Board is not present and shall exercise such other powers and duties as may from time to time be assigned to him or her by the Board or as prescribed by these Bylaws. For purposes of these Bylaws, "***Independent Director***" has the meaning ascribed to such term under the rules of the exchange upon which the Corporation's Common Stock is primarily traded.

Section 4.5: President. The person holding the office of Chief Executive Officer shall be the President of the Corporation unless the Board shall have designated one individual as the President and a different individual as the Chief Executive Officer of the Corporation. Subject to the provisions of these Bylaws and to the direction of the Board, and subject to the supervisory

powers of the Chief Executive Officer (if the Chief Executive Officer is an officer other than the President), and subject to such supervisory powers and authority as may be given by the Board to the Chairperson of the Board, and/or to any other officer, the President shall have the responsibility for the general management and control of the business and affairs of the Corporation and the general supervision and direction of all of the officers, employees and agents of the Corporation (other than the Chief Executive Officer, if the Chief Executive Officer is an officer other than the President) and shall perform all duties and have all powers that are commonly incident to the office of President or that are delegated to the President by the Board.

Section 4.6: Chief Financial Officer. The person holding the office of Chief Financial Officer shall be the Treasurer of the Corporation unless the Board shall have designated another officer as the Treasurer of the Corporation. Subject to the direction of the Board and the Chief Executive Officer, the Chief Financial Officer shall perform all duties and have all powers that are commonly incident to the office of Chief Financial Officer, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.7: Treasurer. The person holding the office of Treasurer shall be the Chief Financial Officer of the Corporation unless the Board shall have designated another officer as the Chief Financial Officer of the Corporation. The Treasurer shall have custody of all monies and securities of the Corporation. The Treasurer shall make such disbursements of the funds of the Corporation as are authorized and shall render from time to time an account of all such transactions. The Treasurer shall also perform such other duties and have such other powers as are commonly incident to the office of Treasurer, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.8: Vice President. Each Vice President shall have all such powers and duties as are commonly incident to the office of Vice President or that are delegated to him or her by the Board or the Chief Executive Officer. A Vice President may be designated by the Board to perform the duties and exercise the powers of the Chief Executive Officer or President in the event of the Chief Executive Officer's or President's absence or disability.

Section 4.9: Secretary. The Secretary shall issue or cause to be issued all authorized notices for, and shall keep, or cause to be kept, minutes of all meetings of the stockholders and the Board. The Secretary shall have charge of the corporate minute books and similar records and shall perform such other duties and have such other powers as are commonly incident to the office of Secretary, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.10: Delegation of Authority. The Board may from time to time delegate the powers or duties of any officer of the Corporation to any other officers or agents of the Corporation, notwithstanding any provision hereof.

Section 4.11: Removal. Any officer of the Corporation shall serve at the pleasure of the Board and may be removed at any time, with or without cause, by the Board; *provided* that if the Board has empowered the Chief Executive Officer to appoint any officer of the Corporation, then such officer may also be removed by the Chief Executive Officer. Such removal shall be without prejudice to the contractual rights of such officer, if any, with the Corporation.

ARTICLE V: STOCK

Section 5.1: Certificates; Uncertificated Shares. The shares of capital stock of the Corporation shall be uncertificated shares; *provided, however*, that the resolution of the Board that the shares of capital stock of the Corporation shall be uncertificated shares shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation (or the transfer agent or registrar, as the case may be). Notwithstanding the foregoing, the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be certificated shares. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the Corporation, by any two authorized officers of the Corporation (it being understood that each of the Chairperson of the Board, the Vice-Chairperson of the Board, the Chief Executive Officer, the President, any Vice President, the Treasurer, any Assistant Treasurer, the Secretary and any Assistant Secretary of the Corporation shall be an authorized officer for such purpose), representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were an officer, transfer agent or registrar at the date of issue.

