UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2020

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: 001-39094

PHATHOM PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**82-4151574**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Campus Drive, Suite 102 **Florham Park, New Jersey**	**07932**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (877) 742-8466

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, $0.0001 par value per share	PHAT	Nasdaq Global Select Market

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 6, 2020, the registrant had 28,964,506 shares of common stock ($0.0001 par value) outstanding.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

PHATHOM PHARMACEUTICALS, INC.
Balance Sheets
(Unaudited)
(in thousands, except share and par value amounts)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 226,361	$ 243,765
Prepaid expenses and other current assets	800	11,836
Total current assets	227,161	255,601
Property, plant and equipment, net	862	463
Operating lease right-of-use assets	2,485	933
Other long-term assets	381	181
Total assets	$ 230,889	$ 257,178
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (including related party amounts of $331 and $200, respectively)	$ 4,788	$ 699
Accrued expenses (including related party amounts of $415 and $308, respectively)	16,593	2,319
Accrued interest	302	156
Current portion of long-term debt	5,556	—
Operating lease liabilities, current	431	161
Warrant liabilities	—	413
Total current liabilities	27,670	3,748
Long-term debt, net of discount	41,062	22,777
Operating lease liabilities	1,644	635
Other long-term liabilities	4,125	2,063
Total liabilities	74,501	29,223
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares — 400,000,000; issued shares — 28,964,506; outstanding shares — 25,916,093 at September 30, 2020 and 24,728,258 at December 31, 2019, respectively	3	2
Additional paid-in capital	488,151	484,372
Accumulated deficit	(331,766)	(256,419)
Total stockholders' equity	156,388	227,955
Total liabilities and stockholders' equity	$ 230,889	$ 257,178

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (includes related party amounts of $1,023, $207, $1,676, and $207 respectively)	$ 25,770	$ 4,469	$ 56,494	$ 7,670
In-process research and development	—	—	—	78,897
General and administrative (includes related party amounts of $62, $156, $139, and $174, respectively)	7,060	1,813	16,732	3,955
Total operating expenses	32,830	6,282	73,226	90,522
Loss from operations	(32,830)	(6,282)	(73,226)	(90,522)
Other income (expense):				
Interest income	15	429	1,075	530
Interest expense (includes related party amounts of $0, $(302), $0 and $(498), respectively)	(1,286)	(1,990)	(3,286)	(3,138)
Change in fair value of warrant liabilities (includes related party amounts of $0, $(57,754), $0 and $(59,031), respectively)	—	(57,776)	95	(59,060)
Change in fair value of convertible promissory notes (includes related party amounts of $0, $(732), $0, and $(1,053), respectively)	—	(2,486)	—	(4,928)
Other income (expense)	(4)	(7)	(5)	(7)
Total other income (expense)	(1,275)	(61,830)	(2,121)	(66,603)
Net loss	$ (34,105)	$ (68,112)	$ (75,347)	$ (157,125)
Net loss per share, basic and diluted	$ (1.02)	$ (9.30)	$ (2.29)	$ (22.87)
Weighted-average shares of common stock outstanding, basic and diluted	33,366,237	7,326,090	32,946,128	6,871,471

See accompanying notes

PHATHOM PHARMACEUTICALS, INC.
Statements of Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2019	24,728,258	$ 2	$ 484,372	$ (256,419)	$ 227,955
Conversion of Lender Warrants into equity	—	—	318	—	318
Vesting of restricted shares	425,295	—	—	—	—
Stock-based compensation	—	—	563	—	563
Net loss	—	—	—	(20,141)	(20,141)
Balance at March 31, 2020	25,153,553	$ 2	$ 485,253	$ (276,560)	$ 208,695
Vesting of restricted shares	460,859	1	—	—	1
Stock-based compensation	—	—	828	—	828
Net loss	—	—	—	(21,101)	(21,101)
Balance at June 30, 2020	25,614,412	$ 3	$ 486,081	$ (297,661)	$ 188,423
Vesting of restricted shares	301,681	—	—	—	—
Stock-based compensation	—	—	2,070	—	2,070
Net loss	—	—	—	(34,105)	(34,105)
Balance at September 30, 2020	25,916,093	$ 3	$ 488,151	$ (331,766)	$ 156,388

PHATHOM PHARMACEUTICALS, INC.
Statements of Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2018	—	—	$ 2	$ (1,288)	$ (1,286)
Merger of entities under common control into the Company	6,760,334	—	—	—	—
Vesting restrictions placed on previously issued and outstanding common stock	(3,373,408)	—	—	—	—
Issuance of common stock	1,491,072	—	—	—	—
Vesting of restricted shares	1,054,192	—	—	—	—
Net loss	—	—	—	(1,251)	(1,251)
Balance at March 31, 2019	5,932,190	$ —	$ 2	$ (2,539)	$ (2,537)
Issuance of common stock in connection with license agreement	1,084,000	—	5,885	—	5,885
Vesting of restricted shares	203,078	—	—	—	—
Stock-based compensation	—	—	29	—	29
Net loss	—	—	—	(87,762)	(87,762)
Balance at June 30, 2019	7,219,268	$ —	$ 5,916	$ (90,301)	$ (84,385)
Vesting of restricted shares	201,721	—	—	—	—
Stock-based compensation	—	—	36	—	36
Net loss	—	—	—	(68,112)	(68,112)
Balance at September 30, 2019	7,420,989	$ —	$ 5,952	$ (158,413)	$ (152,461)

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (75,347)	$ (157,125)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	217	2
Stock-based compensation	3,461	66
Amortization of debt discount	904	243
Acquired in-process research and development	—	78,897
Change in fair value of warrant liabilities (includes related party amounts of $0 and $59,031, respectively)	(95)	59,060
Change in fair value of convertible promissory notes (includes related party amounts of $0 and $1,053, respectively)	—	4,928
Other	158	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets (includes the change in related party amounts of $0, and $17, respectively)	11,034	(3,147)
Accounts payable and accrued expenses (includes the change in related party amounts of $238, and $186, respectively)	18,506	1,603
Accrued interest (includes the change in related party amounts of $0 and $483, respectively)	146	2,347
Operating right-of-use asset and lease liabilities	(272)	—
Other long-term assets	(200)	—
Net cash used in operating activities	(41,488)	(13,126)
Cash flows from investing activities		
Cash paid for purchased in-process research and development	—	(25,118)
Cash paid for property, plant and equipment	(916)	(26)
Net cash used in investing activities	(916)	(25,144)
Cash flows from financing activities		
Proceeds from initial public offering, net of issuance costs	—	(1,299)
Proceeds from issuance of convertible promissory notes	—	88,324
Net proceeds from issuance of long-term debt	25,000	24,850
Net cash provided by financing activities	25,000	111,875
Net (decrease) increase in cash and cash equivalents	(17,404)	73,605
Cash and cash equivalents – beginning of period	243,765	879
Cash and cash equivalents – end of period	$ 226,361	$ 74,484
Supplemental disclosure of cash flow information		
Interest paid	$ 2,235	$ 549
Supplemental disclosure of noncash investing and financing activities		
Exchange of accrued interest for convertible promissory notes	$ —	$ 27
Issuance of Takeda Warrants in connection with Takeda License	$ —	$ 47,894
Issuance of common stock in connection with Takeda License	$ —	$ 5,885
Issuance of common stock warrants in connection with long-term debt	$ —	$ 419
Property and equipment purchases included in accounts payable and accrued liabilities	$ 39	$ —
Final interest payment fee	$ 2,063	$ 2,063
Operating lease liabilities arising from obtaining right-of-use assets	$ 1,396	$ —
Conversion of Lender Warrants into equity	$ 318	$ —
Unpaid initial public offering costs	$ —	$ 714

See accompanying notes.

1. Organization, Basis of Presentation and Summary of Significant Accounting Policies

Organization

Phathom Pharmaceuticals, Inc. (the "Company" or "Phathom") was incorporated in the state of Delaware in January 2018 under the name North Bridge IV, Inc. On March 13, 2019, the Company changed its name to Phathom Pharmaceuticals, Inc. and merged with YamadaCo IIA, Inc. ("YamadaCo"), a Delaware corporation formed in September 2017, with Phathom being the surviving entity (the "Merger"). All activities of YamadaCo prior to 2018 related to formation and were insignificant. The Company is a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases.

On October 29, 2019, the Company completed its initial public offering (the "IPO") and issued 10,997,630 shares of common stock for net proceeds of approximately $191.5 million.

Stock Split

On October 11, 2019, the Company effected a 2.168-for-1 forward stock split of its common stock (the "Forward Stock Split"). The par value of the common stock was not adjusted as a result of the Forward Stock Split and the authorized shares were increased to 50,000,000 shares of common stock in connection with the Forward Stock Split. In conjunction with the Company's IPO, the authorized shares of common stock were increased to 400,000,000. The accompanying financial statements and notes to the financial statements give retroactive effect to the Forward Stock Split for all periods presented, unless otherwise indicated.

Basis of Presentation

The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The accompanying financial statements include the accounts of the Company (the receiving entity) and YamadaCo, prior to the Merger. The Company and YamadaCo were entities under the common control of Frazier Life Sciences IX, L.P. ("Frazier") as a result of, among other things, Frazier's; (i) ownership of a majority of the outstanding capital stock of both companies, (ii) financing of both companies, (iii) control of the board of directors of both companies, and (iv) management of both companies. Both the Company and YamadaCo were formed for the purpose of identifying potential assets around which to form an operating company. As the merged entities were under common control, the financial statements report the financial position, results of operations and cash flows of the Company and YamadaCo as though the transfer of net assets and equity interests had occurred at the beginning of 2018. All intercompany accounts and transactions have been eliminated.

Interim results may not be indicative of the results that may be expected for the full year. In the opinion of management, these unaudited financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited financial statements.

Liquidity and Capital Resources

From inception to September 30, 2020, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial product candidate, vonoprazan, meeting with regulatory authorities, preparing for and managing the Phase 3 clinical trials of vonoprazan, and providing other general and administrative support for these operations. The Company has a limited operating history, has never generated any revenue, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development and preparation for commercialization of vonoprazan. From inception to September 30, 2020, the Company has funded its operations through the issuance of convertible promissory notes, commercial bank debt and the sale of 10,997,630 shares of common stock for net proceeds of approximately $191.5 million in its 2019 IPO.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. Management is required to perform a two-step analysis over the Company's ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2).

Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these financial statements were available to be issued. There can be no assurance that the Company will be successful in acquiring additional funding (if needed), that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Use of Estimates

The preparation of the Company's financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to accruals for research and development expenses, and the valuation of convertible promissory notes, warrant liabilities and various other equity instruments. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results could differ materially from those estimates and assumptions.

Fair Value Option

As permitted under Accounting Standards Codification ("ASC") 825, *Financial Instruments*, ("ASC 825"), the Company has elected the fair value option to account for its convertible promissory notes issued since inception. In accordance with ASC 825, the Company records these convertible promissory notes at fair value with changes in fair value recorded in the statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes were recognized in earnings as incurred and not deferred.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, are classified within the Level 1 designation discussed above, while prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. Warrant liabilities and convertible promissory notes are recorded at fair value on a recurring basis.

The Company has no financial assets measured at fair value on a recurring basis. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

Liabilities measured at fair value on a recurring basis are as follows (in thousands):

		Fair Value Measurements at Reporting Date Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2019:				
Warrant liabilities	$ 413	—	—	413
Total	$ 413	$ —	$ —	$ 413

The warrant liabilities consist of warrants (the "Lender Warrants") issued in connection with the loan and security agreement (the "Loan Agreement") for commercial bank debt (see Note 7). The Lender Warrants were accounted for as liabilities as they contained a holder put right under which the lenders could have required the Company to pay cash in exchange for the Lender Warrants. The fair value of the Lender Warrants was estimated on the date of grant using the Black-Scholes option-pricing model with an expected term equal to the remaining contractual term of the warrants. The Company estimates its expected stock volatility based on the historical volatility of a set of peer companies, which are publicly traded, and expects to continue to do so until it has adequate historical data regarding the volatility of its own publicly-traded stock price. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company uses an expected dividend yield of zero based on the fact that the Company has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future. When the Company drew down the Term Loan B under the Loan Agreement in March 2020 (see Note 7), the Lenders' put right expired, and the Company recorded a final fair value adjustment and reclassified the Lender Warrants balance of $0.3 million to additional paid-in-capital.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Warrant Liabilities
Balance at December 31, 2019	413
Change in fair value	(95)
Reclassification of Lender Warrants into equity (Note 7)	(318)
Balance at September 30, 2020	$ —

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts and money market funds.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property, Plant, and Equipment, Net

Property, plant and equipment are recorded at cost, less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset. Computer equipment and related software are depreciated over two to three years. Furniture and fixtures are depreciated over three years. Leasehold improvements are amortized over the lesser of the lease term or the estimated useful lives of the related assets. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property, plant and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through September 30, 2020.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash

flows is substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate between lease and non-lease components.

Research and Development Expenses and Accruals

All research and development costs are expensed in the period incurred and consist primarily of salaries, payroll taxes, employee benefits, stock-based compensation charges for those individuals involved in research and development efforts, external research and development costs incurred under agreements with contract research organizations and consultants to conduct and support the Company's ongoing clinical trials of vonoprazan, and costs related to manufacturing vonoprazan for clinical trials.

