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, 2022

OR

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

For the transition period from _____to_____.

Commission File Number: 001-39094

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 7, 2022, the registrant had 41,620,855 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 196,838	$ 183,259
Prepaid expenses and other current assets	975	3,267
Total current assets	197,813	186,526
Property, plant and equipment, net	831	650
Operating lease right-of-use assets	2,482	1,914
Other long-term assets	805	341
Total assets	$ 201,931	$ 189,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (including related party amounts of $80 and $1,343, respectively)	7,135	5,150
Accrued clinical trial expenses	139	1,402
Accrued expenses (including related party amounts of $2,383 and $2,330, respectively)	13,289	11,405
Accrued interest	686	477
Current portion of revenue interest financing liability	945	—
Operating lease liabilities, current	685	487
Total current liabilities	22,879	18,921
Long-term debt, net of discount	93,878	89,671
Revenue interest financing liability	102,850	—
Operating lease liabilities	1,247	1,183
Other long-term liabilities	7,500	7,500
Total liabilities	228,354	117,275
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares — 40,000,000; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; authorized shares — 400,000,000; issued shares — 41,620,874 and 31,656,035 at September 30, 2022 and December 31, 2021, respectively; outstanding shares — 41,143,826 and 30,511,226 at September 30, 2022 and December 31, 2021, respectively	3	3
Treasury stock — 19 and 1 at September 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	645,620	601,523
Accumulated deficit	(672,046)	(529,370)
Total stockholders' (deficit) equity	(26,423)	72,156
Total liabilities and stockholders' equity	$ 201,931	$ 189,431

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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development (includes related party amounts of $77, $849, $1,800, and $2,695, respectively)	$19,020	$16,608	$55,495	$58,786
General and administrative (includes related party amounts of $0, $0, $0, and $16, respectively)	23,509	16,529	70,303	43,254
Total operating expenses	42,529	33,137	125,798	102,040
Loss from operations	(42,529)	(33,137)	(125,798)	(102,040)
Other income (expense):				
Interest income	726	8	845	35
Interest expense	(9,277)	(1,485)	(17,703)	(4,013)
Other expense	(11)	(2,048)	(20)	(2,039)
Total other expense	(8,562)	(3,525)	(16,878)	(6,017)
Net loss and comprehensive loss	$(51,091)	$(36,662)	$(142,676)	$(108,057)
Net loss per share, basic and diluted	$(1.32)	$(0.98)	$(3.72)	$(2.94)
Weighted-average shares of common stock outstanding, basic and diluted	38,820,266	37,299,351	38,379,292	36,748,492

See accompanying notes.

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

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Capital	Deficit	Equity
Balance at December 31, 2021	30,511,226	$ 3	1	$ 601,523	$ (529,370)	$ 72,156
Cashless exercise of common stock warrants	7,359,285	—	18	—	—	—
401(k) matching contribution	16,756	—	—	254	—	254
Vesting of restricted shares	222,595	—	—	—	—	—
Stock-based compensation	—	—	—	5,775	—	5,775
ESPP shares issued	39,951	—	—	515	—	515
Net loss	—	—		—	(40,665)	(40,665)
Balance at March 31, 2022	38,149,813	$ 3	19	$ 608,067	$ (570,035)	$ 38,035
Vesting of restricted shares	222,590	—	—	—	—	—
Stock-based compensation	—	—	—	5,885	—	5,885
Net loss	—	—	—	—	(50,920)	(50,920)
Balance at June 30, 2022	38,372,403	$ 3	19	$ 613,952	$ (620,955)	$ (7,000)
Issuance of common stock from exercise of stock options	—	—	—	—	—	—
401(k) matching contribution	84,784	—	—	862	—	862
Vesting of restricted shares	222,595	—	—	—	—	—
Issuance of common stock under ATM facility	2,414,897	—	—	24,596	—	24,596
Stock-based compensation	—	—	—	5,816	—	5,816
ESPP shares issued	49,147	—	—	394	—	394
Net loss	—	—	—	—	(51,091)	(51,091)
Balance at September 30, 2022	41,143,826	$ 3	19	$ 645,620	$ (672,046)	$ (26,423)

See accompanying notes.

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

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Capital	Deficit	Equity
Balance at December 31, 2020	28,516,010	$ 3	—	$ 579,755	$ (385,487)	$ 194,271
Issuance of common stock from exercise of stock options	36,998	—	—	412	—	412
401(k) matching contribution	8,356	—	—	323	—	323
Vesting of restricted shares	301,656	—	—	—	—	—
Stock-based compensation	—	—	—	3,818	—	3,818
ESPP shares issued	13,490	—	—	358	—	358
Net loss	—	—	—	—	(34,843)	(34,843)
Balance at March 31, 2021	28,876,510	$ 3	—	$ 584,666	$ (420,330)	$ 164,339
Issuance of common stock from exercise of stock options	8,000	—	—	104	—	104
Vesting of restricted shares	301,659	—	—	—	—	—
Stock-based compensation	—	—	—	4,237	—	4,237
Net loss	—	—	—	—	(36,552)	(36,552)
Balance at June 30, 2021	29,186,169	$ 3	—	$ 589,007	$ (456,882)	$ 132,128
Issuance of common stock from exercise of stock options	50,073	—	—	1,265	—	1,265
401(k) matching contribution	18,394	—	—	580	—	580
Vesting of restricted shares	776,045	—	—	—	—	—
Stock-based compensation	—	—	—	4,419	—	4,419
ESPP shares issued	16,747	—	—	461	—	461
'Issuance of warrants	—	—	—	1,290	—	1,290
Net loss	—	—	—	—	(36,662)	(36,662)
Balance at September 30, 2021	30,047,428	$ 3	—	$ 597,022	$ (493,544)	$ 103,481

See accompanying notes.

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (142,676)	$ (108,057)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	452	386
Stock-based compensation	17,476	12,474
Issuance of PIK interest debt	2,594	130
Accrued interest on revenue interest financing liability	8,349	—
Amortization of debt discount	1,613	3,088
Other	1,128	722
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets (includes the change in related party amounts of $0, and $82, respectively)	2,292	3,177
Accounts payable and accrued expenses (includes the change in related party amounts of $(1,210), and $1,251, respectively)	4,762	(9,629)
Accrued clinical trial expenses	(1,263)	(9,506)
Accrued interest	209	(98)
Operating right-of-use asset and lease liabilities	(306)	75
Other long-term assets	(464)	43
Net cash used in operating activities	(105,834)	(107,195)
Cash flows from investing activities		
Cash paid for property, plant and equipment	(629)	(228)
Net cash used in investing activities	(629)	(228)
Cash flows from financing activities		
Proceeds from issuance of common stock from exercise of stock options	—	1,781
Repayment of long-term debt	—	(54,125)
Net proceeds from issuance of long-term debt	—	96,889
Net proceeds from revenue interest financing transaction	95,446	—
Net proceeds from issuance of common stock under ATM facility	24,596	—
Net cash provided by financing activities	120,042	44,545
Net increase (decrease) in cash and cash equivalents	13,579	(62,878)
Cash and cash equivalents – beginning of period	183,259	287,496
Cash and cash equivalents – end of period	$ 196,838	$ 224,618
Supplemental disclosure of cash flow information		
Interest paid	$ 4,938	$ 2,920
Supplemental disclosure of noncash investing and financing activities		
Issuance of common stock warrants in connection with long-term debt	$ —	$ 1,290
Property and equipment purchases included in accounts payable and accrued liabilities	$ 4	$ 9
Final interest payment fee	$ —	$ 7,500
Operating lease liabilities arising from obtaining right-of-use assets	$ 554	$ —
Settlement of ESPP liability in common stock	$ 909	$ 819
Settlement of 401(k) liability in common stock	$ 1,116	$ 903

See accompanying notes.

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

Organization and Basis of Presentation

Phathom Pharmaceuticals, Inc., or the Company or Phathom, was incorporated in the state of Delaware in January 2018. The Company is a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases. The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP.

Liquidity and Capital Resources

From inception to September 30, 2022, 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, managing the clinical trials of vonoprazan, preparing for commercialization of its initial products containing 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 additional net losses in the future as it continues to develop and prepares for commercialization of vonoprazan. From inception to September 30, 2022, the Company has funded its operations through the issuance of convertible promissory notes, commercial bank debt, revenue interest financing debt, the sale of 10,997,630 shares of common stock for net proceeds of approximately $191.5 million in its 2019 IPO, the sale of 2,250,000 shares of common stock for net proceeds of approximately $88.6 million in its December 2020 follow-on public offering, and the sale of 2,414,897 shares of common stock for net proceeds of approximately $24.6 million in its September 2022 issuance of common stock under the ATM Offering (see note 8).