Section 5.2: Lost, Stolen or Destroyed Stock Certificates; Issuance of New Certificates or Uncertificated Shares. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate previously issued by it, alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to agree to indemnify the Corporation and/or to give the Corporation a bond sufficient to indemnify it, against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

Section 5.3: Other Regulations. Subject to applicable law, the Certificate of Incorporation and these Bylaws, the issue, transfer, conversion and registration of shares represented by certificates and of uncertificated shares shall be governed by such other regulations as the Board may establish.

ARTICLE VI: INDEMNIFICATION

Section 6.1: Indemnification of Officers and Directors. Each person who was or is made a party to, or is threatened to be made a party to, or is involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, legislative, investigative or any other type whatsoever, preliminary, informal or formal, including any arbitration or other alternative dispute resolution (including but not limited to giving testimony or responding to a subpoena) and including any appeal of any of the foregoing (a "***Proceeding***"), by reason of the fact that such person (or a person of whom such person is the legal representative), is or was a director or officer of the Corporation or a Reincorporated Predecessor (as defined below) or, while serving as a director or officer of the Corporation or a Reincorporated Predecessor, is or was serving at the request of the Corporation as a director, officer, employee,

agent or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise or non-profit entity, including service with respect to employee benefit plans (for purposes of this Article VI, an “**Indemnitee**”), shall be indemnified and held harmless by the Corporation to the fullest extent permitted by the DGCL as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expenses, costs, liability and loss (including attorneys’ fees, judgments, fines, ERISA excise taxes and penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such Indemnitee in connection therewith. Such indemnification shall continue as to an Indemnitee who has ceased to be a director or officer of the Corporation or a Reincorporated Predecessor (as defined below) or, while serving as a director or officer of the Corporation or a Reincorporated Predecessor, is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise or non-profit entity, including service with respect to employee benefit plans and shall inure to the benefit of such Indemnitees’ heirs, executors and administrators. Notwithstanding the foregoing, subject to Section 6.5 of this Article VI, the Corporation shall indemnify any such Indemnitee seeking indemnity in connection with a Proceeding (or part thereof) initiated by such Indemnitee only if such Proceeding (or part thereof) was authorized by the Board or such indemnification is authorized by an agreement approved by the Board. As used herein, the term the “Reincorporated Predecessor” means a corporation that is merged with and into the Corporation in a statutory merger where (a) the Corporation is the surviving corporation of such merger, or (b) the primary purpose of such merger is to change the corporate domicile of the Reincorporated Predecessor to Delaware.

Section 6.2: Advancement of Expenses. Notwithstanding any other provision of these Bylaws, the Corporation shall pay all reasonable expenses (including attorneys’ fees) incurred by an Indemnitee in defending any Proceeding in advance of its final disposition; provided, however, that if the DGCL then so requires, the advancement of such expenses (i.e., payment of such expenses as incurred or otherwise in advance of the final disposition of the Proceeding) shall be made only upon delivery to the Corporation of an undertaking, by or on behalf of such Indemnitee, to repay such amounts if it shall ultimately be determined by a court of competent jurisdiction in a final judgment not subject to appeal that such Indemnitee is not entitled to be indemnified under this Article VI or otherwise. Any advances of expenses or undertakings to repay pursuant to this Section 6.2 shall be unsecured, interest free and without regard to Indemnitee’s ability to pay.

Section 6.3: Non-Exclusivity of Rights. The rights conferred on any person in this Article VI shall not be exclusive of any other right that such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote or consent of stockholders or disinterested directors, or otherwise. Additionally, nothing in this Article VI shall limit the ability of the Corporation, in its discretion, to indemnify or advance expenses to persons whom the Corporation is not obligated to indemnify or advance expenses pursuant to this Article VI.

Section 6.4: Indemnification Contracts. The Board is authorized to cause the Corporation to enter into indemnification contracts with any director, officer, employee or agent of the Corporation, or any person serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, partnership, joint venture, trust or other

enterprise or non-profit entity, including employee benefit plans, providing indemnification or advancement rights to such person. Such rights may be greater than those provided in this Article VI.