The Company has entered into various research and development contracts with clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of or after performance are reflected in the accompanying balance sheets as prepaid expenses or accrued liabilities, respectively. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

In-Process Research and Development

The Company evaluates whether acquired intangible assets are a business under applicable accounting standards. Additionally, the Company evaluates whether the acquired assets have a future alternative use. Intangible assets that do not have future alternative use are considered acquired in-process research and development. When the acquired in-process research and development assets are not part of a business combination, the value of the consideration paid is expensed on the acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

General and Administrative Expenses

General and administrative expenses consist of salaries, stock-based compensation, facilities and third-party expenses. General and administrative expenses are associated with the activities of the executive, finance, accounting, information technology, legal, medical affairs and human resource functions.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis. The Company recognizes forfeitures as they occur. The Company also maintains an employee stock purchase program ("ESPP") under which it may issue shares. The Company estimates the fair value of stock options and shares that will be issued under the ESPP using the Black-Scholes option-pricing model, which requires the use of estimates. The Company recognizes stock-based compensation cost for shares that it will issue under the ESPP on a straight-line basis over the requisite service period of the award.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the statement of operations in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company’s comprehensive loss was the same as its reported net loss for all periods presented.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

Net Loss Per Share

For the three and nine months ended September 30, 2019, the net loss per share was recast to include in the numerator the net losses of both the Company and YamadaCo and include in the denominator the weighted-average outstanding shares of both the Company and YamadaCo. Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company included 7,588,000 shares of common stock under its warrant (the “Takeda Warrant”) issued to Takeda Pharmaceutical Company Limited (“Takeda”) in connection with a May 2019 license agreement (see Note 4) in the calculation of basic weighted-average common shares outstanding from the time it became exercisable at the Company’s IPO because the Takeda Warrant is exercisable for little consideration. For the three and nine months ended September 30, 2020, the Company has excluded weighted-average unvested shares of 3,186,269 and 3,606,378, respectively, from the weighted-average number of common shares outstanding, compared to 4,550,428 and 3,342,544, respectively, for the same periods in 2019. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Dilutive common stock equivalents are comprised of unvested common stock, options, warrants and convertible promissory notes. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities (warrants, stock options, and common shares subject to repurchase) would be antidilutive.

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 implements an impairment model, known as the current expected credit loss model, based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize, as an allowance, its estimate of expected credit losses. ASU 2016-13 is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted. The Company adopted this guidance effective January 1, 2020, and the adoption did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, modifies and adds disclosure requirements on fair value measurements. The standard is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. The Company adopted this guidance effective January 1, 2020, and the adoption did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which simplifies the accounting for income taxes. ASU 2019-12 is effective for annual reporting periods, and interim periods within those annual periods, beginning after December 15, 2020 on a prospective basis, and early adoption is permitted. The Company does not expect the adoption of ASU 2019-12 will have a significant impact on its financial statements.

2. Balance Sheet Details

Property, Plant and Equipment, net

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

	September 30, 2020	December 31, 2019
Computer equipment and software	$ 304	$ 152
Furniture and fixtures	729	306
Leasehold improvements	54	13
	1,087	471
Less: accumulated depreciation	(225)	(8)
Total property, plant and equipment, net	$ 862	$ 463

Depreciation expense for the three and nine months ended September 30, 2020 was approximately $88,000 and $217,000, respectively. Depreciation expense for the three and nine months ended September 30, 2019 was approximately $2,000. No property, plant or equipment was disposed of during the nine months ended September 30, 2020 or the year ended December 31, 2019.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued R&D expenses	$ 13,361	$ 384
Accrued compensation expenses	2,468	1,052
Accrued professional & consulting expenses	762	478
Accrued other	2	405
Total accrued expenses	$ 16,593	$ 2,319

3. Related Party Transactions

Frazier is a principal stockholder of the Company and is represented on the Company's board of directors. The Company has conducted operations within office space controlled by Frazier and Frazier allocated a portion of the costs associated with this office space to the Company. In addition, Frazier paid for various goods and services, such as employee wages, insurance and expense reimbursements and various administrative services associated with the operations of the Company and charged the Company for those expenses. As of September 30, 2020 and December 31, 2019, the Company had outstanding accounts payable and accrued expenses due to Frazier in the amount of $35,000 and $0.1 million, respectively, related to these shared operating expenses. For the three months ended September 30, 2020 and 2019, the Company incurred $62,000 and $0.2 million, respectively, of shared operating expenses. For the nine months ended September 30, 2020 and 2019, the Company incurred $0.1 million and $0.3 million, respectively, of shared operating expenses. In addition to the shared operating expenses, the Company issued convertible promissory notes to Frazier during 2018 and 2019 (see Note 5).

Frazier is a principal stockholder in PCI Pharma Services ("PCI"). In the third quarter of 2019, the Company engaged PCI for clinical manufacturing services. As of September 30, 2020 and December 31, 2019, the Company had $0.6 million and $0.3 million, respectively, outstanding accounts payable and accrued expenses related to these manufacturing services. For the three and nine months ended September 30, 2020, the Company incurred $0.9 million and $1.5 million, respectively, of expenses related to services performed by PCI. For the three and nine months ended September 30, 2019, the Company incurred $0.2 million of expenses related to services performed by PCI.

Mountain Field LLC ("Mountain Field") is an entity owned by the chairman of the Company's board of directors. During 2019, the Company charged Mountain Field for certain rent and payroll related expenses. These shared expenses were allocated based on usage of the related facilities and time incurred by personnel. For the nine months ended September 30, 2019, the Company charged Mountain Field $0.1 million for shared expenses. There were no such expenses for the three month periods ended September 30, 2019 and 2020 or the nine months ended September 30, 2020.

Takeda became a common stockholder of the Company in connection with the May 2019 license agreement (see Note 4). In conjunction with this license, Takeda provides proprietary supplies for the Company's ongoing clinical development of vonoprazan in addition to the exclusive license for the commercialization of vonoprazan in the United States, Canada and Europe. As of September 30, 2020 and December 31, 2019, the Company had $22,000 and $0.1 million, respectively, in outstanding accounts payable and accrued expenses related to these supply services. The Company did not have any such expenses incurred for the three and nine months ended September 30, 2020 and 2019 related to services performed by Takeda.

On May 5, 2020, the Company entered into a Commercial Supply Agreement (the "Commercial Supply Agreement") with Takeda, pursuant to which Takeda will supply commercial quantities of vonoprazan bulk drug product. Pursuant to the Commercial Supply Agreement, Takeda has agreed to supply the Company with and the Company has agreed to purchase from Takeda certain quantities of vonoprazan bulk drug product according to approved specifications at a fixed price per batch of bulk drug product in order to commercialize vonoprazan in accordance with the Takeda License. Unless terminated earlier, the term of the Commercial Supply Agreement extends for a period of two years from the date the Company places an order for bulk drug product for the first commercial launch of vonoprazan in any jurisdiction in the licensed territory, provided that this two-year period will expire no later than December 31, 2023. The Commercial Supply Agreement will terminate immediately upon the termination of the Takeda License in accordance with its terms. As of September 30, 2020, the Company had $0.1 million in outstanding accounts payable and accrued expenses related to these bulk drug product costs. For the three and nine months ended September 30, 2020, the Company incurred $0.1 million of expenses related to the Commercial Supply Agreement. The Company has a remaining minimum purchase obligation of approximately $2.4 million related to this agreement.

4. Commitments and Contingencies

License Agreement

On May 7, 2019, the Company entered into a license agreement with Takeda pursuant to which it was granted an exclusive license to commercialize vonoprazan fumarate in the United States, Canada and Europe (the "Takeda License"). The Company also has the right to sublicense its rights under the agreement, subject to certain conditions. The agreement will remain in effect, on a country-by-country and product-by-product basis, until the later of (i) the expiration of the last to expire valid patent claim covering vonoprazan fumarate alone or in combination with at least one other therapeutically active ingredient, (ii) the expiration of the applicable regulatory exclusivity and (iii) 15 years from the date of first commercial sale, unless earlier terminated. The Company may terminate the Takeda License upon six months' written notice. The Company and Takeda may terminate the Takeda License in the case of the other party's insolvency or material uncured breach. Takeda may terminate the Takeda License if the Company challenges, or assists in challenging, licensed patents.

In consideration of the Takeda License, the Company (i) paid Takeda $25.0 million in cash, (ii) issued Takeda 1,084,000 shares of its common stock at a fair value of $5.9 million, (iii) issued the Takeda Warrant to purchase 7,588,000 shares of its common stock at an exercise price of $0.00004613 per share at an initial fair value of $47.9 million, and (iv) issued a right to receive an additional common stock warrant (the "Takeda Warrant Right") should Takeda's fully-diluted ownership of the Company represent less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of then outstanding convertible promissory notes, calculated immediately before the closing of the Company's IPO, with a nominal initial fair value due to the low probability of issuance. The Takeda Warrant Right expired without effect since no fair value had been allocated to it upon completion of the IPO, and no additional warrant was issued. In addition, the Company is obligated to pay Takeda up to an aggregate of $250.0 million in sales milestones upon the achievement of specified levels of product sales, and a low double-digit royalty rate on aggregate net sales of licensed products, subject to certain adjustments. The Company incurred $0.1 million of transaction costs in connection with the Takeda License. The Takeda Warrant has an exercise price of $0.00004613 per share, expires on May 7, 2029 and became exercisable upon the consummation of the IPO. Following the October 11, 2019 increase in the Company's authorized shares of common stock to 50,000,000, the Company recorded a non-cash charge related to the final fair value adjustment of the Takeda Warrants and reclassified the full balance of $144.2 million from warrant liabilities to additional paid-in capital.

Contingencies

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

5. Convertible Promissory Notes

Frazier Convertible Note Financing

From January 2018 to April 2019, the Company issued convertible promissory notes to Frazier (the "Frazier Notes") for an aggregate of $2.4 million and bearing interest at per annum rates ranging from 1.68% to 2.55%. Of the Frazier Notes, $1.9 million were issued in 2018 and $0.5 million were issued in April 2019. Due to certain embedded features within the Frazier Notes, the Company elected to account for these notes and all their embedded features under the fair value option. The Company recorded changes in the fair value of the Frazier Notes in the statements of operations until May 2019, when the Frazier Notes and related accrued interest were exchanged, at their then fair value of $2.4 million, for the convertible promissory notes issued by the Company in May 2019 (the "May 2019 Notes"). For the nine months ended September 30, 2019, the Company recognized $50,000 of other income in the statements of operations related to decreases in the fair value of the Frazier Notes. For the nine months ended September 30, 2019, the Company recognized $15,000 of interest expense in connection with the Frazier Notes. No interest expense or changes in fair value related to the Frazier Notes were recorded in the three months ended September 30, 2019, as the Frazier Notes were exchanged in May 2019. The Company did not have any such expenses incurred for the three and nine months ended September 30, 2020 in connection with the Frazier Notes.

May 2019 Convertible Note Financing

In May 2019, the Company entered into a note purchase agreement under which it issued the unsecured May 2019 Notes for an aggregate of $90.3 million, resulting in gross proceeds to the Company of $87.8 million in cash and $2.4 million related to the exchange of the Frazier Notes and related accrued interest for the May 2019 Notes. Including the conversion of the Frazier Notes, Frazier purchased $20.0 million of the May 2019 Notes. The May 2019 Notes bore interest at a rate of 6% per annum and were subordinated to borrowings under the Company's loan and security agreement (see Note 7).

Due to certain embedded features within the May 2019 Notes, the Company elected to account for these notes and all their embedded features under the fair value option. The outstanding principal and accrued interest of the May 2019 Notes automatically converted into 6,107,918 shares of common stock immediately prior to the completion of the IPO on October 29, 2019.

6. Lease Commitments

As of September 30, 2020, the Company had operating leases for office space in both Buffalo Grove, Illinois and Florham Park, New Jersey, with remaining lease terms of 4.6 years and 4.9 years, respectively. Both operating leases contain an option to extend the term for one additional five year period, which was not considered in the determination of the right-of-use asset or lease liability as the Company did not consider it reasonably certain that it would exercise such options.

The total rent expense for the three and nine months ended September 30, 2020 was approximately $0.2 million and $0.4 million, respectively. There was no rent expense for the three and nine months ended September 30, 2019.

The following table summarizes supplemental balance sheet information related to the operating leases as of September 30, 2020 and December 31, 2019.

	September 30, 2020	December 31, 2019
Assets:		
Operating lease right-of-use assets	2,485	933
Total right-of-use assets	$ 2,485	$ 933
Liabilities:		
Operating lease liabilities, current	431	161
Operating lease liabilities, non-current	1,644	635
Total operating lease liabilities	$ 2,075	$ 796

As of September 30, 2020, the future minimum annual lease payments under the operating leases were as follows (in thousands):

2020	$	120
2021		490
2022		503
2023		516
2024		529
Thereafter		342
Total minimum lease payments	$	2,500
Less: amount representing interest		(425)
Present value of operating lease liabilities		2,075
Less: operating lease liabilities, current		(431)
Operating lease liabilities	$	1,644
Weighted-average remaining lease term (in years)		4.81
Weighted-average incremental borrowing rate		7.25%

Operating cash flows for the nine months ended September 30, 2020 included $0.8 million in cash payments for operating leases, $0.6 million of which were prepaid lease payments. There were no lease costs for the nine months ended September 30, 2019.

7. Debt

Total debt consists of the following (in thousands):

	September 30, 2020
Long-term debt, current portion	$ 5,556
Long-term debt, non-current portion	44,444
Unamortized debt discount	(3,382)
Total debt, net of debt discount	$ 46,618

On May 14, 2019, the Company entered into a loan and security agreement (the “Loan Agreement”, and all amounts borrowed thereunder the “Term Loans”) with Silicon Valley Bank (“SVB”), as administrative and collateral agent, and lenders including SVB and WestRiver Innovation Lending Fund VIII, L.P. (“WestRiver”). The Company borrowed $25.0 million (“Term Loan A”) at the inception of the Loan Agreement and an additional $25.0 million (“Term Loan B”) on March 16, 2020.