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 in accordance with GAAP. 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 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 various 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 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.

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.

As of September 30, 2022, the estimated fair value of the Company's long-term debt approximated the carrying amount given its floating interest rate basis. The fair value of the Company's long-term debt was estimated for disclosure purposes only and was determined based on quoted market data for valuation, and thus categorized as Level 2 in the fair value hierarchy.

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, 2022.

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. In addition, the Company elected the short-term lease exception for leases with an initial term of one year or less. Consequently, such leases are not recorded on the Company's balance sheets.

Revenue Interest Financing Liability

The Company entered into a revenue interest financing agreement, or the Revenue Interest Financing Agreement, with entities managed or advised by NovaQuest Capital Management, or NQ, Sagard Holdings Manager LP, or Sagard, and Hercules Capital, Inc., or Hercules, together with NQ and Sagard, the Initial Investors, in which the Company received funds in return for royalties on net sales of products containing vonoprazan. The net proceeds received under the transaction were recognized as short-term and long-term liabilities with interest expense based on an imputed effective rate derived from the expected future payments. The Company recalculates the effective interest rate each period based on the current carrying value and the revised estimated future payments. Changes in future payments from previous estimates are included in current and future financing expense.

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 with forfeitures recognized as they occur.

The Company also maintains an employee stock purchase program, or ESPP, under which it may issue shares. The Company estimates the fair value of shares that will be issued under the ESPP, and of stock options using the Black-Scholes valuation 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.

Beginning in 2022, the Tax Cuts and Jobs Act, or TCJA, eliminates the option to deduct research and development expenditures currently and requires taxpayers to amortize domestic and foreign research and development expenditures over 5 years and 15 years, respectively. The requirement did not impact cash from operations in the current period.

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

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 until its exercise because the Takeda Warrant was exercisable for little consideration. As of September 30, 2022, all Takeda Warrants has been exercised and no Takeda Warrants remain exercisable. For the three and nine months ended September 30, 2022, the Company has excluded weighted-average unvested shares of 577,931 and 798,643, respectively, from the weighted-average number of common shares outstanding, compared to 1,666,535 and 2,173,246, respectively for the same periods in 2021. 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 and warrants. For the 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

There were no recently adopted accounting standards which would have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board or other standard setting bodies on the Company's financial statements as well as material updates to previous assessments, if any, from the Company's Annual Report on Form 10-K for the year ended December 31, 2021. There were no new material accounting standards issued in the first three quarters of 2022 that impacted the Company.

2. Balance Sheet Details

Property, Plant and Equipment, net

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

	September 30, 2022	December 31, 2021
Computer equipment and software	$ 940	$ 646
Furniture and fixtures	1,086	780
Leasehold improvements	109	76
Total property, plant and equipment, gross	2,135	1,502
Less: accumulated depreciation and amortization	(1,304)	(852)
Total property, plant and equipment, net	$ 831	$ 650

Depreciation expense for the three months ended September 30, 2022 and 2021 was approximately $175,000 and $130,000, respectively. Depreciation and amortization expense for the nine months ended September 30, 2022 and 2021, was approximately $452,000 and $386,000, respectively. No property, plant or equipment was disposed of during the nine months ended September 30, 2022 or the year ended December 31, 2021.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued research and development expenses	$ 4,282	$ 3,165
Accrued compensation expenses	5,655	6,344
Accrued professional & consulting expenses	3,321	1,855
Accrued other	31	41
Total accrued expenses	$ 13,289	$ 11,405

3. Related Party Transactions

Frazier is a principal stockholder of the Company. Previously, the Company 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, 2022 and December 31, 2021 the Company had outstanding accounts payable and accrued expenses due to Frazier in the amount of $0, related to these shared operating expenses. For the three months ended September 30, 2022 and 2021, the Company incurred $0, respectively, of shared operating expenses. For the nine months ended September 30, 2022 and 2021, the Company incurred $0 and $16,000, respectively, of shared operating expenses.

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, 2022 and December 31, 2021, the Company had $1.1 million and $1.7 million, respectively, outstanding accounts payable and accrued expenses related to these manufacturing services. For the three months ended September 30, 2022 and 2021, the Company incurred $0.1 million and $0.6 million, respectively, of expenses related to services performed by PCI. For the nine months ended September 30, 2022 and 2021, the Company incurred $0.5 million and $2.2 million, respectively, of expenses related to services performed by PCI.

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. On May 5, 2020, the Company entered into a Commercial Supply Agreement, or the Commercial Supply Agreement, with Takeda, pursuant to which Takeda will supply commercial quantities of vonoprazan bulk drug product or drug substance. 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 or drug substance 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. In connection with the Takeda License, the Company entered into a temporary services agreement, or the Temporary Services Agreement, with Takeda on November 24, 2020. Pursuant to the Temporary Services Agreement, Takeda agreed to provide or procure the provision of services related to the ongoing clinical development of vonoprazan. The Temporary Services Agreement will terminate immediately upon termination of the Takeda License in accordance with its terms. As of September 30, 2022 and December 31, 2021, the Company had $1.4 million and $0.9 million, respectively, in outstanding accounts payable and accrued expenses related to these agreements. For the three months ended September 30, 2022 and 2021, the Company incurred $0 and $0.2 million, respectively, of expenses related to these agreements. For the nine months ended September 30, 2022 and 2021, the Company incurred $1.3 million and $0.4 million, respectively, of expenses related to these agreements. The Company has no remaining minimum purchase obligation related to these agreements.

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, or, 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, or, 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 Takeda Warrant had an exercise price of $0.00004613 per share was to expire on May 7, 2029 and became exercisable upon the consummation of the IPO. As of September 30, 2022, all Takeda Warrants have been exercised.

Purchase Commitments

In December 2020, the Company entered into a supply agreement with Sandoz pursuant to which Sandoz will supply commercial quantities of amoxicillin capsules and clarithromycin tablets, package these antibiotics with vonoprazan, and provide in finished convenience packs. The supply agreement commits the Company to a minimum purchase obligation of approximately $3.8 million in the first 24-month period following the launch of the product. The Company has not incurred any expenses under the agreement during the nine months ended September 30, 2022 and 2021.

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. Lease Commitments

As of September 30, 2022, the Company had operating leases for office space in both Buffalo Grove, Illinois and Florham Park, New Jersey, with remaining lease terms of 2.6 years and 2.9 years, respectively. All 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 months ended September 30, 2022 and 2021 was approximately $0.3 million and $0.2 million, respectively. The total rent expense for the nine months ended September 30, 2022 and 2021 was approximately $0.7 million and $0.6 million, respectively.

The following table summarizes supplemental balance sheet information related to the operating leases (in thousands):

	September 30, 2022	December 31, 2021
Assets:		
Operating lease right-of-use assets	2,482	1,914
Total right-of-use assets	$ 2,482	$ 1,914
Liabilities:		
Operating lease liabilities, current	685	487
Operating lease liabilities, non-current	1,247	1,183
Total operating lease liabilities	$ 1,932	$ 1,670

As of September 30, 2022, the future minimum annual lease payments under the operating leases were as follows (in thousands):

2022	$ 163
2023	733
2024	752
Thereafter	513
Total minimum lease payments	$ 2,161
Less: amount representing interest	(229)
Present value of operating lease liabilities	1,932
Less: operating lease liabilities, current	(685)
Operating lease liabilities	$ 1,247
Weighted-average remaining lease term (in years)	2.69
Weighted-average incremental borrowing rate	7.73%

Operating cash flows for the nine months ended September 30, 2022 and 2021 included cash payments for operating leases of approximately $1.0 million and $0.5 million, respectively.

On February 8, 2022, the Company entered into an operating lease for 6,250 rentable square feet of additional office space in Florham Park, New Jersey. The lease liability and the corresponding right-of-use asset associated with this lease obligation was recorded upon the June 14, 2022 commencement date of the lease.

The Company also entered into one year leases for passenger vehicles during 2022. The Company elected the short-term lease exception for these leases and did not recognize a right-of-use asset and operating lease liability related to these leases.