Section 6.5: Right of Indemnitee to Bring Suit.

6.5.1 Right to Bring Suit. If a claim under Section 6.1 or 6.2 of this Article VI is not paid in full by the Corporation within sixty (60) days after a written claim has been received by the Corporation, except in the case of a claim for an advancement of expenses, in which case the applicable period shall be twenty (20) days, the Indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If the Indemnitee is successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Indemnitee also shall be entitled to be paid, to the fullest extent permitted by law, the expense of prosecuting or defending such suit.

6.5.2 Effect of Determination. Neither the absence of a determination prior to the commencement of such suit that indemnification of or the providing of advancement to the Indemnitee is proper in the circumstances because the Indemnitee has met the applicable standard of conduct set forth in applicable law, nor an actual determination that the Indemnitee has not met such applicable standard of conduct, shall create a presumption that the Indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the Indemnitee, be a defense to such suit.

6.5.3 Burden of Proof. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VI, or otherwise, shall be on the Corporation.

Section 6.6: Nature of Rights. The rights conferred upon Indemnitees in this Article VI shall be contract rights and such rights shall continue as to an Indemnitee who has ceased to be a director or officer and shall inure to the benefit of the Indemnitee's heirs, executors and administrators.

Section 6.7: Amendment or Repeal. Any amendment, repeal or modification of any provision of this Article VI that adversely affects any right of an Indemnitee or an Indemnitee's successors shall be prospective only, and shall not adversely affect any right or protection conferred on a person pursuant to this Article VI and existing at the time of such amendment, repeal or modification.

Section 6.8: Insurance. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise or non-profit entity against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

ARTICLE VII: NOTICES

Section 7.1: Notice.

7.1.1 Form and Delivery. Except as otherwise specifically required in these Bylaws (including, without limitation, Section 7.1.2 of these Bylaws) or by applicable law, all notices required to be given pursuant to these Bylaws may (a) in every instance in connection with any delivery to a member of the Board, be effectively given by hand delivery (including use of a delivery service), by depositing such notice in the mail, postage prepaid, or by sending such notice by overnight express courier, facsimile, electronic mail or other form of electronic transmission and (b) be effectively delivered to a stockholder when given by hand delivery, by depositing such notice in the mail, postage prepaid or, if specifically consented to by the stockholder as described in Section 7.1.2 of these Bylaws, by sending such notice by facsimile, electronic mail or other form of electronic transmission. Any such notice shall be addressed to the person to whom notice is to be given at such person's address as it appears on the records of the Corporation. The notice shall be deemed given (a) in the case of hand delivery, when received by the person to whom notice is to be given or by any person accepting such notice on behalf of such person, (b) in the case of delivery by mail, upon deposit in the mail, (c) in the case of delivery by overnight express courier, when dispatched, and (d) in the case of delivery via facsimile, electronic mail or other form of electronic transmission, at the time provided in Section 7.1.2 of these Bylaws.

7.1.2 Electronic Transmission. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation, or these Bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given in accordance with Section 232 of the DGCL. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if (a) the Corporation is unable to deliver by electronic transmission two consecutive notices given by the Corporation in accordance with such consent and (b) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice; *provided, however*, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action. Notice given pursuant to this Section 7.1.2 shall be deemed given: (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice; (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of such posting and the giving of such separate notice; and (iv) if by any other form of electronic transmission, when directed to the stockholder.

7.1.3 Affidavit of Giving Notice. An affidavit of the Secretary or an Assistant Secretary of the Corporation or of the transfer agent or other agent of the Corporation that the notice has been given in writing or by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 7.2: Waiver of Notice. Whenever notice is required to be given under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, a written waiver of notice, signed by the person entitled to notice, or waiver by electronic transmission by such person, whether before or after the time stated therein, shall be deemed equivalent to notice.

Attendance

of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any waiver of notice.