The Term Loans bear interest at a floating rate of the higher of the Wall Street Journal Prime rate plus 1.75% (5% at September 30, 2020) or 7.25%. Under the original Loan Agreement, the monthly payments consisted of interest-only through May 31, 2021. On March 11, 2020, the Company entered into the first amendment (the “Amendment”) to the Loan Agreement. Pursuant to the Amendment, the interest-only payment period was extended either (i) until December 31, 2021, if the Company receives positive data from its Phase 3 clinical trial in *H. pylori* infection sufficient to file a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”); or (ii) until November 30, 2022, if the Company receives positive data from its Phase 3 clinical trials in both indications for vonoprazan sufficient to file an NDA with the FDA; provided, in each case, that the Company had drawn down an additional $25.0 million, Term Loan B, pursuant to the Loan Agreement. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest through the maturity date of May 1, 2024. In addition, the Company is obligated to pay a final payment fee of 8.25% of the original principal amount of the Term Loans. As of September 30, 2020, the aggregate final payment fee for the Term Loans of $4.1 million has been recorded as an other long-term liability.

The Company may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.0% of the then outstanding principal balance and payment of a pro rata portion of the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

The borrowings under the Loan Agreement are collateralized by substantially all of the Company's assets, excluding intellectual property and certain other assets. The Loan Agreement includes affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding its operating accounts. The negative covenants include, among others, limitations on the Company's ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. The Loan Agreement also contains customary events of default, including bankruptcy, the failure to make payments when due, and a material adverse change. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company would begin to bear interest at a rate that is 4.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by SVB, as collateral agent. As of September 30, 2020, the Company was in compliance with all applicable covenants under the Loan Agreement.

In connection with the Loan Agreement, the Company issued the Lender Warrants to purchase stock of the Company, which expire ten years from the date of issuance. Upon completion of the IPO in 2019, the Lender Warrants became exercisable for 16,446 shares of common stock. The Lender Warrants included a put option pursuant to which, in the event that the Company did not draw down Term Loan B on or before March 31, 2020, the warrant holders could have required that the Company repurchase the warrants for a total aggregate repurchase price of $0.5 million. Upon the Term Loan B draw in March 2020, the Lender Warrants became exercisable and the put option related to the Lender Warrants expired. Accordingly, the Company recorded a final fair value adjustment and reclassified the Lender Warrants balance of $0.3 million to additional paid-in-capital.

The initial $0.4 million fair value of the Lender Warrants, the $4.1 million final payment fee and $0.2 million of debt issuance costs have been recorded as debt discount and are being amortized to interest expense using the effective interest method over the term of the Term Loans. During the three and nine months ended September 30, 2020, the Company recognized $1.3 million and $3.3 million, respectively, of interest expense, including amortization of the debt discount, in connection with the Loan Agreement, compared to $0.6 million and $0.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, the Company had outstanding Term Loans of $50.0 million and accrued interest of $0.3 million.

Future minimum principal and interest payments under the Term Loans, including the final payment fee, as of September 30, 2020 are as follows (in thousands):

Year ending December 31:		
2020	$	916
2021		13,219
2022		19,065
2023		17,840
2024		11,198
Total principal and interest payments		62,238
Less interest and final payment fee		(12,238)
Total term loan borrowings	$	50,000

8. Stockholders' Equity

Common Stock

In March 2019, subsequent to the Merger, the Company sold 1,491,072 shares of the Company's common stock to Frazier.

In March 2019, the founders granted the Company a repurchase right for the 3,373,408 shares of common stock originally purchased in 2018. The Company has the right, but not the obligation, to repurchase unvested shares in the event the founder's relationship with the Company is terminated, subject to certain limitations, at the original purchase price of the stock. The repurchase right lapsed for 843,352 shares in March 2019 and the repurchase right for the remaining 2,530,056 shares lapses in equal monthly amounts over the following 48-month period ending in March 2023. The fair value of the founder shares at the date the repurchase right was granted is being recognized as stock-based compensation expense on a straight-line basis over the vesting period. As of September 30, 2020, 1,581,285 shares of common stock were subject to repurchase by the Company and the associated repurchase liability was not significant. The amount of recognized and unrecognized stock-based compensation related to the founder stock was immaterial for all periods presented.

In May 2019, the Company issued Takeda 1,084,000 shares of common stock in connection with the Takeda License.

For the period from January 1, 2019 to May 6, 2019, the Company issued 2,524,852 shares of common stock to various employees and consultants of the Company for aggregate proceeds of approximately $1,000. Upon issuance, these shares were subject to a repurchase option by the Company at the original purchase price of the shares. The repurchase rights generally lapse as to 25% of the shares on the first anniversary of the vesting commencement date, and the repurchase right lapses as to 1/48th of the shares each one-month period thereafter, subject to the purchaser remaining continuously an employee, consultant or director of the Company. In November 2019, the Company repurchased 17,560 shares at the original purchase price for an aggregate purchase price of $5.20. As of September 30, 2020, 1,467,128 shares remain available for repurchase by the Company and the associated repurchase liability was not significant.

On October 29, 2019, upon completion of the IPO, the Company sold 10,997,630 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,434,473 additional shares at a public offering price of $19.00 per share. The net proceeds were approximately $191.5 million, after deducting underwriting discounts, commissions and offering costs.

A summary of the Company's unvested shares is as follows:

Balance at December 31, 2019	4,236,248
Share vesting	(1,187,835)
Balance at September 30, 2020	3,048,413

For accounting purposes, unvested shares of common stock are considered issued, but not outstanding until they vest.

Common stock reserved for future issuance consists of the following:

	September 30, 2020
Common stock warrants	7,604,446
Stock options and performance-based awards outstanding	2,740,255
Shares available for issuance under the 2019 Incentive Plan	2,518,853
Shares available for issuance under the ESPP Plan	559,645
Balance at September 30, 2020	13,423,199

Preferred Stock

The Company is authorized to issue up to 40 million shares of preferred stock. As of September 30, 2020, and December 31, 2019, there were no shares of preferred stock issued or outstanding.

Equity Incentive Plan

The Company's 2019 Equity Incentive Plan (the "Existing Incentive Plan") provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards to eligible recipients, including employees, directors or consultants of the Company. The Company had 2,231,739 shares of common stock authorized for issuance under the Existing Incentive Plan, of which, 1,400,528 stock options and 16,260 restricted stock awards were granted in 2019. As a result of the adoption of the 2019 Incentive Award Plan (the "2019 Plan") in October 2019, no further shares are available for issuance under the Existing Incentive Plan.

2019 Incentive Award Plan

In October 2019, the board of directors adopted, and the Company's stockholders approved the 2019 Plan, which became effective in connection with the IPO. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The number of shares initially available for issuance will be increased by (i) the number of shares subject to stock options or similar awards granted under the Existing Incentive Plan that expire or otherwise terminate without having been exercised in full after the effective date of the 2019 Plan and unvested shares issued pursuant to awards granted under the Existing Incentive Plan that are forfeited to or repurchased by the Company after the effective date of the 2019 Plan, with the maximum number of shares to be added to the 2019 Plan pursuant to clause (i) above equal to 1,416,788 shares, and (ii) an annual increase on January 1 of each calendar year beginning in 2020 and ending in 2029, equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by the board of directors. The Company initially had 2,700,000 shares of common stock available for issuance under the 2019 Plan, of which, 1,134,977 stock options were granted and 204,750 performance-based units were granted during the nine months ended September 30, 2020. As of September 30, 2020, 2,518,853 shares remain available for issuance, which includes the annual increase of 1,158,580 shares that were authorized on January 1, 2020.

Performance-based Units

In July 2020, the Company granted 204,750 performance-based stock units ("PSU") whereby vesting depends upon the approval by the U.S. Food and Drug Administration ("FDA") of vonoprazan for *H. pylori* and then, or concurrent with, erosive esophagitis. As of September 30, 2020, the PSU milestones had not been achieved. As of September 30, 2020, no related compensation cost had been recognized. The following table summarizes PSU activity under the 2019 Incentive Award Plan during the nine months ended September 30, 2020.

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at December 31, 2019	—	$ —
Granted	204,750	32.06
Vested	—	—
Forfeited	—	—
Unvested balance at September 30, 2020	204,750	$ 32.06

As of September 30, 2020, there was approximately $6.6 million of related unrecognized compensation cost, which will begin to be recognized when vesting is probable.

Employee Stock Purchase Plan

In October 2019, the board of directors adopted, and the Company's stockholders approved, the Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the IPO. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation, which includes a participant's gross base compensation for services to the Company, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. A total of 270,000 shares of common stock was initially reserved for issuance under the ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2020 and ending in 2029, by an amount equal to the lesser of: (i) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the board of directors. As of September 30, 2020, 559,645 shares of common stock remain available for issuance, which includes the annual increase of 289,645 shares that were authorized on January 1, 2020.

The ESPP is considered a compensatory plan, and the Company recorded related stock-based compensation of $0.1 million for the three and nine months ended September 30, 2020. The weighted-average assumptions used to estimate the fair value of ESPP awards using the Black-Scholes option valuation model were as follows:

	Nine Months Ended September 30,	
	2020	2019
Assumptions:		
Expected term (in years)	1.00	—
Expected volatility	76.25%	—
Risk free interest rate	0.15%	—
Dividend yield	—	—

The estimated weighted-average fair value of ESPP awards during 2020 was $13.66. As of September 30, 2020, the total unrecognized compensation expense related to the ESPP was $0.4 million, which is expected to be recognized over a weighted-average period of approximately 1 year.

As of September 30, 2020, no shares of common stock had been issued under the ESPP.

Stock Options

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company, prior to the IPO on October 29, 2019, was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees was determined utilizing the "simplified" method for awards. The expected term of stock options granted to non-employees was equal to the contractual term of the option award. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield was zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2019	1,400,528	$ 9.10	9.69	$ 30,874
Options granted	1,134,977	32.14		
Options exercised and shares vested	—	—		
Options cancelled	—	—		
Balance at September 30, 2020	2,535,505	$ 19.41	9.27	$ 43,767
Options exercisable as of September 30, 2020	141,367	$ 12.58	8.98	$ 3,405

The estimated weighted-average fair value of employee and nonemployee director stock options granted during 2020 was $18.68. As of September 30, 2020, the Company had $24.7 million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 3.8 years.

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option valuation model were as follows:

	Nine Months Ended September 30,	
	2020	2019
Assumptions:		
Expected term (in years)	5.23	6.07
Expected volatility	56.24%	60.17%
Risk free interest rate	0.36%	1.58%
Dividend yield	—	—

Stock-Based Compensation Expense

Stock-based compensation expense recognized for all equity awards, including founder stock, has been reported in the statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development expense	$ 604	$ 8	$ 842	$ 8
General and administrative expense	1,466	29	2,619	58
Total	$ 2,070	$ 37	$ 3,461	$ 66

9. Subsequent Event

On November 10, 2020, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC, or Jefferies, pursuant to which the Company may offer and sell shares of its common stock having an aggregate sales proceeds of up to $125.0 million, from time to time, through an at-the-market equity offering program under which Jefferies acts as sales agent.

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 the unaudited interim financial statements and notes thereto included in this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2019 ("2019 Form 10-K").

Forward Looking Statements

The following discussion and other parts of this quarterly report contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, research and development plans and costs, the impact of COVID-19, the timing and likelihood of regulatory filings and approvals, commercialization plans, pricing and reimbursement, the potential to develop future product candidates, the timing and likelihood of success of the plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. The forward-looking statements in this quarterly report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, operating results, business strategy, short-term and long-term business operations and objectives. These forward-looking statements speak only as of the date of this quarterly report and are subject to a number of risks, uncertainties and assumptions, including those described in the Part II, Item 1A under the heading "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal, or GI, diseases. Our initial product candidate, vonoprazan, is an oral small molecule potassium competitive acid blocker, or P-CAB. P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown rapid, potent, and durable anti-secretory effects and has demonstrated clinical benefits over the current standard of care as a single agent in the treatment of gastroesophageal reflux disease, or GERD, and in combination with antibiotics for the treatment of *H. pylori* infection. Takeda Pharmaceutical Company Limited, or Takeda, developed vonoprazan and has received marketing approval in thirteen countries in Asia and Latin America. Vonoprazan generated over $670 million in net sales in its fifth full year on the market since its approval in Japan in late 2014. In May 2019, we in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda. We initiated two pivotal Phase 3 clinical trials in the fourth quarter of 2019 for vonoprazan: one for the treatment of erosive GERD (PHALCON-EE), also known as erosive esophagitis, and a second for the treatment of *H. pylori* infection (PHALCON-HP). We have received qualified infectious disease product, or QIDP, and Fast Track designations from the U.S. Food and Drug Administration, or FDA, for vonoprazan in combination with certain antibiotics for the treatment of *H. pylori* infection. QIDP designation also provides potential eligibility for priority review and extension of any regulatory exclusivity awarded, if approved. Vonoprazan has the potential to be the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years. In addition, we continue to plan to pursue vonoprazan lifecycle extension strategies in areas with clear unmet need, clinical rationale, and commercial justification. For example, one indication for which we are evaluating is whether to study vonoprazan for potential use in non-erosive reflux disease or NERD with daily and/or on-demand, or as-needed, dosing regimens.

In March 2020, we announced a pause in randomization of new patients in our Phase 3 trials. The decision was not based on any study-related COVID-19 infections or other safety events, but supported global efforts to combat COVID-19, and aligned with guidance from the American Society of Gastrointestinal Endoscopy, or ASGE, on limiting endoscopies, which are required in both Phase 3 clinical trials. During the pause, we worked with our clinical trial sites to ensure uninterrupted clinical trial supply, and supported the continuation of patients who were enrolled in our Phase 3 trials prior to the randomization pause while providing for their safety and the safety of physicians and other staff at the clinical trial sites. On June 15, 2020, we announced that we had restarted randomization of new patients on a site-by-site basis in both of our Phase 3 trials. To date, we have not experienced any interruption in our clinical trial supply, however, there is no guarantee that, as COVID-19 continues, it will not disrupt our supply chain in the future.