6. Debt

Total debt consists of the following (in thousands):

	September 30, 2022
Long-term debt, current portion	$ —
Long-term debt, non-current portion	103,585
Unamortized debt discount	(9,707)
Total debt, net of debt discount	$ 93,878

On September 17, 2021, or the Closing Date, the Company entered into a Loan and Security Agreement, or, the Loan Agreement, with Hercules Capital, Inc., in its capacity as administrative agent and collateral agent and as a lender, or, in such capacity, the Agent or Hercules, and the other financial institutions that from time to time become parties to the Loan Agreement as lenders, or, collectively, the Lenders.

The Loan Agreement provides for term loans in an aggregate principal amount of up to $200.0 million, or the Term Loan, under multiple tranches. The tranches consist of (i) a first tranche consisting of term loans in an aggregate principal amount of $100.0 million, all of which was funded to the Company on the Closing Date, or First Advance, (ii) a second tranche consisting of up to an additional $50.0 million, which became available to the Company upon achievement of the protocol-specified primary efficacy endpoints in the Company's Phase 3 trial studying vonoprazan for the healing and maintenance of healing of erosive esophagitis with acceptable safety data, such that the results support the submission of a New Drug Application, or NDA, or supplemental NDA without the need to conduct another Phase 3 study and will be available, if specified conditions are met, through December 15, 2022, see amendment to later date below, (iii) a third and fourth tranches consisting of an additional total $50.0 million, which became available to the Company in May 2022 upon the achievement of (a) Food and Drug Administration, or FDA, approval of the Company's NDA for vonoprazan and amoxicillin, or its New Drug Application for vonoprazan, amoxicillin and clarithromycin, in each case for an indication relating to the treatment of *Helicobacter pylori*, or *H. pylori,* with an approved indication on the claim that is generally consistent with that sought in the Company's NDA submission; and (b) filing of the Company's NDA or supplemental NDA for vonoprazan for indications relating to the healing and maintenance of healing of erosive esophagitis. The third and fourth tranches will remain available until September 30, 2023, and March 31, 2024, respectively.

On September 27, 2022, the Company entered into an amendment to the Loan Agreement, or the Second Loan Amendment, pursuant to which the date the second tranche of funding of $50 million will remain available to the Company has been moved until either February 15, 2023 or, if the PDUFA target action date for the Company's pending NDA is extended beyond the current PDUFA target action date, May 15, 2023, rather than December 15, 2022.

The Company paid a $1.25 million facility charge in connection with closing of the Loan Agreement and would need to pay 0.5% of any advances made under the third and fourth tranches.

The Term Loan will mature on October 1, 2026, or the Maturity Date. The Term Loan bears (i) cash interest at a variable annual rate equal to the greater of (a) 5.50% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 2.25%, or the "Interest Rate", and (ii) payment-in-kind interest at a per annum rate of interest equal to 3.35%. Phathom may make payments of interest only through October 1, 2024, which was extended to October 1, 2025, upon the achievement of the Second Performance Milestone in May 2022 prior to September 30, 2024 and met the condition that no default or event of default exists, and which is further extendable to October 1, 2026, subject to FDA approval of the Company's NDA (or supplemental NDA) for vonoprazan for an indication relating to the healing and maintenance of healing of erosive esophagitis with an approved indication on the label that is generally consistent with that sought in the Company's NDA submission (or supplemental NDA submission), or the Third Performance Milestone, on or prior to September 30, 2025 and no default or event of default exists (the "interest only period"). After the interest-only period, the principal balance and related interest will be required to be repaid in equal monthly installments and continuing until the Maturity Date.

In addition, the Company is obligated to pay a final payment fee of 7.50% of the original principal amount of amounts actually advanced under the Term Loan, or, each a Term Loan Advance and together, the Term Loan Advances. As of September 30, 2022, the aggregate final payment fee for the first Term Loan Advance of $7.5 million has been recorded as an other long-term liability.

The Company may elect to prepay all or a portion of the Term Loan Advances prior to maturity, subject to a prepayment fee of up to 1.25% of the then outstanding principal balance of the Term Loan Advances being prepaid. After repayment, no Term Loan amounts may be borrowed again.

As collateral for the obligations, the Company has granted to Hercules a senior security interest in all of Company's right, title, and interest in, to and under substantially all of Company's property, inclusive of intellectual property.

The Loan Agreement contains customary closing fees, prepayment fees and provisions, events of default, and representations, warranties and covenants, including a financial covenant requiring Phathom to maintain certain levels of cash subject to a control agreement in favor of the Agent (minus accounts payable not paid within 120 days of invoice), or Qualified Cash, and commencing on May 15, 2023, trailing three-month net product revenue from the sale of vonoprazan and products containing vonoprazan. The revenue covenant will be waived at any time in which the Company maintains Qualified Cash equal to at least 60.0% (prior to the Third Performance Milestone), and 35% (following the Third Performance Milestone) of the total outstanding Term Loan principal amount, or the Company's market capitalization is at least $900.0 million. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable by Hercules, as collateral agent. As of September 30, 2022, the Company was in compliance with all applicable covenants under the Loan Agreement.

Under the Second Loan Amendment, the commencement date for the covenant based on trailing three-month net product revenue from the sale of vonoprazan and products containing vonoprazan was moved from May 15, 2023, to November 15, 2023.

In connection with the entry into the Loan Agreement, the Company issued to Hercules a warrant, or, the Warrant, to purchase a number of shares of the Company's common stock equal to 2.5% of the aggregate amount of the Term Loan advances funded, and will issue to Hercules additional warrants when future Term Loan advances are funded. On the Closing Date, the Company issued a Warrant for 74,782 shares of common stock. The Warrant will be exercisable for a period of seven years from the date of issuance at a per-share exercise price equal to $33.43, which was the closing price of the Company's common stock on September 16, 2021. The Warrant is exercisable any time until September 17, 2028 and had an initial fair value of approximately $1.3 million.

The initial $1.3 million fair value of the Warrant, the $7.5 million final interest payment fee and $3.1 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 Loan.

Future minimum principal and interest payments under the Term Loan, including the final payment fee, as of September 30, 2022 are as follows (in thousands):

Year ending December 31:		
2022	$	2,181
2023		9,119
2024		9,459
2025		31,833
2026		106,530
Total principal and interest payments		159,122
Less interest and final payment fee		(59,122)
Total term loan borrowings	$	100,000

Prior to the Loan Agreement with Hercules, the Company had a loan with Silicon Valley Bank, or SVB, and approximately $54.3 million of the proceeds from the First Advance was used to satisfy in full and retire the Company's indebtedness under the SVB Term Loan with SVB, including accrued interest through the payoff date.

During the three and nine months ended September 30, 2022, the Company recognized $3.4 million and $9.2 million, respectively, of interest expense, including amortization of the debt discount, in connection with the Hercules Loan Agreement compared to $1.5 million and $4.0 million, respectively, for the same periods in 2021 in connection with the Hercules Loan Agreement and SVB Term Loan. As of September 30, 2022, the Company had outstanding loan balance of $103.6 million and accrued interest of $0.7 million.

7. Revenue Interest Financing Liability

On May 3, 2022, Phathom entered into a Revenue Interest Financing Agreement with Initial Investors NQ, Sagard, and Hercules pursuant to which the Company will receive up to $260 million in funding from the Initial Investors. Under the terms of the Revenue Interest Financing Agreement, the Company received $100 million at the initial closing and can receive an additional $160 million upon FDA approval of vonoprazan for treatment of erosive esophagitis on or before March 31, 2024. At any time prior to December 31, 2022, the Company also has the right to obtain a written commitment from a third party for up to $15 million of funding upon FDA approval of vonoprazan for erosive esophagitis. In addition, the Company has the right at any time prior to June 30, 2024, to obtain a written commitment from a third party for up to $25 million of funding upon achievement of a sales milestone. The Initial Investors have a right of first offer if the Company seeks to obtain such additional funding. The total amount funded by the Initial Investors and any subsequent investors is referred to herein as the Investment Amount.

Under the Revenue Interest Financing Agreement, the investors are entitled to receive a 10% royalty on net sales of products containing vonoprazan. The royalty rate is subject to a step-down on net sales exceeding certain annual thresholds and if the Company receives FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease, or NERD. The investors' right to receive royalties on net sales will terminate when the investors have aggregate payments equal to 200% of the Investment Amount. In addition, at any time after the earlier of (i) April 30, 2024 and (ii) the date that the payment for erosive esophagitis regulatory approval is made, the Company has the right to make a cap payment equal to 200% of the Investment Amount less any royalties already paid, at which time the agreement will terminate.