ARTICLE VIII: INTERESTED DIRECTORS

Section 8.1: Interested Directors. No contract or transaction between the Corporation and one or more of its members of the Board or officers, or between the Corporation and any other corporation, partnership, association or other organization in which one or more of its directors or officers are members of the board of directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board or committee thereof that authorizes the contract or transaction, or solely because his, her or their votes are counted for such purpose, if: (a) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the Board or the committee, and the Board or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum, (b) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the stockholders, or (c) the contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, a committee thereof, or the stockholders.

Section 8.2: Quorum. Interested directors may be counted in determining the presence of a quorum at a meeting of the Board or of a committee which authorizes the contract or transaction.

ARTICLE IX: MISCELLANEOUS

Section 9.1: Fiscal Year. The fiscal year of the Corporation shall be determined by resolution of the Board.

Section 9.2: Seal. The Board may provide for a corporate seal, which may have the name of the Corporation inscribed thereon and shall otherwise be in such form as may be approved from time to time by the Board.

Section 9.3: Form of Records. Any records administered by or on behalf of the Corporation in the regular course of its business, including its stock ledger, books of account and minute books, may be kept on or by means of, or be in the form of, any other information storage device, method or one or more electronic networks or databases (including one or more distributed electronic networks or databases), electronic or otherwise, *provided* that the records so kept can be converted into clearly legible paper form within a reasonable time and otherwise comply with the DGCL. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to any provision of the DGCL.

Section 9.4: Reliance Upon Books and Records. A member of the Board, or a member of any committee designated by the Board shall, in the performance of such person's duties, be

fully protected in relying in good faith upon the books and records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of the Corporation's officers or employees, or committees of the Board, or by any other person as to matters the member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 9.5: Certificate of Incorporation Governs. In the event of any conflict between the provisions of the Certificate of Incorporation and these Bylaws, the provisions of the Certificate of Incorporation shall govern.

Section 9.6: Severability. If any provision of these Bylaws shall be held to be invalid, illegal, unenforceable or in conflict with the provisions of the Certificate of Incorporation, then such provision shall nonetheless be enforced to the maximum extent possible consistent with such holding and the remaining provisions of these Bylaws (including without limitation, all portions of any section of these Bylaws containing any such provision held to be invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation, that are not themselves invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation) shall remain in full force and effect.

Section 9.7: Time Periods. In applying any provision of these Bylaws which requires that an act be done or not be done a specified number of days prior to an event or that an act be done during a period of a specified number of days prior to an event, calendar days shall be used, the day of the doing of the act shall be excluded, and the day of the event shall be included.

ARTICLE X: AMENDMENT

Notwithstanding any other provision of these Bylaws, any alteration, amendment or repeal of these Bylaws, and any adoption of new Bylaws, shall require the approval of the Board or the stockholders of the Corporation as expressly provided in the Certificate of Incorporation.

ARTICLE XI: EXCLUSIVE FORUM

Unless the Corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including 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. Any person or entity purchasing or otherwise acquiring or holding any interest in any security of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XI.

**CERTIFICATION OF RESTATED BYLAWS
OF
THIRD HARMONIC BIO, INC.**

(a Delaware Corporation)

I, Robert Ho, certify that I am Secretary of Third Harmonic Bio, Inc., a Delaware corporation (the “**Corporation**”), that I am duly authorized to make and deliver this certification, that the attached Bylaws are a true and complete copy of the Restated Bylaws of the Corporation in effect as of the date of this certificate.

Dated: September 19, 2022

/s/ Robert Ho
Robert Ho
Secretary

**CERTIFICATION 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 Quarterly Report on Form 10-Q 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: November 9, 2022

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

**CERTIFICATION 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 Quarterly Report on Form 10-Q 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: November 9, 2022

/s/ Robert Ho

Robert Ho

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION 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 Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2022 (the "Report") 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: November 9, 2022

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

**CERTIFICATION 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 Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2022 (the "Report") 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: November 9, 2022

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