Despite the pause in randomization, we expect to complete enrollment of the erosive esophagitis trial in the fourth quarter of 2020, and of the *H. pylori* trial in the first quarter of 2021. In addition, we expect that topline data from the *H. pylori* trial will be available in the second quarter of 2021 and topline data from the erosive esophagitis trial will be available in the second half of 2021, and that the successful completion of our Phase 3 clinical trials, together with the existing clinical data, will support regulatory submissions in 2021 and 2022 for marketing approval for the treatment of *H. pylori* infection and erosive esophagitis, respectively. However, our assumptions used to determine expected timelines for clinical trials and regulatory filings may not be correct due to a number of factors, including the uncertainties regarding COVID-19 and its potential further impact on our operations and clinical trials, and we may experience delays in the completion of such trials beyond our expected timelines and resulting delays in the filing of our regulatory submissions. Any delays in the completion of our clinical trials and regulatory filings or disruption in our supply chain could have a material adverse effect on our business, financial condition and results of operations.

In addition to our focus on the well-being of physicians and other staff at the clinical trial sites and the patients currently participating in our trials, we are actively working with each study site to implement measures to avoid study protocol violations, to minimize any disruption of treatment visits, to accommodate for other patient visit delays caused by limited access to healthcare facilities, to continue monitoring and supporting patients leveraging alternative methods (e.g., phone or virtual visits), and to properly record protocol violations and other information that may be related to COVID-19. In this respect, we are also incorporating recent direction and flexibility provided by regulatory authorities, including the FDA in its March 2020 Guidance (updated September 21, 2020) entitled "FDA Guidance on Conduct of Clinical Trials of Medicinal Products during COVID-19." This guidance is continually being updated by the FDA and updates can be found on the FDA's website at www.fda.gov. In addition, we may refer to guidance documents provided by other regulatory agencies, such as, for example, the European Medicines Agency's "Implications of coronavirus disease (COVID-19) on methodological aspect of ongoing clinical trials" found on www.ema.europe.eu, which are also continually being updated. We will continue to evaluate the impact of COVID-19 on our business and as additional information and guidance about its impact on our industry is available.

As of September 30, 2020, we received agreement from FDA on our proposed initial Pediatric Study Plans for the treatment of *H. pylori* infection and for the healing of erosive esophagitis and relief of heartburn, and maintenance of erosive esophagitis and relief of heartburn. We also received, in October 2020, a positive opinion from the European Paediatric Committee on the agreement of a Paediatric Investigational Plan for the treatment of gastroesophageal reflux disease and the treatment of *H. pylori* infection.

We commenced our operations in 2018 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing our initial product candidate, vonoprazan, meeting with regulatory authorities, preparing for and managing our Phase 3 clinical trials of vonoprazan, and providing other general and administrative support for these operations. Our operations to date have been funded primarily through the issuance of convertible promissory notes, commercial bank debt, and the proceeds from our initial public offering, or IPO. From our inception through September 30, 2020, we have raised aggregate gross proceeds of $90.3 million from the issuance of convertible promissory notes in 2019, $50.0 million of commercial bank debt, and net proceeds from our IPO of $191.5 million from the sale of 10,997,630 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,434,473 additional shares at a public offering price of $19.00 per share, after deducting underwriting discounts, commissions and offering costs. As of September 30, 2020, we had cash and cash equivalents of $226.4 million. Based on our current operating plan, and subject to the potential delays and cost increases resulting from the evolving COVID-19 pandemic, we believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into the second half of 2022.

We do not have any products approved for sale and have incurred net losses since our inception. Our net losses for the nine month periods ended September 30, 2020 and 2019 were $75.3 million and $157.1 million, respectively. As of September 30, 2020, we had an accumulated deficit of $331.8 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities, and pre-commercialization activities. We expect our expenses and operating losses will increase substantially as we advance vonoprazan through clinical trials, seek regulatory approval for vonoprazan, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution if we obtain marketing approval for vonoprazan, protect our intellectual property, expand our general and administrative support functions, including hiring additional personnel, and incur additional costs associated with operating as a public company.

We have never generated any revenue and do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for vonoprazan, which will not be for several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of vonoprazan, if ever, we expect to finance our cash needs through equity offerings, our existing loan and security agreement, or the Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, and this risk could be exacerbated by the impact of COVID-19 on global economic conditions. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us 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.

Financial Operations Overview

Our financial statements include our accounts (the receiving entity) and the accounts of YamadaCo IIA, Inc., or YamadaCo, prior to being merged into a single entity effective March 13, 2019. We and YamadaCo were entities under common control of Frazier Life Sciences IX, L.P., or Frazier, as a result of, among other things, Frazier's: (i) ownership of a majority of the outstanding capital stock of both companies; (ii) financing of both companies; (iii) control of the board of directors of both companies; and (iv) management of both companies. Both Phathom and YamadaCo were formed for the purpose of identifying potential assets around which to form an operating company. As the merged entities were under common control, the financial statements report the financial position, results of operations and cash flows of Phathom and YamadaCo as though the transfer of net assets and equity interests had occurred at the beginning of 2018. All intercompany accounts and transactions have been eliminated.

License Agreement with Takeda

On May 7, 2019, we and Takeda entered into an exclusive license, or the Takeda License, pursuant to which we in-licensed the U.S., European, and Canadian rights to vonoprazan fumarate. During the term of the Takeda License, we and our affiliates are not permitted to commercialize any pharmaceutical product, other than vonoprazan, that treats acid-related disorders, except for certain generic and OTC competing products in specified circumstances. We will be responsible at our cost for the development, manufacture and commercialization of vonoprazan products. We are required to use commercially reasonable efforts to develop and commercialize the vonoprazan products in our licensed territory.

Under the Takeda License, Takeda has the sole right and authority, with our input, to prepare, file, prosecute, and maintain all Takeda and joint patents on a worldwide basis at its own cost. We are responsible, at our cost, for preparing, filing, prosecuting, and maintaining patents on inventions made solely by us in connection with vonoprazan, subject to input from Takeda.

We paid Takeda upfront consideration consisting of a cash fee of $25.0 million, 1,084,000 shares of our common stock, a warrant to purchase 7,588,000 shares of our common stock at an exercise price of $0.00004613 per share, or the Takeda Warrant, and issued Takeda a right to receive an additional common stock warrant, or the Takeda Warrant Right, if Takeda's fully-diluted ownership of the Company represented less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of then outstanding convertible promissory notes, calculated immediately prior to the closing of our IPO. The Takeda Warrant Right expired without effect since no fair value had been allocated to it upon completion of our IPO, and no additional warrant was issued. We agreed to make milestone payments to Takeda upon achieving certain tiered aggregate annual net sales of licensed products in the United States, Europe, and Canada up to a total maximum milestone amount of $250.0 million. We also agreed to make tiered royalty payments at percentages in the low double digits on net sales of licensed products, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis from the first commercial sale of such product in such country, until the latest of expiration of the licensed patents covering the applicable product, expiration of regulatory exclusivity in such country, or 15 years following first commercial sale in such country.

Components of Results of Operations

Operating Expenses

Research and Development

To date, our research and development expenses have related to the development of vonoprazan. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, and consultants to conduct and support our ongoing clinical trials of vonoprazan; and
- costs related to the manufacturing of vonoprazan for our clinical trials.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of vonoprazan. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials and nonclinical studies of vonoprazan or any future product candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses evaluated in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate; and
- delays and cost increases as a result of COVID-19.

In-Process Research and Development

In-process research and development expenses relate to the Takeda License, and include the $78.9 million purchase price of the acquired research and development assets. The purchase price of the Takeda License consisted of the following: (i) $25.0 million in cash; (ii) issuance to Takeda of 1,084,000 shares of our common stock at a fair value of $5.9 million; (iii) issuance of the Takeda Warrant at an initial fair value of $47.9 million; (iv) issuance of the Takeda Warrant Right, with a nominal initial fair value due to the low probability of issuance; and (v) $0.1 million of transaction costs incurred by us. The fair value of the Takeda Warrant and Takeda Warrant Right were derived from the model used to estimate the fair value of our common stock and the fair value of the common stock was determined using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. We utilized a scenario-based analysis that estimated the fair value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, including various initial public offering, stay private and dissolution scenarios, and applying a discount for lack of marketability. We considered various stay private scenarios using the income approach and allocated the indicated equity value to each class of equity based on the current-value method. We also considered various initial public offering scenarios based on expected equity values in an initial public offering and allocated the indicated equity value to each class of equity on a fully-diluted basis considering the dilutive impacts of the unsecured convertible promissory notes we issued in May 2019, or the May 2019 Notes, and the Lender Warrants.

There were significant judgments and estimates inherent in the determination of the fair value of our common stock prior to our 2019 IPO. These judgments and estimates included assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our fair value per share of common stock could have been significantly different.

General and Administrative

General and administrative expenses consist of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance, accounting, legal, human resources and other administrative functions, legal fees relating to intellectual property and corporate matters, and professional fees for accounting and consulting services. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercial preparation activities for vonoprazan and, if any future product candidate receives marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Interest Income

Interest income consists of interest on our money market fund.

Interest Expense

Interest expense consists of interest on our outstanding commercial bank debt at a floating per annum interest rate which was 7.25% as of September 30, 2020, and amortization of the commercial bank debt discount recorded in connection with the fair value of warrants issued to the lenders, the debt issuance costs incurred, and the obligation to make a final payment fee.

Change in Fair Value of Warrant Liabilities

In connection with the entry into the Loan Agreement, we issued the lenders warrants to purchase our capital stock, or the Lender Warrants. The Lender Warrants were accounted for as liabilities as they contained a holder put right under which the lenders could have required us to pay cash in exchange for the warrants. We adjusted the carrying value of the Lender Warrants to their estimated fair value at each reporting date, with any change in fair value of the warrant liabilities recorded as an increase or decrease to change in fair value of warrant liabilities in the statements of operations. The Lender Warrants were accounted for at fair value using the Black-Scholes option-pricing model with an expected term equal to the remaining contractual term of the warrants. When we drew down an additional $25.0 million, or the Term Loan B, in March 2020, the Lender put right expired, and we recorded a final fair value adjustment and reclassified the Lender Warrants balance of $0.3 million to additional paid-in-capital.

Change in Fair Value of Convertible Promissory Notes

We issued convertible promissory notes in 2018 and 2019 for which we elected the fair value option. We adjusted the carrying value of our convertible promissory notes to their estimated fair value at each reporting date, with any change in fair value of the convertible promissory notes recorded as an increase or decrease to change in fair value of convertible promissory notes in our statements of operations.

Prior to their exchange into convertible promissory notes issued in May 2019, the fair value of convertible promissory notes issued from inception through April 2019 was estimated using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholders, including conversions in subsequent equity financings, change of control transactions, settlement and dissolution. The fair value of the convertible promissory notes issued in May 2019 was estimated using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transaction and dissolution scenarios.

The notes issued in May 2019 and related accrued interest thereon were converted into 6,107,918 shares immediately prior to the completion of our IPO.

Results of Operations

Comparison of the Nine months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
Operating expenses:			
Research and development	$ 56,494	$ 7,670	$ 48,824
In-process research and development	—	78,897	(78,897)
General and administrative	16,732	3,955	12,777
Total operating expenses	73,226	90,522	(17,296)
Loss from operations	(73,226)	(90,522)	17,296
Other income (expense):			
Interest income	1,075	530	545
Interest expense	(3,286)	(3,138)	(148)
Change in fair value of warrant liabilities	95	(59,060)	59,155
Change in fair value of convertible promissory notes	—	(4,928)	4,928
Other income (expense)	(5)	(7)	2
Total other income (expense)	(2,121)	(66,603)	64,482
Net loss	$ (75,347)	$ (157,125)	$ 81,778

Research and Development Expenses. Research and development expenses were $56.5 million and $7.7 million for the nine months ended September 30, 2020 and 2019, respectively. The increase of $48.8 million consisted of $39.9 million of clinical trial costs and $2.5 million of chemistry manufacturing and controls ("CMC") costs related to vonoprazan, $4.2 million of personnel-related expenses, $1.0 million of consulting expenses, $0.5 million of expenses related to regulatory requirements, and $0.7 million of other operating expenses.

In-Process Research and Development Expenses. We had no in-process research and development expenses for the nine months ended September 30, 2020. The $78.9 million of in-process research and development expenses for the nine months ended September 30, 2019 consisted of the purchase price for the research and development assets we acquired as part of the Takeda License.

General and Administrative Expenses. General and administrative expenses were $16.7 million and $4.0 million for the nine months ended September 30, 2020 and 2019, respectively. The increase of $12.7 million was due to increases of $6.0 million in personnel-related expenses, $4 million in professional services expenses for accounting, audit, tax, valuation and other services, $2.1 million of insurance premiums related to general operating matters, $0.2 million of consulting expenses, and $0.5 million of other operating expenses, partially offset by a $0.1 million decrease in legal fees related to corporate and intellectual property matters. Due to the planned continued buildout of administrative and commercial functions we expect general and administrative expenses to increase in future periods.