If the investors have not received aggregate payments of at least 100% of the Investment Amount by December 31, 2028, and at least 200% of the Investment Amount by December 31, 2037, each a Minimum Amount, then the Company will be obligated to make a cash payment to the investors in an amount sufficient to gross the investors up to the applicable Minimum Amount.

Upon the occurrence of an event of default taking place prior to April 1, 2025, between April 1, 2025, and April 1, 2028, and after April 1, 2028, the Company is obligated to pay 1.30 times Investment Amount, 1.65 times Investment Amount, and 2.0 times investment amount, respectively, less any amounts the Company previously paid pursuant to the agreement.

Upon the occurrence of a change in control event taking place prior to the earlier of April 1, 2024, or FDA approval of vonoprazan for erosive esophagitis, the Company is obligated to pay 200% of the Investment Amount plus either 15% of the Investment Amount if occurrence prior to May 3, 2023, or plus 30% of the Investment Amount if occurrence thereafter.

During the nine months ended September 30, 2022, the Company received gross proceeds of $100.0 million before deducting transaction costs of $4.6 million, which resulted in net proceeds of $95.4 million.

The Company has evaluated the terms of the Revenue Interest Financing Agreement and concluded that the features of the Investment Amount are similar to those of a debt instrument. Accordingly, the Company has accounted for the transaction as a debt obligation with interest expense based on an imputed effective rate derived from the initial carrying value of the obligation and the expected future payments. The Company recalculates the effective interest rate each period based on the current carrying value and the revised estimated future payments. Changes in future payments from previous estimates are included in the current and future financing expense. The carrying value of the revenue interest financing liability was $103.8 million as of September 30, 2022.

Total revenue interest financing liability consists of the following (in thousands):

	September 30, 2022
Beginning liability balance	$ —
Proceeds from the Revenue Interest Financing Agreement	100,000
Less: transaction costs	(4,554)
Less: royalty payments and payables	-
Plus: interest expense	8,349
Ending liability balance	$ 103,795

During the three and nine months ended September 30, 2022, the Company recognized $5.6 million and $8.3 million, respectively, of interest expense in connection with the revenue interest financing liability.

The Company will record liabilities associated with additional funding upon FDA approval of vonoprazan for erosive esophagitis and achievement of the sales milestone when such contingent events occur. To determine the accretion of the liability related to the Revenue Interest Financing Agreement, the Company is required to estimate the total amount of future royalty payments and estimated timing of such payments based on the Company's revenue projections. As royalty payments are made, the balance of the debt obligation will be effectively repaid. Based on the Company's periodic review, the exact timing of repayment is likely to be different in each reporting period as compared to those estimated in the Company's initial revenue projections. A significant increase or decrease in actual net sales of vonoprazan compared to the Company's revenue projections could impact the interest expense associated with the revenue interest financing liability. Also, the Company's total obligation can vary depending on change in control or default events and the achievement of FDA approval of vonoprazan for erosive esophagitis and achievement of the sales milestone.

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, 2022, 158,127 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, 2022, 318,902 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.

In November 2020, the Company entered into an Open Market Sale Agreement℠, or, the Sales Agreement, with Jefferies LLC, or, the Sales Agent, under which it may, from time to time, sell shares of its common stock having an aggregate offering price of up to $125.0 million through the Sales Agent, or, the ATM Offering. Pursuant to the Sales Agreement, the Company will pay the Sales Agent a commission for its services in acting as an agent in the sale of common stock in an amount equal to 3% of the gross sales price per share sold. In September 2022, the Company sold 2,414,897 shares for net proceeds of approximately $24.6 million under the ATM offering after deducting $0.8 million of issuance costs. As of September 30, 2022, the Company has utilized $25.4 million of the available $125.0 million under the ATM Offering.

On December 16, 2020, the Company completed an underwritten public offering, in which it sold 2,250,000 shares of its common stock at a price of $42.00 per share for total gross proceeds of $94.5 million. The net purchase price after deducting underwriting discounts and commissions was $39.48 per share, which generated net proceeds of $88.8 million. The Company incurred an additional $0.2 million of offering expenses in connection with this public offering.

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

Unvested shares at December 31, 2021	1,144,809
Share vesting	(667,780)
Unvested shares at September 30, 2022	477,029

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, 2022
Common stock warrants	91,228
Stock options, PSUs and RSUs outstanding	6,880,160
Shares available for issuance under the 2019 Incentive Plan	1,056,415
Shares available for issuance under the ESPP Plan	752,938
Shares reserved for future issuance at September 30, 2022	8,780,741

Preferred Stock

The Company is authorized to issue up to 40 million shares of preferred stock. As of September 30, 2022 and December 31, 2021, 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. 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. As of September 30, 2022, 1,056,415 shares remain available for issuance, which reflects 2,584,868 of stock option, performance-based unit, or PSU, and restricted stock unit, or RSU, awards granted, and 285,737 of awards cancelled or forfeited, during the nine months ended September 30, 2022 as well as an annual increase of 1,582,802 shares authorized on January 1, 2022.

Performance-based Units

During 2020, the Company granted the initial PSUs whereby vesting depends upon the approval by the FDA of vonoprazan for *H. pylori* and then, or concurrent with, erosive esophagitis. In 2022, the Company granted an additional 37,500 PSUs to employees. As of September 30, 2022, the PSU milestones had not been achieved and 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, 2022.

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at December 31, 2021	394,300	$ 32.23
Granted	37,500	20.06
Vested	-	-
Forfeited	(12,750)	36.01
Unvested balance at September 30, 2022	419,050	$ 31.03

As of September 30, 2022, there was approximately $13.0 million of related unrecognized compensation cost, which will be recognized upon vesting.

Restricted Stock Units

During 2022, the Company granted 855,437 RSUs with vesting over time. The following table summarizes RSU activity under the 2019 Incentive Award Plan during the nine months ended September 30, 2022.

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at December 31, 2021	-	$ -
Granted	855,437	10.79
Vested	-	-
Forfeited	(15,800)	13.82
Unvested balance at September 30, 2022	839,637	$ 10.73

As of September 30, 2022, the Company had $7.3 million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 1.6 years.

Employee Stock Purchase Plan

In October 2019, the board of directors adopted, and the Company's stockholders approved, the Employee Stock Purchase Plan, or 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, 2022, 752,938 shares of common stock remain available for issuance, which includes the 89,098 shares sold to employees during the nine months ended September 30, 2022.

The ESPP is considered a compensatory plan, and for the three and nine months ended September 30, 2022, the Company recorded related stock-based compensation of $0.0 and $0.3 million, respectively, compared to $0.1 million and $0.3 million, respectively, for the same periods in 2021. 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,	
	2022	2021
Assumptions:		
Expected term (in years)	0.50	0.69
Expected volatility	68.59%	76.25%
Risk free interest rate	2.04%	0.09%
Dividend yield	-	-

The estimated weighted-average fair value of ESPP awards for the nine months ended September 30, 2022 and 2021, were $3.98 and $14.66, respectively. As of September 30, 2022, the total unrecognized compensation expense related to the ESPP was $236,000, which is expected to be recognized over a weighted-average period of approximately 3.5 months.

401(k) Plan

The Company established a 401(k) savings plan during the year ended December 31, 2020. The Company's contributions to the plan are discretionary. During the three and nine months ended September 30, 2022, the Company incurred $0.2 million and $1.1 million, respectively, of expense related to estimated employer contribution liabilities, which was based on a 75% match of employees' contributions during the periods, compared to $0.1 million and $0.7 million, respectively, for the same periods in 2021. In August 2021, the Board of Directors approved a semi-annual discretionary match for 2021, which was settled by contributing 18,394 shares. In January 2022, the Board of Directors approved a second semi-annual discretionary match for 2021, which was settled by contributing 16,756 shares. In July 2022, the Board of Directors approved a semi-annual match for 2022, which was settled by contribution 84,784 shares.