Other Income (Expense). Other expense of $2.1 million for the nine months ended September 30, 2020 consisted of $3.3 million of interest expense on outstanding commercial bank debt partially offset by $1.1 million of interest income and $0.1 million of other income related to the decrease in the fair value of warrant liabilities. Other expense of $66.6 million for the nine months ended September 30, 2019 consisted of $59.1 million of other expense related to the increase in the fair value of warrant liabilities, $4.9 million of other expense related to the increase in the fair value of our convertible promissory notes, $2.2 million of interest expense on our outstanding convertible promissory notes, $0.9 million of interest expense on outstanding commercial bank debt, partially offset by $0.5 million of interest income.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		
	2020	**2019**	**Change**
Operating expenses:			
Research and development	$ 25,770	$ 4,469	$ 21,301
General and administrative	7,060	1,813	5,247
Total operating expenses	32,830	6,282	26,548
Loss from operations	(32,830)	(6,282)	(26,548)
Other income (expense):			
Interest income	15	429	(414)
Interest expense	(1,286)	(1,990)	704
Change in fair value of warrant liabilities	—	(57,776)	57,776
Change in fair value of convertible promissory notes	—	(2,486)	2,486
Other income (expense)	(4)	(7)	3
Total other income (expense)	(1,275)	(61,830)	60,555
Net loss	$ (34,105)	$ (68,112)	$ 34,007

Research and Development Expenses. Research and development expenses were $25.8 million and $4.5 million for the three months ended September 30, 2020 and 2019, respectively. The increase of $21.3 million consisted of $17.5 million of clinical trial costs and $1.4 million of CMC costs related to vonoprazan, $1.6 million of personnel-related expenses, $0.2 million of consulting expenses, $0.2 million of expenses related to regulatory requirements, and $0.4 million of other operating expenses.

General and Administrative Expenses. General and administrative expenses were $7.1 million and $1.9 million for the three months ended September 30, 2020 and 2019, respectively. The increase of $5.2 million was due to increases of $1.2 million in professional services expenses for accounting, audit, tax, valuation and other services, $3.0 million in personnel-related expenses, $0.7 million of insurance premiums related to general operating matters, $0.2 million in consulting fees and $0.1 million in legal fees. Due to the planned continued buildout of administrative and commercial functions we expect general and administrative expenses to increase in future periods.

Other Income (Expense). Other expense of $1.3 million for the three months ended September 30, 2020 consisted of interest expense on outstanding commercial bank debt. Other expense of $61.8 million for the three months ended September 30, 2019 consisted of $57.7 million of other expense related to the increase in the fair value of warrant liabilities, $2.5 million of other expense related to the increase in the fair value of our convertible promissory notes, $1.4 million of interest expense on our outstanding convertible promissory notes, $0.6 million of interest expense on outstanding commercial bank debt, partially offset by $0.4 million of interest income.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2020, we had cash and cash equivalents of $226.4 million.

Commercial Bank Debt

On May 14, 2019, we entered into the Loan Agreement with Silicon Valley Bank, or SVB, as administrative and collateral agent, and lenders SVB and WestRiver Innovation Lending Fund VIII, L.P. We borrowed $25.0 million, Term Loan A, at the inception of the Loan Agreement and the additional $25.0 million, Term Loan B, in March 2020, which we collectively refer to as the Term Loans. As of September 30, 2020, we had outstanding Term Loans of $50.0 million and accrued interest of $0.3 million.

The Term Loans bear interest at a floating rate of the higher of the Wall Street Journal Prime rate plus 1.75% (5% at September 30, 2020) or 7.25%. Under the original Loan Agreement, the monthly payments consisted of interest-only through May 31, 2021. Pursuant to the first amendment to the Loan Agreement entered into on March 11, 2020, the interest-only payment period was extended either (i) until December 31, 2021, if we receive positive data from our Phase 3 clinical trial in *H. pylori* infection sufficient to file a new drug application, or NDA, with the FDA; or (ii) until November 30, 2022, if we receive positive data from our Phase 3 clinical trials in both indications for vonoprazan sufficient to file an NDA with the FDA; provided, in each case, that we had drawn down an additional $25.0 million, Term Loan B, pursuant to the Loan Agreement. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest through the maturity date of May 1, 2024.

In addition, we are obligated to pay a final payment fee of 8.25% of the original principal amount of the Term Loans. We may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.0% of the then outstanding principal balance and payment of a pro rata portion of the final payment fee. After repayment, no Term Loan amounts may be borrowed again. The borrowings under the Loan Agreement are collateralized by substantially all of our assets, excluding intellectual property and certain other assets. We have agreed not to encumber our intellectual property assets without SVB's prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loans, in which case our intellectual property will automatically be included within the assets securing the Term Loans.

The Loan Agreement contains certain customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding our operating accounts. The negative covenants include, among others, limitations on our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by us would begin to bear interest at a rate that is 4.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by SVB, as collateral agent. As of September 30, 2020, we were in compliance with all applicable covenants under the Loan Agreement.

In connection with the Loan Agreement, we issued the Lender Warrants, which became exercisable when we borrowed Term Loan B in March 2020. The Lender Warrants are exercisable for 16,446 shares of common stock. The Lender Warrants expire ten years from the date of issuance. The Lender Warrants included a put option pursuant to which, in the event that we did not draw down Term Loan B on or before March 31, 2020, the warrant holders could have required us to repurchase the warrants for a total aggregate repurchase price of $0.5 million. Upon the Term Loan B draw in March 2020, the put option related to the Lender Warrants expired, at which time we recorded a final fair value adjustment and reclassified the Lender Warrants balance of $0.3 million to additional paid-in-capital.

Convertible Note Financings

From January 2018 to April 2019, we issued an aggregate of $2.4 million of convertible promissory notes to Frazier, or the Frazier Notes, bearing interest at per annum rates ranging from 1.68% to 2.55%. In May 2019, these notes and related accrued interest were exchanged, at their then fair value of $2.4 million, for the May 2019 convertible promissory notes described below.

On May 7, 2019, we entered into a note purchase agreement under which we issued an aggregate of $90.3 million of May 2019 Notes resulting in gross proceeds to us of $87.8 million in cash and $2.4 million related to the exchange of the Frazier Notes. Including the conversion of the Frazier Notes, Frazier purchased $20.0 million of the May 2019 Notes. The May 2019 Notes bore an interest at a rate of 6% per annum and were subordinated to borrowings under our Loan Agreement. Immediately prior to the completion of our IPO on October 29, 2019, the May 2019 Notes automatically converted into 6,107,918 shares of common stock, representing the outstanding principal and interest of the May 2019 notes at the date of automatic conversion.

At-the-Market-Offering

On November 10, 2020, we entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC (the "Sales Agent"), under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $125.0 million through the Sales Agent (the "ATM Offering"). Sales of our common stock made pursuant to the Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 to be filed on November 10, 2020, following such time as the registration statement is declared effective by the SEC. We are not obligated to, and we cannot provide any assurances that we will, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by the Sales Agent or us at any time.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements into the second half of 2022. We expect our current cash and cash equivalents will allow us to complete our ongoing Phase 3 clinical trials of vonoprazan for the treatment of erosive esophagitis and *H. pylori* infection. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, type, number, scope, results, costs, and timing of our clinical trials of vonoprazan and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including feedback received from regulatory authorities;
- delays and cost increases as a result of COVID-19;
- the costs and timing of manufacturing for vonoprazan or any future product candidates, including commercial scale manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of vonoprazan or any future product candidates;
- the costs of obtaining, maintaining, and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities for vonoprazan or any future product candidate;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;

- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. 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 our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Including our existing cash and cash equivalents we believe that we have sufficient working capital on hand to fund operations such that there is no substantial doubt as to our ability to continue as a going concern at the date the financial statements were issued. There can be no assurance that we will be successful in acquiring additional funding, that our projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
Net cash provided by (used in):			
Operating activities	$ (41,488)	$ (13,126)	$ (28,362)
Investing activities	(916)	(25,144)	24,228
Financing activities	25,000	111,875	(86,875)
Net increase (decrease) in cash	$ (17,404)	$ 73,605	$ (91,009)

Operating Activities

Net cash used in operating activities was approximately $41.5 million and $13.1 million for the nine months ended September 30, 2020 and 2019, respectively. The net cash used in operating activities for the nine months ended September 30, 2020 was due to approximately $70.7 million spent on ongoing research and development and general and administrative activities, partially offset by a $29.2 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $11 million decrease in prepaid clinical activities, and an $18.4 million increase in accounts payable and accrued expenses in support of the growth in our operating activities, partially offset by a $0.2 million increase in other long-term assets. The net cash used in operating activities for the nine months ended September 30, 2019 was due to approximately $13.9 million spent on ongoing research and development and general and administrative expenses, partially offset by a $0.8 million net change in operating assets and liabilities. The net change in operating assets and liabilities related to a $2.3 million increase in accrued interest on our outstanding convertible promissory notes and commercial bank debt and a $1.6 million increase in accounts payable and accrued expenses in support of the growth in our operating activities, partially offset by a $3.1 million increase in prepaid clinical activities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2020 was primarily due to the cash we paid for acquiring property, plant and equipment. Net cash used in investing activities for the nine months ended September 30, 2019 was primarily due to the cash we paid, including transaction costs, to acquire the Takeda License.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 was due to our commercial bank debt proceeds of $25.0 million related to the Term Loan B drawdown. Net cash provided by financing activities for the nine months ended September 30, 2019 was $111.9 million, due to $88.3 million of net proceeds from our issuance of convertible promissory notes, $24.9 million of net proceeds from our commercial bank debt and offset by $1.3 million in issuance costs related to the IPO.

Contractual Obligations and Commitments

Other than disclosed below, there were no material changes outside the ordinary course of our business during the nine months ended September 30, 2020 to the information regarding our contractual obligations that was disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our 2019 Form 10-K.

On March 16, 2020, we drew down the additional $25.0 million Term Loan B. As of September 30, 2020, we had outstanding Term Loans of $50.0 million and accrued interest of $0.3 million.

On May 5, 2020, the Company entered into a Commercial Supply Agreement with Takeda, pursuant to which Takeda will supply commercial quantities of vonoprazan bulk drug product. The Company incurred $0.1 million of expenses related to the Commercial Supply Agreement through the nine months ended September 30, 2020. The Company has a remaining minimum purchase obligation of approximately $2.4 million related to this agreement.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For a description of our critical accounting policies, please see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgments and Estimates" contained in our 2019 Form 10-K. There have not been any material changes to the critical accounting policies discussed therein during the nine months ended September 30, 2020.

Other Company Information

JOBS Act

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

The information required by this item is included in Note 1, Organization, Basis of Presentation and Summary of Significant Accounting Policies included in Part 1, Item 1 of this quarterly report.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2020, there have been no material changes surrounding our market risk, including interest rate risk, foreign currency exchange risk, and inflation risk, from the discussion provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative Disclosures About Market Risk" of our 2019 Form 10-K.

Item 4. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC 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 our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this quarterly report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the nine months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

Other than as set forth below, there have been no material changes to the risk factors disclosed in Part I, Item 1A, "Risk Factors" of our 2019 Form 10-K, other than as previously reported in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

On October 24, 2019, our registration statement on Form S-1 (File No. 333-234020) was declared effective by the SEC for our initial public offering. At the closing of the offering on October 29, 2019, we sold 10,997,630 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,434,473 additional shares, at an initial public offering price of $19.00 per share and received gross proceeds of $209.0 million, which resulted in net proceeds to us of approximately $191.5 million, after deducting underwriting discounts and commissions of approximately $14.6 million and offering-related transaction costs of approximately $2.9 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Goldman Sachs & Co. LLC, Jefferies LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering.

As of September 30, 2020, the net proceeds from our initial public offering have been applied as follows: $37.6 million towards the clinical development of vonoprazan and $18.0 million towards working capital and general corporate purposes.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

On November 10, 2020, we entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC (the "Sales Agent"), under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $125.0 million through the Sales Agent (the "ATM Offering").

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Sales Agents may sell the shares by methods deemed to be an "at the market offering" offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on or through the Nasdaq Global Select Market or any other existing trading market for the common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. Subject to the terms and conditions of the Sales Agreement, the Sales Agent will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable law and regulations, to sell the shares from time to time, based upon our instructions. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 to be filed on November 10, 2020, following such time as the registration statement is declared effective by the SEC.

We will pay the Sales Agent a commission for its services in acting as agent in the sale of common stock in an amount equal to 3% of the gross sales price per share sold. We have also agreed to provide Jefferies with customary indemnification and contribution rights. We are not obligated to, and we cannot provide any assurances that we will, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by the Sales Agent or us at any time.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the Sales Agreement, a copy of which will be filed as Exhibit 1.2 to our Registration Statement on Form S-3 filed on November 10, 2020 with the SEC and is incorporated herein by reference.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	10/29/19	3.1	
3.2	Amended and Restated Bylaws	8-K	09/25/2020	3.2	
4.1	Form of Common Stock Certificate	S-1/A	10/15/19	4.1	
4.2	Warrant to purchase shares of common stock issued to Takeda Company Limited, dated May 7, 2019	S-1	9/30/19	4.2	
4.3	Warrant to purchase stock issued to Silicon Valley Bank, dated May 14, 2019	S-1	9/30/19	4.3	
4.4	Warrant to purchase stock issued to WestRiver Innovation Lending Fund VIII, L.P., dated May 14, 2019	S-1	9/30/19	4.4	
4.5	Note Purchase Agreement, dated May 7, 2019, by and among the Registrant and the other parties party thereto, as amended	S-1/A	10/15/19	4.5	
4.6	Description of Registered Securities	10-K	12/31/19	4.6	
10.1†	Amendment No. 1 to Takeda License Agreement, dated September 21, 2020				X
31.1	Certification of Chief Executive Officer of Phathom Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer of Phathom Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Report Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Calculation Linkbase Document				X
101.LAB	XBRL Taxonomy Label Linkbase Document				X
101.PRE	XBRL Presentation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X

† Certain portions of this exhibit, that are not material and would likely cause competitive harm to the registrant if publicly disclosed, have been redacted pursuant to Item 601(b)(10) of Regulation S-K.