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, 2021	4,186,729	$ 27.53	8.43	$ 13,973
Options granted	1,691,931	14.75		
Options exercised and shares vested	—	—		
Options forfeited, expired or cancelled	(257,187)	29.79		
Balance at September 30, 2022	5,621,473	$ 23.58	8.09	$ 4,290
Options exercisable as of September 30, 2022	2,262,491	$ 24.69	7.31	$ 2,631

The estimated weighted-average fair value of employee and nonemployee director stock options granted during 2022 was $8.46 per option. As of September 30, 2022, the Company had $42.4 million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 2.0 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,	
	2022	2021
Assumptions:		
Expected term (in years)	5.88	6.00
Expected volatility	66.01%	67.37%
Risk free interest rate	2.00%	0.65%
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 and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expense	$ 1,418	$ 1,024	$ 3,876	$ 2,910
General and administrative expense	4,398	3,395	13,600	9,564
Total	$ 5,816	$ 4,419	$ 17,476	$ 12,474

9. Subsequent Event

On November 1, 2022, the Company announced the placement of the remaining $40 million in non-dilutive capital under its up to $300 million Revenue Interest Financing Agreement. This commitment provides an additional $15 million upon FDA approval of vonoprazan for treatment of EE and $25 million for achievement of a sales milestone.

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, 2021 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, 2021 ("2021 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 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 numerous countries in Asia and Latin America as well as Russia. Vonoprazan generated approximately $850 million in net sales in its seventh 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.

In 2021 we reported topline data from two pivotal Phase 3 clinical trials for vonoprazan: one for the treatment of *H. pylori* infection (PHALCON-HP), and a second for the treatment of erosive GERD (PHALCON-EE), also known as erosive esophagitis, or EE. In April 2021, we reported positive topline data from PHALCON-HP, and in October 2021, we reported positive topline data from PHALCON-EE. In September 2021, we submitted new drug applications (NDAs) for two treatment regimens containing vonoprazan for the treatment of *H.* pylori infection, vonoprazan triple therapy (vonoprazan, amoxicillin, clarithromycin) and vonoprazan dual therapy (vonoprazan, amoxicillin), and in November 2021, the U.S. Food and Drug Administration, or FDA, accepted both NDAs for filing, granted each of them Priority Review, and assigned us a Prescription Drug User Fee Act (PDUFA) action date in May 2022. In addition, both of our *H. pylori* NDAs received qualified infectious disease product (QIDP) designations which provides a potential extension of any regulatory exclusivity awarded following approval. On May 3, 2022, we received FDA approval for vonoprazan triple therapy, under the brand name VOQUEZNA™ TRIPLE PAK™ and vonoprazan dual therapy, under the brand name VOQUEZNA™ DUAL PAK™, in each case for the treatment of *H. pylori* infection in adults. Further, in March 2022, we submitted an NDA for the use of vonoprazan as a treatment for adults for the healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn, which was accepted for filing by the FDA in May 2022, with a PDUFA action date of January 11, 2023. In August 2022, we announced that, consistent with current FDA recommendations for all chemically synthesized drug compounds such as vonoprazan, we had previously initiated post-approval testing to determine whether nitrosamine impurities were present in vonoprazan drug product. These tests showed trace levels of a nitrosamine impurity that is not described within the FDA guidance document entitled "Control of Nitrosamine Impurities in Human Drugs – Guidance for Industry." We are continuing to work with the FDA to obtain approval of, and are prepared to implement an additional test method, specification, including proposed acceptable intake limit, and additional controls to address this impurity prior to releasing our first vonoprazan-based products to the market. These additional activities resulted in a delay of the planned VOQUEZNA™ TRIPLE PAK™ and VOQUEZNA™ DUAL PAK™ commercial launches. We currently expect commercial launch of these products, as well as, if approved, VOQUEZNA™ tablets for EE, in the first quarter of 2023.

We have also progressed our clinical development program in NERD. In February 2022, we reported positive topline data from a Phase 2 trial studying vonoprazan for on-demand treatment of NERD, and based on the positive results from this study are in discussions with FDA regarding a Phase 3 trial design for this novel dosing regimen. Also in February 2022, we commenced, and in October 2022, we completed, enrollment of patients in a Phase 3 trial studying vonoprazan, dosed on a once-daily basis, for the treatment of NERD with topline data for the primary endpoint expected in the first quarter of 2023 and topline results for the full trial expected later in 2023. Additionally, we plan to discuss with the FDA our proposed development plan to study vonoprazan as a treatment for eosinophilic esophagitis, or EoE.

We plan to independently commercialize vonoprazan in the United States. We also plan to seek commercial partnerships for vonoprazan in Europe and Canada, expand development of vonoprazan into other indications, dosing regimens and alternative formulations and packaging, and in-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner.

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, conducting our clinical trials of vonoprazan, preparing applications for regulatory approval for vonoprazan and preparing for commercial launch. Our operations to date have been funded primarily through the issuance of convertible promissory notes, commercial bank debt, the proceeds from our initial public offering and our follow-on public offering. From our inception through September 30, 2022, we have raised aggregate gross proceeds of $90.3 million from the issuance of convertible promissory notes, $100.0 million of debt, $100.0 million of revenue interest financing liability, net proceeds from our initial public offering 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, net proceeds of $88.6 million from the sale of 2,250,000 shares of common stock at a public offering price of $39.48 per share after deducting underwriting discounts and commissions, and an additional $0.2 million in offering costs, and the sale of 2,414,897 shares of common stock for net proceeds of approximately $24.6 million in its September 2022 issuance of common stock under the ATM Offering.

We have incurred net losses since our inception. Our net losses for the nine-month periods ended September 30, 2022 and 2021 were $142.7 million and $108.1 million, respectively. As of September 30, 2022, we had an accumulated deficit of $672.0 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 additional clinical trials, seek further regulatory approval for vonoprazan, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution, 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 commence commercialization of our initial approved products. 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, Revenue Interest Financing Agreement 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.

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 as well as for qualification of future third party commercial manufacturing.

We plan to continue to invest in research and development 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.

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 significantly increase in the future to support our continued research and development activities, pre-commercial preparation activities in light of the recent approvals of VOQUEZNA™ TRIPLE PAK™ and VOQUEZNA™ DUAL PAK™ to treat *H. Pylori* infection in adults 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

Beginning on May 3, 2022, interest expense includes interest on the Revenue Interest Financing Agreement, which is based on the imputed effective rate derived from expected future payments and the carrying value of the obligation. The Company recalculates the effective interest rate each period based on the current carrying value and the revised estimated future payments. Changes in future payments from previous estimates are included in current and future financing expense.

Beginning on September 17, 2021, interest expense includes interest on the Hercules Loan Agreement, which consists of (i) cash interest at a variable annual rate equal to the greater of (a) 5.50% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 2.25% (the "Interest Rate"), (ii) payment-in-kind interest at a per annum rate of interest equal to 3.35%, and (iii) amortization of the Hercules Loan Agreement 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.

Prior to September 17, 2021, interest expense consisted of interest on our outstanding commercial bank debt with SVB at a variable annual rate equal to the greater of (a) 7.25% and (b) Prime Rate (as reported by the Wall Street Journal) plus 1.75% and amortization of the SVB Term Loan 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.

Results of Operations

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 55,495	$ 58,786	$ (3,291)
General and administrative	70,303	43,254	27,049
Total operating expenses	125,798	102,040	23,758
Loss from operations	(125,798)	(102,040)	(23,758)
Other income (expense):			
Interest income	845	35	810
Interest (expense)	(17,703)	(4,013)	(13,690)
Other (expense)	(20)	(2,039)	2,019
Total other (expense)	(16,878)	(6,017)	(10,861)
Net loss	$ (142,676)	$ (108,057)	$ (34,619)

Research and Development Expenses. Research and development expenses were $55.5 million and $58.8 million for the nine months ended September 30, 2022 and 2021, respectively. The decrease of $3.3 million consisted of a reduction of $4.0 million of expenses related to regulatory requirements and $3.0 million of clinical trial costs in 2022, partially offset by increase of $1.9 million of chemistry manufacturing and controls, or CMC, costs related to vonoprazan, and $1.8 million of personnel-related, consulting and other research expenses.