* This certification is deemed not filed for purpose 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.

PHATHOM PHARMACEUTICALS, INC.

Date: November 10, 2020

By: /s/ Terrie Curran
Terrie Curran
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 10, 2020

By: /s/ Todd P. Branning
Todd P. Branning
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. THE OMISSIONS HAVE BEEN INDICATED BY "[***]."

Exhibit 10.1

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (this "Agreement") is made effective as of April 30, 2020 (the "Effective Date") by and between Takeda Pharmaceutical Company Limited, a company incorporated under the laws of Japan having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan ("Takeda") and Phathom Pharmaceuticals, Inc., a company incorporated under the laws of Delaware having its principal place of business at 2150 E. Lake Cook Road, Suite 800, Buffalo Grove, Illinois 60089, U.S.A. ("Company"). Takeda and Company are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Takeda and Company are parties to that certain License Agreement effective as of May 7, 2019 ("License Agreement") pursuant to which Takeda granted to Company a license in the Field in the Territory to Develop and exclusively Commercialize pharmaceutical products containing the Compound (as those terms are defined in the Licensed Agreement), and referred to as "Products" in the License Agreement, in the Field in the Territory;

WHEREAS, pursuant to the License Agreement, the Parties have entered into good faith discussions to agree on terms under which Takeda will supply Bulk Drug Product to Company; and

WHEREAS, on the terms and conditions set out below, Takeda has agreed to supply to Company, and Company has agreed to purchase from Takeda, certain quantities of Bulk Drug Product for use to Commercialize the Product in the Territory.

NOW, THEREFORE, and in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. DEFINITIONS. As used in this Agreement, the following terms shall have the following meanings, and all other capitalized terms used but not otherwise defined in this Agreement shall have their respective meanings set forth in the License Agreement:

   (A) "API" means active pharmaceutical ingredient, vonoprazan fumarate Compound.

   (B) "Bulk Drug Product" means drug Product in bulk form (not packaged and labeled), to be supplied to Company under this Agreement, meeting the Specifications.

   (C) "cGMPs" means the current good manufacturing practices, as specified in Applicable Law of the Territory, applicable to the manufacture of Bulk Drug Product for use in the Territory.

   (D) "Detectable Defects" has the meaning in Section 8(A).

(E) "Manufacturing Change" means any change to the Specifications and to the manufacturing and/or testing processes used in connection with manufacturing Bulk Drug Product pursuant to this Agreement.

(F) "Payments" has the meaning set forth in Section 3(C).

(G) "Purchase Price" means the purchase price of Bulk Drug Product supplied to Company hereunder.

(H) "Quality Agreement" has the meaning set forth in Section 6(C).

(I) "Specifications" means the specifications set forth on the attached Exhibit 1 as may be amended pursuant to Section 6.

(J) "Term" has the meaning set forth in Section 16(A)

(K) "Territory" has the meaning set forth in the License Agreement.

2. PRODUCT SUPPLY.

(A) Bulk Drug Product Purchase and Supply. Subject to the terms and conditions set forth in this Agreement, Takeda shall supply to Company, and Company shall purchase from Takeda, Bulk Drug Product in the dosage form and as per quantities set forth in Exhibit 2 of this Agreement for Company's use. Takeda has no obligation to supply Bulk Drug Product to Company in any form or quantity other than as expressly provided in this Agreement.

(B) Additional Services: Any services other than the supply of Bulk Drug Product and related costs shall be agreed in writing by the Parties before performance of such services. Company shall be responsible for such agreed upon costs. The costs associated with Takeda staff hours in the performance of activities under Sections 2(B)(i), 2(B)(ii) and 2(C), below, shall be determined in accordance with the hourly rate agreed by the Parties in Section 5.5 of the License Agreement.

(i) Pre-Approval Inspection. If required by a Regulatory Authority, Takeda shall prepare for and host pre-approval inspections. [***] prior to the submission of the first NDA or MAA for a Product by Company, the Parties shall enter into good faith negotiations for an agreement defining the activities, costs and responsibilities relating to such inspections. This agreement shall be mutually agreed upon and executed before the first such NDA or MAA submission by Company. For the avoidance of doubt, any such agreed upon costs incurred by Takeda for pre-approval inspections, including pre-approval inspection readiness assessment, or inspections related specifically to the Bulk Drug Product relevant for the Territory shall be solely borne by the Company.

(ii) Technology Transfer to a Third Party Manufacturer. Any additional service, including technical advice and supply of materials set forth in Exhibit 3, in each case as necessary for technology transfer, other than the provision of technical transfer documents in accordance with Section 5.5 of the License Agreement and Exhibit F of the License Agreement, and related costs shall be paid by Company and agreed in writing by the Parties before any performance of such services. The Parties shall enter into good faith negotiations to agree on reasonable additional support Company needs to develop and execute technology transfers to its own API and Bulk Drug Product CMOs.

(C) Other Services: For the avoidance of doubt, except as provided in Sections 2(A) and 2(B) of this Agreement, Takeda has no obligation to provide other services to Company under this Agreement. In the event any other services under this Agreement are identified as necessary to enable the Commercialization of the Product in the Territory, the Parties shall enter into good faith negotiations to agree terms for the provision of such other services.

3. PURCHASE PRICE, INVOICING AND PAYMENT.

(A) Purchase Price. In consideration for Takeda's agreement to supply Bulk Drug Product under this Agreement, Company shall pay Takeda the Purchase Price for each delivery of Bulk Drug Product set forth on Exhibit 2 of this Agreement.

(B) Purchase Price; Invoices. Upon delivery of Bulk Drug Product in accordance with the terms of Section 7, Takeda shall invoice Company for the applicable Purchase Price of such Bulk Drug Product. Takeda shall send all such invoices in PDF format to phathom.ap@phathompharma.com. Company shall pay Takeda's invoice for the Purchase Price within thirty (30) days of the date of invoice, in accordance with Section 3(D). For the sake of clarity, any undisputed amount in (i) any invoice due for additional services or (ii) any invoice due for Bulk Drug Product that the Company has not ordered despite its obligation to order as provided for under Section 5(A) shall be paid by the Company within thirty (30) days of the date of invoice.

(C) Taxes. Company shall pay any applicable taxes, such as sales, use, excise, value-added, service, goods and services, and consumption taxes imposed by relevant taxing authority as a result of payments it makes to Takeda pursuant to this Agreement ("Payments"). All other taxes, such as income tax, gross receipts tax, foreign withholding tax, etc., applicable to the Payments, shall be the sole responsibility of Takeda. Each Party will provide to the other Party any resale exemption, multiple points of use certificates, treaty certification and other exemption information reasonably requested by the other Party.

(D) Payment of Purchase Price and Exchange Rate. Company shall make all Payments due to Takeda hereunder in U.S. Dollars by wire transfer of immediately available funds into an account designated by Takeda. The rate of exchange to be used in

computing the amount of currency equivalent in U.S. Dollars owed to a Party under this Agreement, including any Payments that Company opts to make to Takeda in U.S. Dollars, shall be the monthly average exchange rate between each currency of origin and U.S. Dollars as reported by The Wall Street Journal East Coast Edition. The monthly average exchange rate shall be the average of (i) the exchange rate published on the last day of the month; and (ii) the exchange rate published on the last day of the preceding month.

(E) Late Payment. If Takeda does not receive payment of any undisputed amount due on or before the due date, simple interest shall thereafter accrue on the amount due to Takeda until the date of payment at the per annum rate of two percent (2%) over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Law, whichever is lower.

4. REGULATORY ACTIVITIES AND RESPONSIBILITIES; INSPECTIONS AND AUDITS.

(A) General Obligations of Takeda. Takeda shall, or shall cause its Affiliates or Third Parties on its behalf, in Takeda's sole discretion, to perform its obligations under this Agreement in compliance with all Applicable Law, including all cGMPs, and in accordance with the Quality Agreement.

(B) General Obligations of Company. Company shall obtain and maintain at its expense all licenses and permits as well as all Regulatory Approvals required for Company's use of Bulk Drug Product in accordance with the terms of this Agreement and the License Agreement. Company shall, and shall ensure that its Affiliates, Third Party subcontractors and any employees and agents of Company involved in the use of Bulk Drug Product comply with the requirements and restrictions of any licenses and permits and Applicable Law concerning the use of Bulk Drug Product in the Territory.

(C) Regulatory Authority Inspections.

(i) Takeda shall allow any competent Regulatory Authority access to Takeda's facilities to perform inspections of such facilities and cGMPs documents that are applicable to the Bulk Drug Product(s) or service(s) provided to the Company under this Agreement.

(ii) Takeda will notify Company within [***] of any contacts with Regulatory Authorities (both written and verbal) related to Bulk Drug Product to be supplied under this Agreement. Takeda shall inform Company within: (a) [***] of planned impending Regulatory Authority inspections that affect Bulk Drug Product(s) or service(s) provided under this Agreement, (b) [***] of an unannounced Regulatory Authority inspection that affect Bulk Drug Product(s) or such service(s), and (c) [***] of any Regulatory Authority action (e.g., withdrawal of necessary permits and licenses, warning letters, etc.) and/or critical observations that affect Bulk Drug

Product(s), such facilities, or such service(s). Takeda shall cooperate, and shall use reasonable efforts to cause any contract facility to cooperate, with such Regulatory Authority and Company during such inspection. Takeda shall provide Company with regular updates regarding the status of such inspection and any communications by such Regulatory Authorities relating to Bulk Drug Product or the bulk form of the API, provided that with respect to any critical issues Takeda shall provide Company updates within [***]. In addition, Takeda shall promptly notify Company of all contacts with, or audits or inspections by, Regulatory Authorities (both written and verbal) that would reasonably be expected to adversely affect the ability of any party to manufacture Bulk Drug Product or the bulk form of the API used to manufacture Bulk Drug Product anywhere in the world.

(iii) The Parties shall consult and agree in preparing commitments to competent Regulatory Authorities or in responding to observations made during Regulatory Authority inspections that relate directly to the Bulk Drug Product(s) or service(s) provided under this Agreement, including any notice of inspection, notice of violation or other similar notice received by Takeda affecting manufacture, testing, storage or handling of any Bulk Drug Product or the facilities used therefor. Following receipt of the inspection observations of such Regulatory Authority, Takeda shall promptly provide Company with a copy of the inspection report and also provide Company with copies of any written communications received from Regulatory Authorities with respect to such facilities promptly after receipt, to the extent such written communications relate to Bulk Drug Product or API or the manufacture thereof, and shall prepare the response to any such observations. If documentation includes confidential information, Company shall be entitled to have access to these documents during the audit under the confidentiality terms set forth in the License Agreement. Company shall provide its comments to the response of these observations within [***]. Takeda shall provide the final written responses to the applicable Regulatory Authority and a copy of such final written responses that affect the Bulk Drug Product(s) or such service(s) to Company. In the event that there are inspectional observations (FDA Form 483, or equivalent), Takeda shall inform Company within [***] of receipt from the applicable Regulatory Authority and Company shall have the opportunity to review and provide Takeda with comments to Takeda's response. Company shall provide its comments to the response of these observations within [***]. The contents of Takeda's response shall be determined by Takeda in its sole discretion; provided that Takeda shall provide Company with a copy of any such response prior to submission to such Regulatory Authority and Takeda shall consider in good faith Company's comments with respect to such response.

(iv) Takeda shall ensure resolution of all observations identified by any such Regulatory Authority within the committed timeframe.

(D) Communications with Regulatory Authorities. Except as provided in Section 4(C), any and all other communications from and to Regulatory Authorities related to the manufacture of Bulk Drug Product to be supplied under this Agreement will be handled in accordance with the terms and conditions of the Quality Agreement, or as otherwise agreed in writing by Takeda and Company.

(E) Company Inspections and Audits.

(i) Takeda shall allow an [***] pre-scheduled audit to perform inspections of the authorized facilities and all documents relevant to the Bulk Drug Product(s) and/or service(s) provided under this Agreement, with prior notification of [***] by Company, with up to [***] Company auditors (or a Third Party designee) access to the premises for up to [***], or as many days as appropriate relative to such service(s) or Bulk Drug Product(s). Takeda shall cooperate, and shall use reasonable efforts to cause the contract facility to cooperate, with Company during such inspection. As necessary, Company shall provide a request in advance when additional time is needed to conduct audit activities. As often as necessary, Takeda shall allow 'for cause' audits with immediate notice, or for other audits such as for pre-approval inspection readiness with advanced notice from the Company.

(ii) During such audits, Takeda shall allow Company the right to observe the service(s) provided under this Agreement and to observe the use of all associated raw materials and packaging components for the Bulk Drug Product(s) to ensure adherence to the agreed upon standards.

(iii) Company shall provide to Takeda a detailed audit observation report, listing all observations, if any, as discussed during the on-site audit (the "Audit Report") within [***]. Takeda shall provide to Company a written response, including corrective actions and preventative actions ("CAPA") plan for all observations documented in the Audit Report, within [***] of receipt thereof.

(iv) Takeda shall ensure timely resolution of all deficiencies identified by Company within the committed timeframe.

5. ORDERING AND PURCHASING.

(A) Ordering

(i) The Parties have agreed that the Company shall order a certain minimum number of batches of Bulk Drug Product each year as described in Exhibit 2 of this Agreement, such minimum being binding. In the event the Company does not buy the minimum number of batches of Bulk Drug Product, other than as a result of Takeda's inability to supply such batches for any reason, or as a result of Force Majeure pursuant to Section 17(C), the Company shall pay to Takeda the amount corresponding to the missing batches.

(ii) The Company is entitled to order Bulk Drug Product up to the maximum number of batches specified in Exhibit 2 of this Agreement. Takeda has no obligation to supply Bulk Drug Product above the maximum number of batches specified in Exhibit 2. After July 15, 2020 and prior to termination of this Agreement, the Company may request additional batches of Bulk Drug Product beyond maximum quantity defined in Exhibit 2. After July 15, 2020, and upon written request of Company if Takeda can support additional batches of Bulk Drug Product, such evaluation to be at its sole discretion, [***], the Parties will agree in writing to add the additional batches of Bulk Drug Product to this Agreement, which addition may also include some amendments to the delivery forecast in Exhibit 3.

(B) Purchase Orders.

(i) Issuance of Purchase Orders. Company shall submit a purchase order to Takeda for each purchase of Bulk Drug Product at least [***] in advance of the applicable delivery date. Bulk Drug Product will be ordered in number of batches. The purchase orders shall specify the dosage and the requested date of delivery.

(ii) Acceptance of Purchase Orders. Takeda will confirm Company's purchase order within [***] after receipt. Other than the delivery date, any terms and conditions contained in any Company purchase order will not be binding on Takeda, provided however that delivery shall be considered to have occurred on due date despite the Bulk Drug Product being delivered [***] before or after the delivery date specified in the purchase order. To the extent of any conflict between a purchase order and this Agreement, this Agreement will control. The Parties have agreed on a delivery forecast attached in Exhibit 3 and Company shall place purchase orders to Takeda according to the terms of this Agreement considering this agreed delivery forecast.

(C) Notice of Potential Inability to Supply.

(i) Takeda shall inform Company of any events that may prevent Takeda from supplying all of the Bulk Drug Product included in any purchase order submitted by the Company by the requisite delivery date as soon as reasonably practicable after becoming aware of such events. In the event Takeda notifies Company of a potential inability to supply a Bulk Drug Product by the requisite delivery date, the Parties shall discuss in good faith how to resolve the matter.

(ii) Takeda enters into this Agreement based on the evaluation of the markets upon the Effective Date with acknowledgement that this situation may change in the next years. Takeda will not be considered in breach of its material obligations under the Agreement in the event that Takeda cannot supply agreed maximum quantities, as set forth in Exhibit 2, because of

higher needs of supply of Product for its commercialization outside of the Territory. Takeda commits to keeping Phathom informed of the supply perspective and will consider the following in allocation decisions:

(a) Patients in the Licensee's Territory may need the Product; and

(b) If there is no other way for the Company to secure Bulk Drug Product than from Takeda.

6. MANUFACTURING.

(A) Conformance. All units of Bulk Drug Product shall conform to Applicable Law, including all cGMPs, and the Specifications upon delivery to Company.

(B) Control of Manufacturing Changes.

(i) Manufacturing Changes requested by Takeda. Takeda may request Manufacturing Changes. Takeda shall provide Company with written notice providing details and reason for any such requested Manufacturing Changes. Costs related to such Manufacturing Changes shall solely borne by Takeda.

(ii) Manufacturing Changes requested by the Company or required by the Regulatory Authorities.

(a) Company may request Manufacturing Changes. Company shall provide Takeda with details and the reason for any Manufacturing Changes requested by Company or required by Regulatory Authorities. Manufacturing Changes requested by Company, upon requirement of the Regulatory Authorities or not, will be at the Company's sole cost.

(b) Company hereby acknowledges that as of the Effective Date, the Specifications for Bulk Drug Product attached in Exhibit 1 of this Agreement are the specifications approved by the Regulatory Authority in Japan and are used as reference by the Parties. Notwithstanding the foregoing, the Parties acknowledge and agree that such specifications are expected to change in order to manufacture Bulk Drug Product for the Territory, and the Parties will negotiate in good faith the costs of any such changes. Any change to the Specifications for Bulk Drug Product will be at Company's sole cost, which may include capex and opex related costs.

(iii) All Manufacturing Changes, including those described in Sections 6(B)(i) and (ii), above, shall require the written approval of both Company and Takeda prior to implementation, which approval shall not be unreasonably withheld, conditioned or delayed. The procedure for managing these changes shall be detailed in the Quality Agreement.

(C) Quality. If the Parties have not executed a quality agreement governing the quality terms relating to supply of Bulk Drug Product under this Agreement ("Quality Agreement") contemporaneously with the execution of this Agreement, the Parties will execute a Quality Agreement within [***] after the Effective Date.

(D) Without limiting the foregoing, Takeda shall:

(i) maintain a retention program for all cGMPs documents and records in accordance with Applicable Law; and not destroy any of the foregoing without the prior written consent of Company; and

(ii) prepare an Annual Product Review/Product Quality Review for the Product(s), as required per Applicable Law, and provide such review to Company.

7. DELIVERY, TITLE AND RISK OF LOSS.

(A) Delivery Terms; Title; Risk of Loss. Bulk Drug Product will be delivered to Company EXW (Incoterms 2010) Takeda's facility in Hikari City, Japan. Transfer of title will transfer to Company upon delivery to the carrier. Company shall procure, at its expense, insurance, covering damage or loss to Bulk Drug Product during transport as from delivery.

(B) Importer of Record/Export. Company shall be the "Importer of Record" of Bulk Drug Product supplied under this Agreement. As the Importer of Record, Company shall be responsible for all aspects of importing such Bulk Drug Product, including: (i) customs and other regulatory clearance; (ii) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery; and (iii) keeping all records, documents, correspondence and tracking information required by Applicable Law arising out of or in connection with the importation or delivery. If requested by Company, Takeda shall reasonably assist Company in obtaining any required license from the applicable Japanese Regulatory Authority to export the Bulk Drug Product.

8. NON-CONFORMING PRODUCT/RETURNS.

(A) Claims for Detectable Defects. Company shall promptly, but in no event later than [***] after delivery of the Bulk Drug Product notify Takeda of the existence and nature of any defect in or failure of the Bulk Drug Product to comply with Section 4(A) or Section 14(B) that could have been detected by a reasonable physical inspection of the Bulk Drug Product at the time of delivery ("Detectable Defects"). If such notice is not provided to Takeda within such [***] period, then Company will be deemed to have accepted such Bulk Drug Product and Takeda will have no further responsibility for such Detectable Defects.

(B) Claims for Non-Detectable Defects. Company shall notify Takeda within [***] upon discovery of any defect in or failure of Bulk Drug Product to comply with Section 4(A) or Section 14(B) that at the time of delivery was not a Detectable Defect. Company shall provide such notice prior to expiry of shelf life for such Bulk Drug Product. Claims for which Company does not provide notice to Takeda prior to expiry of the shelf life for the Bulk Drug Product shall be forever waived and barred. Permitted claims that are submitted by Company shall state in reasonable detail (reasonably sufficient to enable Takeda to identify the nature of the problem or to dispute the same) the nature of such alleged defect.

(C) Provision of Samples. Company shall, within [***] of a request by Takeda, provide samples of any Bulk Drug Product alleged to be defective and copies of written reports or investigations performed to date by or on behalf of Company on such Bulk Drug Product.

(D) Referral to Independent Laboratory. In the event of a dispute between the Parties as to any defect in a Bulk Drug Product (including whether a defect was a Detectable Defect or a non-Detectable Defect, or whether such defect existed in such Bulk Drug Product on or before Company's acceptance), that is not resolved within thirty (30) days of a claim being made to Takeda pursuant to Section 8(A) or 8(B), and subject to Section 8(E), the matter will be submitted to an independent laboratory reasonably acceptable to the Parties that shall examine the Bulk Drug Product at issue. The decision of the independent laboratory with respect to the existence or timing of any defect in the Bulk Drug Product and its cause shall be binding upon the Parties. Company shall bear the fees and expenses of the independent laboratory, unless the independent laboratory finds that the defect was due to Takeda's negligence or willful misconduct, in which case Takeda shall bear such fees and expenses.

(E) Replacement Product; Defective Product. Following a claim from Company pursuant to Section 8(A) or 8(B), in the event that Takeda accepts Company's claim as valid or in the event that the independent laboratory decides in favor of Company's claim, subject to the last sentence of this paragraph, Takeda shall replace the defective Bulk Drug Product as soon as reasonably practicable and will have no other obligation towards Company in relation to that defective Bulk Drug Product. Any Bulk Drug Product that is agreed or determined to be defective shall be, as directed by Takeda, either destroyed by Company or returned to Takeda, in either case at Takeda's expense. Except for Takeda's obligations under Section 10 or 15, Takeda shall have no liability for defective Bulk Drug Product other than as provided in this Section 8.

9. STORAGE AND DISTRIBUTION.

(A) Company's Responsibilities. Company shall, at its sole expense, store, handle, transport, and package, distribute and use Bulk Drug Product delivered to Company in compliance with the requirements set out in the Quality Agreement, the Product Regulatory Approval and all Applicable Law. Company shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.

(B) Company Storage, Handling and Transport of Product. Company shall obtain at its sole expense all equipment, facilities and personnel necessary for Company to store, handle, transport, and package, distribute and use Bulk Drug Product in accordance with the terms hereof and shall pay all other expenses in connection therewith. If Company, for any reason (other than as a result of a claim for a defect pursuant to Section 8(A) or 8(B)), refuses to take delivery or possession of any Bulk Drug Product, Company shall, notwithstanding Section 15(B), reimburse Takeda for any resulting direct, out-of-pocket, storage, warehousing, handling or transportation fees that Takeda may incur.

(C) Takeda's Responsibilities. Takeda shall ensure that is its facilities used to manufacture, handle, package, test, and store Bulk Drug Product(s) meet appropriate controlled cGMPs conditions and Bulk Drug Product(s) specifications. Takeda shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations, including by implementing an appropriate housekeeping, sanitation and pest control program with appropriate monitoring and review. Takeda will not use any facilities to manufacture, handle, package, test, or store Bulk Drug Product(s) that have not been previously qualified and/or approved by Company. Takeda will ensure that the operations and the facilities, utilities and equipment used (including the disposal of any residue or waste), complies with all applicable local and national laws, rules, regulations, guidelines, Regulatory Approvals and/or Clinical Trial Application ("CTA") and registered requirements, including: cGMPs/ISO requirements, PIC/S Guidelines, EU regulations, as detailed in The Rules Governing Medicinal Product(s)s in the European Community – Eudralex Volume IV-Good Manufacturing Practice for Medicinal Product(s), cGMPs for IMPs 2017/1569, EU Clinical Trials Regulations (CTR) 536/2014, on the manufacture, handling, release and distribution of Bulk Drug Product(s). Takeda will control access to premises and facilities, particularly those areas where cGMPs activities are performed, and will ensure adequate space is available for the organization and separation of equipment and materials to prevent contamination and mixups. Takeda will maintain current design drawings for critical utilities, facility design and classification, and personnel, equipment, and material flow. Takeda will ensure that Company is aware of issues that may pose a hazard to Takeda's premises, equipment, or personnel.

10. PRODUCT RECALL.

(A) If either Party becomes aware of information relating to any Bulk Drug Product that indicates that a unit or batch of Bulk Drug Product may not conform to the Specifications therefor, or that potential adulteration, misbranding, or other issues have arisen that relate to the safety or efficacy of Bulk Drug Products, it shall promptly so notify the other Party. Company shall have the right and responsibility to control any recall, field correction, or withdrawal of, including any FDA field alert or EMA rapid report relating to, Bulk Drug Product ("Recall") that is required by Regulatory Authorities in the Territory. In addition, Company shall have the right, at its discretion, to conduct any Recall in the Territory that is not so required by such Regulatory Authorities but that Company deems to be appropriate.

Company shall be solely responsible for (i) making the final decision regarding reporting to any Regulatory Authority in the Territory regarding any Recall of the Bulk Drug Product in the Territory and (ii) initial and ongoing communication with the Regulatory Authorities in the Territory regarding reporting and/or Recall of the Bulk Drug Product in the Territory. Each Party shall conduct any Bulk Drug Product Recall in its respective territory in accordance with written procedures and manage the recovery of Bulk Drug Product(s) from their respective markets.

(B) The Parties shall exchange their internal standard operating procedures ("SOPs") for conducting Recalls reasonably in advance of the First Commercial Sale of any Product in the Territory, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. Each Party shall maintain a quality system and SOP to conduct a complete and rapid Recall of the Bulk Drug Product(s), which procedure shall ensure: (i) that the Recall can be put into operation during and outside normal business hours and (ii) periodic challenges of the Recall system to ensure expedited retrieval of traceability information.

(C) Immediately, but no more than [***] after occurrence or discovery, Takeda shall report and provide any data or information that could result in reporting to a Regulatory Authority in the Territory (including FDA field alert, EMA rapid report, biological product deviation report, etc.) or the Recall of Bulk Drug Product(s), including: (i) stability out of specifications (whether confirmed or not confirmed), (ii) information concerning any incident that causes the Bulk Drug Product(s) or its labeling to be mistaken for, or applied to, another article, (iii) bacterial contamination, or any significant chemical, physical, or other change or deterioration in the distributed Bulk Drug Product(s), and (iv) failure of one or more distributed batches of the Bulk Drug Product(s) to meet the established Specifications. Takeda shall inform Company within [***] of discovery of a potential Recall of the Bulk Drug Product(s). Takeda will inform Company of any recall actions concerning potentially related product(s) outside the Territory prior to informing the applicable regulatory authorities. Notwithstanding anything to the contrary in the foregoing, Company will have the sole right to inform the applicable regulatory authorities in the Territory regarding any potential Recall actions relating to the Bulk Drug Product(s).

(D) Takeda will provide to Company any information or documentation and assist with any investigation or activities to support the reporting to a Regulatory Authority (e.g., field alert, EMA rapid report, etc.) or Recall, as requested by Company. All such responses to Company's requests shall be expedited. Takeda shall use reasonable efforts to complete investigation reports within an appropriate timeframe as required by the regulatory reporting requirements of Applicable Law in the Territory.