General and Administrative Expenses. General and administrative expenses were $70.3 million and $43.3 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of $27.0 million was due to increases of $14.5 million in professional services expenses for commercial, medical affairs and other services, $11.7 million in personnel-related expenses, $2.5 million in legal and other expenses in 2022, partially offset by a $1.7 million reduction in consulting 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 $16.9 million for the nine months ended September 30, 2022 consisted of interest expense under the Hercules Loan and Revenue Interest Financing Agreements, partially offset by interest income on deposits. Other expense of $6.0 million for the nine months ended September 30, 2021 consisted of $4.0 million of interest expense on outstanding commercial bank debt and $2.0 million of charges related to early extinguishment of debt.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 19,020	$ 16,608	$ 2,412
General and administrative	23,509	16,529	6,980
Total operating expenses	42,529	33,137	9,392
Loss from operations	(42,529)	(33,137)	(9,392)
Other income (expense):			
Interest income	726	8	718
Interest (expense)	(9,277)	(1,485)	(7,792)
Other (expense)	(11)	(2,048)	2,037
Total other (expense)	(8,562)	(3,525)	(5,037)
Net loss	$ (51,091)	$ (36,662)	$ (14,429)

Research and Development Expenses. Research and development expenses were $19.0 million and $16.6 million for the three months ended September 30, 2022 and 2021, respectively. The increase of $2.4 million consisted of increases of $6.0 million of clinical trial cost, $0.6 million of chemistry manufacturing and controls, or CMC, costs related to vonoprazan, and $0.3 million of personnel-related costs and other research expenses, partially offset by a decrease of $4.5 million in expenses related to regulatory requirements.

General and Administrative Expenses. General and administrative expenses were $23.5 million and $16.5 million for the three months ended September 30, 2022 and 2021, respectively. The increase of $7.0 million was due to increases of $3.5 million in personnel-related costs, $3.0 million in professional services expenses for commercial, medical affairs and other services, and $0.5 million of legal, consulting and other expenses. 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 $8.6 million for the three months ended September 30, 2022 consisted of interest expense under the Hercules Loan and Revenue Interest Financing Agreements, partially offset by interest income on deposits. Other expense of $3.5 million for the three months ended September 30, 2021 consisted of $2.0 million of charges related to early extinguishment of debt and $1.5 million interest expense on outstanding commercial bank debt.

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, 2022, we had cash and cash equivalents of $196.8 million.

Loan Agreement with Hercules

On September 17, 2021, (the “Closing Date”), we entered into a Loan and Security Agreement (the “Loan Agreement”) with Hercules Capital, Inc., in its capacity as administrative agent and collateral agent and as a lender (in such capacity, the “Agent” or “Hercules”) and the other financial institutions that from time to time become parties to the Loan Agreement as lenders (collectively, the “Lenders”).

The Loan Agreement provides for term loans in an aggregate principal amount of up to $200.0 million (the "Term Loan") under multiple tranches. The tranches consist of (i) a first tranche consisting of term loans in an aggregate principal amount of $100.0 million, all of which was funded on the Closing Date (the "First Advance"), (ii) a second tranche consisting of up to an additional $50.0 million, which became available to us upon achievement of the protocol-specified primary efficacy endpoints in our Phase 3 trial studying vonoprazan for the healing and maintenance of healing of erosive esophagitis with acceptable safety data, such that the results support the submission of a New Drug Application ("NDA") or supplemental NDA without the need to conduct another Phase 3 study and will be available, if specified conditions are met, through December 15, 2022, see amendment to later date below, (iii) a third and fourth tranches consisting of an additional total $50.0 million, which became available to us in May 2022 upon the achievement of (a) FDA approval of our NDA for vonoprazan and amoxicillin, or its NDA for vonoprazan, amoxicillin and clarithromycin, in each case for an indication relating to the treatment of H. pylori with an approved indication on the claim that is generally consistent with that sought in our NDA submission; and (b) filing of an NDA or supplemental NDA for vonoprazan for indications relating to the healing and maintenance of healing of erosive esophagitis. The third and fourth tranches will remain available until September 30, 2023, and March 31, 2024, respectively. We intend to use the proceeds of the Term Loan advances for working capital and general corporate purposes. In addition, approximately $54 million of the proceeds from the First Advance was used to satisfy in full and retire our indebtedness under its previously outstanding credit facility with Silicon Valley Bank (the "SVB Term Loan").

On September 27, 2022, the Company entered into an amendment to the Loan Agreement, or the Second Loan Amendment, pursuant to which the date the second tranche of funding of $50 million will remain available to the Company has been moved until either February 15, 2023 or, if the PDUFA target action date for the Company's pending NDA is extended beyond the current PDUFA target action date, May 15, 2023, rather than December 15, 2022.

The Term Loan will mature on October 1, 2026 (the "Maturity Date"). The Term Loan bears (i) cash interest at a variable annual rate equal to the greater of (a) 5.50% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 2.25% (the "Interest Rate") and (ii) payment-in-kind interest at a per annum rate of interest equal to 3.35%. We may make payments of interest only through October 1, 2024, which was extended to October 1, 2025, upon the achievement of the Second Performance Milestone in May 2022 prior to September 30, 2024 and the condition that no default or event of default exists, and which is further extendable to October 1, 2026, subject to FDA approval of our NDA (or supplemental NDA) for vonoprazan for an indication relating to the healing and maintenance of healing of erosive esophagitis with an approved indication on the label that is generally consistent with that sought in our NDA submission (or supplemental NDA submission) (the "Third Performance Milestone") on or prior to September 30, 2025 and no default or event of default exists (the "interest only period"). After the interest-only period, the principal balance and related interest will be required to be repaid in equal monthly installments and continuing until the Maturity Date.

The Loan Agreement contains customary closing fees, prepayment fees and provisions, events of default, and representations, warranties and covenants, including a financial covenant requiring us to maintain certain levels of cash subject to a control agreement in favor of the Agent (minus accounts payable not paid within 120 days of invoice) ("Qualified Cash"), and commencing on May 15, 2023, trailing three-month net product revenue from the sale of vonoprazan and products containing vonoprazan. The revenue covenant will be waived at any time in which we maintain Qualified Cash equal to at least 60.0% (prior to the Third Performance Milestone), and 35% (following the Third Performance Milestone) of the total outstanding Term Loan principal amount, or our market capitalization is at least $900.0 million.

Under the Second Loan Amendment, the commencement date for the covenant based on trailing three-month net product revenue from the sale of vonoprazan and products containing vonoprazan was moved from May 15, 2023, to November 15, 2023.

As collateral for the obligations, we granted to Hercules a senior security interest in all of our right, title, and interest in, to and under substantially all of our property, inclusive of intellectual property.

In connection with the entry into the Loan Agreement, we issued to Hercules a warrant (the "Warrant") to purchase a number of shares of our common stock equal to 2.5% of the aggregate amount of the Term Loan advances funded, and will issue to Hercules additional warrants when future Term Loan advances are funded. On the Closing Date, we issued a Warrant for 74,782 shares of common stock. The Warrant will be exercisable for a period of seven years from the date of issuance at a per-share exercise price equal to $33.43, which was the closing price of our common stock on September 16, 2021.

Revenue Interest Financing Agreement

On May 3, 2022, we entered into a Revenue Interest Financing Agreement with Initial Investors NQ, Sagard, and Hercules pursuant to which we will receive up to $260 million in funding from the Initial Investors. Under the terms of the Revenue Interest Financing Agreement, we received $100 million at the initial closing and can receive an additional $160 million upon FDA approval of vonoprazan for treatment of erosive esophagitis on or before March 31, 2024. We also have the right to obtain written commitments from third parties at any time prior to December 31, 2022, for up to $15 million of funding upon FDA approval of vonoprazan for erosive esophagitis and, at any time prior to June 30, 2024, for up to $25 million upon achievement of a sales milestone. The Initial Investors have a right of first offer if the Company seeks to obtain such additional funding.

Under the Revenue Interest Financing Agreement, the investors are entitled to receive a 10% royalty on net sales of products containing vonoprazan. The royalty rate is subject to a step-down on net sales exceeding certain annual thresholds and if the Company receives FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease, or NERD. The investors' right to receive royalties on net sales will terminate when the investors have aggregate payments equal to 200% of the Investment Amount. In addition, at any time after the earlier of (i) April 30, 2024 and (ii) the date that the payment for erosive esophagitis regulatory approval is made, we have the right to make a cap payment equal to 200% of the Investment Amount less any royalties already paid, at which time the agreement will terminate.

If the investors have not received aggregate payments of at least 100% of the Investment Amount by December 31, 2028, and at least 200% of the Investment Amount by December 31, 2037, each a Minimum Amount, then we will be obligated to make a cash payment to the investors in an amount sufficient to gross the investors up to the applicable Minimum Amount.

Upon the occurrence of an event of default taking place prior to April 1, 2025, between April 1, 2025, and April 1, 2028, and after April 1, 2028, we are obligated to pay 1.30 times Investment Amount, 1.65 times Investment Amount, and 2.0 times investment amount, respectively, less any amounts previously paid pursuant to the agreement.

Upon the occurrence of a change in control event taking place prior to the earlier of April 1, 2024, or FDA approval of vonoprazan for erosive esophagitis, we are obligated to pay 200% of the Investment Amount plus either 15% of the Investment Amount if occurrence prior to May 3, 2023, or plus 30% of the Investment Amount if occurrence thereafter.

We intend to use the proceeds received under the Revenue Interest Financing Agreement for working capital and general corporate purposes.

At-the-Market-Offering

On November 10, 2020, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or 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, or 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 which was filed on November 10, 2020 and declared effective by the SEC on November 16, 2020. 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. In September 2022, the Company sold 2,414,897 shares for net proceeds of approximately $24.6 million under the ATM offering after deducting $0.8 million of issuance costs. As of September 30, 2022, the Company has utilized $25.4 million of the available $125.0 million under the ATM Offering.

Underwritten Public Offering

On December 16, 2020, the Company completed an underwritten public offering, in which it sold 2,250,000 shares of its common stock at a price of $42.00 per share for total gross proceeds of $94.5 million. The net purchase price after deducting underwriting discounts and commissions was $39.48 per share, which generated net proceeds of $88.8 million. We incurred an additional $0.2 million of offering expenses in connection with the public offering.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents together with the drawdown of the remaining $100 million under our Loan Agreement with Hercules, receipt of amounts potentially available under the revenue interest financing agreement and anticipated future sales of products containing vonoprazan will be sufficient to fund our operations through 2024. We expect such amounts will allow us to complete our ongoing Phase 3 clinical trial studying vonoprazan for NERD (daily dosing), and launch vonoprazan for *H. pylori* and, if approved, erosive esophagitis. 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 global supply chain disruptions, including, without limitation, as a result of the ongoing conflict in the Ukraine;
- 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, together with the proceeds that are currently available to us under the Hercules Loan, 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 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,		
	2022	2021	Change
Net cash provided by (used in):			
Operating activities	$ (105,834)	$ (107,195)	$ 1,361
Investing activities	(629)	(228)	(401)
Financing activities	120,042	44,545	75,497
Net increase (decrease) in cash	$ 13,579	$ (62,878)	$ 76,457

Operating Activities

Net cash used in operating activities was approximately $105.8 million and $107.2 million for the nine months ended September 30, 2022 and 2021, respectively. The net cash used in operating activities for the nine months ended September 30, 2022 was due to approximately $111.0 million spent on ongoing research and development and general and administrative activities, partially offset by a $5.2 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $3.4 million increase in accounts payable and accrued expenses (including clinical trial expenses), a $2.3 million decrease in prepaid assets and other current assets, partially offset by a $0.5 million increase in other long-term assets. The net cash used in operating activities for the nine months ended September 30, 2021 was due to approximately $91.3 million spent on ongoing research and development and general and administrative activities and a $15.9 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $19.1 million decrease in accounts payable and accrued expenses (including clinical trial expenses), partially offset by a $3.2 million decrease in prepaid assets.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 and 2021, was primarily due to the cash we paid for acquiring property, plant and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was due to the net proceeds from the revenue interest financing liability and issuance of common stock under the ATM Offering. Net cash provided by financing activities for the nine months ended September 30, 2021 was due to net proceeds from the loan agreement with Hercules and issuance of common stock from exercise of stock options partially offset by the repayment of the SVB Term Loan.

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, 2022 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 2021 Form 10-K.

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 2021 Form 10-K. There have not been any material changes to the critical accounting policies discussed therein during the nine months ended September 30, 2022.

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, 2022, 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 2021 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, 2022 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

There have been no material changes to the risk factors disclosed in Part I, Item 1A, "Risk Factors" of our 2021 Form 10-K, other than as set forth below.

We currently depend entirely on the success of vonoprazan, which is contained in our only approved products and product candidate. If we are unable to successfully launch and commercialize vonoprazan, obtain additional, required regulatory approvals and advance the clinical development of vonoprazan in additional indications, or experience significant delays in doing so, our business will be materially harmed.

We currently have two approved products and one product candidate, all of which contain vonoprazan, which we in-licensed from Takeda. Our current business depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize products containing vonoprazan in a timely manner. This may make an investment in our company riskier than similar companies that have multiple approved products or product candidates in active development that may be able to better sustain failure of a single product. In May 2022, we received FDA approval for vonoprazan triple therapy, under the brand name VOQUEZNA™ TRIPLE PAK™ and vonoprazan dual therapy, under the brand name VOQUEZNA™ DUAL PAK™, in each case for the treatment of *H. pylori* infection in adults. Further, in March 2022, we submitted an NDA for the use of vonoprazan as a treatment for adults for the healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn, which was accepted for filing by the FDA in May 2022, with a PDUFA action date of January 11, 2023. In February 2022, we initiated a Phase 3 trial for vonoprazan using a daily dosing regimen for the treatment of NERD, with topline data for the primary endpoint expected in the first quarter of 2023 and topline results for the full trial expected in 2023. Our assumptions about vonoprazan's commercial potential are based in large part on the commercial experience of vonoprazan in Japan. However, our assumptions may prove to be wrong, and we may encounter a materially and adversely different development and commercial experience. The success of vonoprazan will depend on several factors, including the following:

- acceptance by the FDA or by comparable foreign regulatory authorities of our proposed design of our clinical trials;
- successful enrollment in clinical trials and completion of clinical trials with favorable results;
- the willingness of the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities to accept the data from the clinical trials and preclinical studies and clinical trials conducted outside of our licensed territories by Takeda and independent investigators as part of the basis for review and approval of vonoprazan;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including one or more NDAs from the FDA and maintaining such approvals;
- making and/or maintaining arrangements with Takeda, Catalent, Sandoz, Evonik or any future third-party manufacturers for, or establishing, commercial manufacturing capabilities and receiving/importing commercial supplies approved by FDA and other regulators from Takeda, Catalent, Sandoz, Evonik or any future third-party manufacturer;
- establishing sales, marketing and distribution capabilities and commercializing vonoprazan, if approved, whether alone or in collaboration with others;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for vonoprazan;

• maintaining an acceptable safety profile of vonoprazan following approval; and

• maintaining and growing an organization of people who can develop and, if approved, commercialize, market, and sell vonoprazan to physicians, patients, healthcare payors, and others in the medical community.

In August 2022, we announced that, consistent with current FDA recommendations for all chemically synthesized drug compounds such as vonoprazan, we previously initiated post-approval testing to determine whether nitrosamine impurities were present in vonoprazan drug product. These tests showed trace levels of a nitrosamine impurity that is not described within the FDA guidance document entitled "Control of Nitrosamine Impurities in Human Drugs – Guidance for Industry." We are continuing to work with the FDA to obtain approval of, and are prepared to implement an additional test method, specification, including proposed acceptable intake limit, and additional controls to address this impurity prior to releasing our first vonoprazan-based products to the market. These additional activities resulted in a delay of the planned VOQUEZNA™ TRIPLE PAK™ and VOQUEZNA™ DUAL PAK™ commercial launches. We currently expect commercial launch of these products, as well as, if approved, VOQUEZNA™ tablets for EE, in the first quarter of 2023. If we are unable to obtain FDA approval for, or are unable to obtain approval for and implement, a test method, a specification and controls to maintain nitrosamine levels in vonoprazan drug product at or below the applicable acceptable intake limit, these product launches may be further delayed, and approval of our EE NDA may also be delayed, which could substantially increase our costs and delay or put at risk our ability to generate revenue and adversely affect our commercial prospects.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful completion of clinical development, regulatory approval and commercialization of vonoprazan, including successfully addressing, to the FDA's and the medical community's satisfaction, the formation of nitrosamine impurities in commercial batches of vonoprazan drug product, which may be significantly delayed beyond our current expectations and may never occur. Although we have obtained marketing approval of two vonoprazan-based treatment regimens for one indication, we have not yet succeeded in launching and successfully commercializing vonoprazan. Any inability to obtain required, additional regulatory approvals for, or, if approved, successfully commercialize vonoprazan, would materially and adversely affect our business, financial condition, prospects and operating results.