(E) All reasonable direct, documented out-of-pocket costs associated with a Recall, including the expenses of notifications and investigations, and destruction or return of the Product subject to the Recall and any costs associated with the distribution of the replacement Product, will be the responsibility of a Party, to the extent its negligence, breach of the License Agreement or of this Agreement, or willful misconduct resulted in the Recall.

11. [Left blank intentionally.]

12. INTELLECTUAL PROPERTY.

(A) Manufacturing Improvement and Inventions. Any Inventions or other Information arising in furtherance of this Agreement shall be subject to the applicable terms of the License Agreement, including those terms set forth in Article 9 thereof.

13. CONFIDENTIALITY. A Party's obligations with respect to any Confidential Information of the other Party received in furtherance of this Agreement shall be governed by the License Agreement, including Article 11 thereof.

14. REPRESENTATIONS AND WARRANTIES.

(A) Mutual Representations, Warranties and Covenants. Each Party hereby represents, warrants and covenants to the other Party that:

(i) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated.

(ii) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(iii) Debarment. Neither it nor any of its Affiliates (a) has been debarred by a Regulatory Authority, (b) is subject to debarment proceedings by a Regulatory Authority or (c) will use, in any capacity, in connection with the activities to be performed under this Agreement, any Person that has been debarred, or who is the subject of debarment proceedings by any Regulatory Authority. If either Party learns that a Person performing on its behalf under this Agreement has been debarred by any Regulatory Authority, or has become the subject of debarment proceedings by any Regulatory Authority, such Party shall so promptly notify the other Party and shall prohibit such Person from performing on its behalf under this Agreement.

(B) Takeda Representations, Warranties and Covenants. Takeda hereby represents, warrants and covenants to Company that Bulk Drug Product supplied to Company under this Agreement, upon delivery to Company in accordance with Section 7(A), and subject to Sections 6(A) and 6(B):

(i) will have been manufactured, tested, released, stored, supplied and otherwise handled in accordance with all Applicable Law (including all regulatory requirements and cGMPs);

(ii) will conform to the then current applicable Specifications;

(iii) will conform with all certificates of analysis, conformance, and release and other cGMPs documents that are generated in connection with Manufacture thereof and provided pursuant to the Quality Agreement; and

(iv) will not be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended or modified from time to time, and its implementing rules, regulations, guidances and requirements of the FDA as may be in effect from time to time.

(C) Company Representation, Warranties and Covenants. Company hereby represents, warrants and covenants to Takeda that:

(i) it shall discharge its obligations pursuant to this Agreement in accordance with all Applicable Law;

(ii) it shall store and maintain Bulk Drug Product in a facility that is properly equipped to store Bulk Drug Product and in accordance with Applicable Law; and

(iii) it shall have in place systems and resources for tracking and reporting all complaints and adverse events relating to the Bulk Drug Product in accordance with the Quality Agreement.

(D) Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THERE ARE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WRITTEN OR ORAL, MADE BY TAKEDA (OR ANY OF ITS AFFILIATES), WITH RESPECT TO BULK DRUG PRODUCT OR OTHERWISE, INCLUDING: (I) ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; (II) ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN THE TRADE; (III) ANY WARRANTY OF DESCRIPTION OR OTHERWISE CREATED BY ANY AFFIRMATION OF FACT OR PROMISE OR SAMPLE OR MODEL; OR (IV) NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

15. INDEMNIFICATION; NO CONSEQUENTIAL DAMAGES.

(A) **Indemnification by Company**. Company hereby agrees to defend, indemnify and hold harmless Takeda and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "Takeda Indemnitee") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, the "Losses"), to which any Takeda Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "Claim") to the extent such Losses arise directly or indirectly out of: (i) the use, handling, storage, sale or other disposition of any Bulk Drug Product by Company, its Affiliate, or its sublicensee, including any use of Bulk Drug Product for Commercialization; (ii) the breach by Company of any warranty, representation, covenant or agreement made by Company in this Agreement; or (iii) the negligence, gross negligence or willful misconduct of Company, its Affiliate or its sublicensee, or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (i) through (iii) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence or willful misconduct of any Takeda Indemnitee or the breach by Takeda of any warranty, representation, covenant or agreement made by Takeda in this Agreement, or are subject to Takeda's indemnification obligations pursuant to Section 15(B).

(B) **Indemnification by Takeda**. Takeda hereby agrees to defend, indemnify and hold harmless Company and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an "Company Indemnitee") from and against any and all Losses to which any Company Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: (i) the breach by Takeda of any warranty, representation, covenant or agreement made by Takeda in this Agreement; or (ii) the negligence, gross negligence or willful misconduct of Takeda or its Affiliate or its licensee (other than Company or its Affiliate), or any officer, director, employee, agent or representative thereof with respect to the Bulk Drug Product supplied to Company pursuant to this Agreement; except, with respect to each of subsections (i) through (ii) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence or willful misconduct of any Company Indemnitee or the breach by Company of any warranty, representation, covenant or agreement made by Company in this Agreement, or are subject to Company's indemnification obligations pursuant to Section 15(A).

(C) **Indemnification Procedures**.

(i) **Notice.** Promptly after a Takeda Indemnitee or a Company Indemnitee (each, an "Indemnitee") receives notice of a pending or threatened Claim, such Indemnitee shall give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Sections 15(A) or 15(B), as applicable (the "Indemnifying Party"). However, an Indemnitee's delay in providing or failure to provide such notice shall not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate prejudice due to the delay or lack of notice.

(ii) **Defense**. Upon receipt of notice under Section 15(C) (i) from the Indemnitee, the Indemnifying Party shall have the duty to either compromise or defend, at its own expense and by legal counsel (reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party shall promptly (and in any event not more than twenty (20) days after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify the Indemnitee with respect to the Claim pursuant to this Section 15 and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, the Indemnifying Party is not liable to the Indemnitee for the fees of other legal counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable expenses of investigation and cooperation. However, the Indemnitee shall have the right to employ separate legal counsel and to control the defense of a Claim at its own expense.

(iii) **Cooperation**. The Indemnitee shall cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party shall keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.

(iv) **Settlement**. If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (which consent shall not be unreasonably withheld, conditioned or delayed), unless: (x) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (y) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (z) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed), and the Indemnifying Party shall be obligated to indemnify the Indemnitee for such settlement as provided in this Section 15.

(D) **Limitation of Liability**. EXCEPT FOR A PARTY'S OBLIGATIONS SET FORTH IN THIS SECTION 15, AND ANY BREACH OF SECTION 13 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

16. TERM AND TERMINATION.

(A) Term. The term of this Agreement shall commence on the Effective Date and except if the agreement is terminated earlier (i) for breach in accordance with Section 16(B) or (ii) automatically upon termination of the License Agreement, it will remain into effect for a period of two (2) years from the order of Bulk Drug Product served by the Company for the first commercial launch in any jurisdiction of the Territory, provided that this two (2) years period shall expire in any case on December 31st, 2023, except if otherwise agreed by the Parties (the "**Term**"). For the avoidance of doubt such first order of Bulk Drug Product shall be placed by the Company with Takeda during the calendar year 2021 by the latest.

(B) Material Breach. Either Party may terminate this Agreement upon the other Party's failure to cure a material breach within the Cure Period. Takeda's failure to deliver any Bulk Drug Product beyond the minimum order quantity will not be deemed a material breach of the Agreement.

(C) Consequences of Termination.

(i) Termination of the License Agreement for Takeda Breach. The following provisions shall apply if this Agreement is terminated by Company pursuant to Section 16(B) hereof or if the License Agreement is terminated by Company pursuant to Sections 13.2 or 13.5 thereof:

(a) Company may cancel any Purchase Order for Bulk Drug Product; and

(b) Company shall have no liability with respect to raw materials on hand or work in progress at Takeda as of the effective date of such termination.

(ii) Other Terminations of the License Agreement. The following provisions shall apply if this Agreement is terminated by Takeda pursuant to Section 16(B) hereof or if the License Agreement is terminated by Takeda pursuant to Sections 13.2, 13.4, or 13.5 thereof or by Company pursuant to Section 13.3 thereof:

(a) Following Company's exercise of its rights under Section 13.6(f) of the License Agreement, Company shall, at Company's expense and at Takeda's election, destroy its remaining inventory of Bulk Drug Product or return it to Takeda; and

(b) Company shall reimburse Takeda within thirty (30) days of the effective date of termination for the total direct cost of all Bulk Drug Product components, raw materials, work in process, the Purchase Price for Bulk Drug Product on hand (including related destruction expenses associated therewith), that were obtained or manufactured by or on behalf of Takeda or any Third Party Manufacturing Bulk

Drug Product on its behalf to meet Company's Purchase Order submitted to Takeda on or before the effective date of termination of this Agreement, except to the extent that Takeda, using commercially reasonable efforts, is able to incorporate, integrate or otherwise use such components, raw materials, work-in-progress including any Bulk Drug Product, in the normal course of Takeda's business operations.

(D) Survival of Obligations. Termination or expiration of this Agreement shall not relieve a Party of any obligation to make a payment that was owed prior to or on the effective date of such termination, including amounts invoiced prior to such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation provided for in this Agreement that expressly survives termination or expiration. All provisions of this Agreement that, in accordance with their terms, are intended to have effect after the expiration or termination of this Agreement shall survive such termination or expiration, including Sections 1, 3, 4 (solely to the extent necessary to fulfill any obligation to a Regulatory Authority after termination or expiration), 8, 9, 10, 12, 13, 14, 15, 16(C), 16(D), 16(E), and 17.

(E) Remedies. Except as otherwise expressly provided herein, exercise by a Party of its rights under this Section 16 shall not limit remedies which may otherwise be available to a Party in law or equity.

17. MISCELLANEOUS.

(A) Any notice, request, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be hand delivered or sent by a recognized overnight delivery service, expenses prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 17(A):

If to Takeda:

Takeda Pharmaceutical Company Limited
2-17-85 Jusohonmachi
Yodogawa-ku, Osaka 532-8686
Attention: GMS TPC SC Manager

Copy to (which alone shall not constitute sufficient notice):

Takeda Pharmaceuticals International AG
Thurgaurstrasse 130
8152 Galttpark-Opfikon (Zurich).
Attention: Regional General Counsel, Legal Department
Email: [***]

If to Company:

Phathom Pharmaceuticals, Inc.
2150 East Lake Cook Drive, Suite 800
Buffalo Grove, IL 60089, U.S.A.
Attention: Chief Operating Officer

Copy to (which alone shall not constitute sufficient notice):

Phathom Pharmaceuticals, Inc.
100 Campus Drive, Suite 102
Florham Park, NJ 07932, U.S.A.
Attention: General Counsel
Email: [***]

and

Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92103, U.S.A.
Attention: Cheston J. Larson
Email: [***]
Facsimile No.: (858) 523-5450

(B) **Designation of Affiliates**. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

(C) **Force Majeure**. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than ninety (90) days, then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure.

(D) **Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed), except that either Party may assign this Agreement without the other Party's consent to (i) any Affiliate, or (ii) to a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock or units, sale of assets or other transaction, but only if the assigning Party has also assigned, in accordance with the terms thereof, the License Agreement to such Third Party successor. Any other assignment or transfer shall require the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed). Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section shall be null, void and of no legal effect.

(E) **Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

(F) **Waiver and Non-Exclusion of Remedies**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

(G) **Further Assurance**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

(H) **Relationship of the Parties**. It is expressly agreed that Takeda, on the one hand, and Company, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency, including for Tax purposes. Neither Takeda nor Company shall have

the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party.

(I) **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

(J) **Construction**. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days, such number refers to calendar days. The captions of this Agreement are for the convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms "including," "include," or "includes" as used herein shall mean "including, but not limited to," and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provision.

(K) **Governing Laws**. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

(L) **Entire Agreement**. This Agreement, including the Exhibits hereto, and together with the License Agreement, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, excluding for clarity the License Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the

event of any inconsistency between the body of this Agreement and the Exhibits to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit or subsequent ancillary agreement, the terms contained in this Agreement shall control.

(M) **Headings**. The headings of each Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Section.

(N) **Dispute Resolution**. Any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder that is not resolved through good faith negotiation between the Parties or as otherwise expressly provided in this Agreement shall be resolved in accordance with Article 14 of the License Agreement.

SIGNATURE PAGE FOLLOWS

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: /s/ Greg Timmons

Name: Greg Timmons

Title: Head of GMS Japan

Date: May 5, 2020

PHATHOM PHARMACEUTICALS, INC.

By: /s/ Terrie Curran

Name: Terrie Curran

Title: Chief Executive Officer

Date: May 1, 2020

By: /s/ Azmi Nabulsi

Name: Azmi Nabulsi

Title: Chief Operating Officer

Date: May 1, 2020

EXHIBIT 1

Specifications for Bulk Drug Product

[***]

EXHIBIT 2

Bulk Drug Product Minimum/Maximum Order Quantities

[***]

EXHIBIT 3

Agreed Delivery Forecastbased on Maximum Number of Batches

[***]

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Terrie Curran, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Phathom Pharmaceuticals, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c) 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

   d) 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 10, 2020

/s/ Terrie Curran
Terrie Curran
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd Branning, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Phathom Pharmaceuticals, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c) 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

   d) 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 10, 2020

/s/ Todd P. Branning

Todd P. Branning
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Phathom Pharmaceuticals, Inc. (the "Company") for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Terrie Curran, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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.

Date: November 10, 2020

/s/ Terrie Curran
Terrie Curran
Chief Executive Officer and President

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Phathom Pharmaceuticals, Inc. (the "Company") for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Todd P. Branning, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, 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.

Date: November 10, 2020

/s/ Todd P. Branning
Todd P. Branning
Chief Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.