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

Unregistered Sales of Equity Securities

None.

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

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	3.1	
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	12/31/21	4.6	
10.1†	Commercial Supply Agreement with Evonik Operations GmbH entered into on August 1, 2022				X
10.2	Second Amendment to the Loan and Security Agreement, dated September 17, 2021, by and among Hercules Capital and the Registrant.				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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Label Linkbase Document				X
101.PRE	Inline XBRL Presentation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

† Portions of this exhibit have been omitted for confidentiality purposes.
* 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, 2022

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

Date: November 10, 2022

By: /s/ Molly Henderson
Molly Henderson
Chief Financial and Business Officer
(Principal Financial and Accounting Officer)

VONOPRAZAN COMMERCIAL SUPPLY AGREEMENT

This **VONOPRAZAN COMMERCIAL SUPPLY AGREEMENT** (this "**Agreement**") effective as of August 1, 2022 ("**Effective Date**") between Phathom Pharmaceuticals, Inc, located at 100 Campus Drive, Suite 102, Florham Park, NJ 07932, USA ("**Purchaser**"), and Evonik Operations GmbH, a limited liability company located at Rodenbacher Chaussee 4, 63457 Hanau (Wolfgang), Germany ("**Supplier**"). Purchaser and Supplier are each sometimes referred to individually as a "**Party**" and together as the "**Parties**".

RECITALS

WHEREAS, Supplier has the expertise, resources, facilities and personnel for the manufacture and supply of Vonoprazan Fumarate ("**Product**") which is also known as TAK-438, and Supplier desires to be engaged to manufacture and supply Product for Purchaser pursuant to the terms and conditions below; and

WHEREAS, Purchaser provided to Supplier the Purchaser Technology Data Package (as defined herein) containing such information, data, documents and records as reasonably necessary for Supplier to manufacture the Product,;

WHEREAS, Purchaser desires to engage Supplier to manufacture and supply Product as ordered by Purchaser, as a raw material in Purchaser's subsequent manufacture of finished pharmaceutical products containing Product as active pharmaceutical ingredient for human use ("**Final Product**"),

WHEREAS, the Agreement will cover a 4 phased approach, with phase 1 being the first commercial campaign (starting after successful completion of the validation campaign, which validation campaign is not subject to this Agreement), and ending with the successful completion of the first commercial campaign ("**Phase 1**"), phase 2 being regular commercial supply from the Supplier Facility in [***] starting after completion of Phase 1 ("**Phase 2**"), phase 3 consisting of validation of the process at the Supplier Facility of [***], and ending with the successful completion of such validation ("**Phase 3**") and phase 4 being commercial supply from [***] after the successful validation in [***] ("**Phase 4**").

WHEREAS, in order to be able to validate the process at the Supplier's Affiliate [***], certain equipment modifications are necessary. Supplier's Affiliate [***] and Purchaser will enter into a separate agreement covering such equipment modification and the funding thereof.

NOW, THEREFORE, in consideration of the foregoing and the promises contained in this Agreement, Purchaser and Supplier, intending to be legally bound, hereby agree as follows:

ARTICLE 1DEFINITIONS.

1.1 Definitions and Exhibits. Unless otherwise defined, initially capitalized terms used in this Agreement, including the recitals, Appendices, Schedules, and Exhibits hereto, shall have the meanings ascribed to them in **Exhibit A**. The Parties hereto agree that the provisions set forth in any appendix, schedule, or exhibit attached hereto are hereby incorporated by reference in this Agreement as if fully set forth herein. In the event there is a conflict or inconsistency between any appendix, schedule, or exhibit and this Agreement, the provisions of this Agreement shall control.

1.2 Interpretation. Each reference herein to a particular Person shall include a reference to such Person's successors and permitted assigns. A reference to any document or agreement shall include such document or agreement as amended, modified or supplemented from time to time in

accordance with its terms. A reference to any law, rule, regulation or statute includes any amendment or modification thereto. The words "herein," "hereof," "hereunder," "hereto," and words of like import shall refer to this Agreement as a whole and not any particular article, section or subdivision of this Agreement. A reference to an article, section, appendix, schedule, or exhibit is a reference to the article, section, appendix, schedule, or exhibit of this Agreement unless otherwise indicated. In this Agreement, the singular includes the plural and the plural includes the singular, and the words "including," "include" and "includes" shall be deemed to be followed by the words "without limitation."

1.3 Order of Interpretation.

1.3.1 Conflict with Quality Agreement. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control for matters unrelated to Product quality, unless otherwise agreed to in writing by the Parties. For matters related to Product quality, the Quality Agreement shall control, unless otherwise agreed to in writing by the Parties.

1.3.2 Pre-Printed Terms and Conditions. Any and all pre-printed terms and conditions on Purchaser's purchase order or Supplier's order confirmation shall have no binding effect as it relates to this Agreement or the subject thereof.

ARTICLE 2TERM AND RENEWAL.

2.1 Initial Term. Subject to earlier termination in accordance with this Agreement, the term of this Agreement shall be effective commencing on the Effective Date and shall continue in effect for an initial term of five (5) years (the "**Initial Term**"). Upon successful completion of Phase 3 on or prior to December 31, 2024, the Initial Term will be extended by additional two (2) years.

2.2 Term; Renewal Term; Notice of Nonrenewal. This Agreement shall automatically renew for subsequent periods of two (2) years (each a "**Renewal Term**"), unless terminated by either Party upon no less than either (a) twenty-four (24) months' prior written notice during the Initial Term or (b) eighteen (18) months' prior written notice during any subsequent Renewal Term, to the end of the relevant Term. The Initial Term and Renewal Term, if any, shall be referred to collectively as the "**Term**."

ARTICLE 3SUPPLY OF PRODUCT.

3.1 Product Specification. Supplier shall manufacture and sell, and Purchaser shall purchase, Product in conformance with the product specification appended hereto at **Exhibit B** ("**Specification**").

3.2 Performance. Supplier shall either on its own or through an Affiliate supply the Product in accordance with the terms and conditions of this Agreement.

3.2.1 Supplier Facility. The Product shall be manufactured at the Supplier Facility. [***].

3.2.2 Compliance. Supplier shall perform its obligations hereunder in compliance with all Applicable Laws, and in a professional, workmanlike, diligent and timely manner.

3.2.3 Subcontracting. Other than an Affiliate, which Supplier is expressly permitted to engage, Supplier will neither employ nor engage any contractor or subcontractor to perform any of Supplier's material obligations under this Agreement without Purchaser's prior written

consent, such consent not to be unreasonably withheld or delayed. For purposes of clarification, Supplier shall not be required to obtain Purchaser's prior written consent to the extent Supplier retains the services of a Third Party to perform Supplier Facility maintenance services, equipment repair and calibration, or other ancillary services in support of its contractual obligations hereunder.

3.2.4 Annual Campaigns. [***].

3.2.5 Maximum Supply Obligation. During each calendar year of the Term, Supplier agrees to manufacture and supply to Purchaser Product up to Supplier's maximum supply obligation volume as set forth in **Exhibit F** ("**Maximum Supply Obligation**").

3.3 Project Managers. Within thirty (30) days following the Effective Date, each Party will appoint (and notify the other Party in writing of the identity of) a representative to act as its project manager for their collaboration under this Agreement ("**Project Manager**"). The Project Managers will serve as the primary contact points between the Parties and will be primarily responsible for facilitating the flow of information, interaction and collaboration between the Parties under this Agreement. Each Party may replace its Project Manager on written notice to the other Party.

3.4 Quality Agreement. The Parties will enter into a Quality Agreement. However, this Agreement will expressly and exclusively govern all provisions regarding the purchase and sale of all Product between the Parties and all terms, obligations, responsibility, and liability regarding same.

3.5 Batch Records. In the course of manufacturing the Product, Supplier will generate Batch Records. The Quality Agreement shall describe whether and how Supplier will make available copies of Batch Records to Purchaser.

3.6 Exclusivity. Supplier shall manufacture and supply Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement. Subject to Article 3.10, Purchaser shall purchase from Supplier the quantities as set forth in **Exhibit F**.

3.7 Audit.

3.7.1 Scope of Audit. Once during each calendar year of the Term of and once for a period of [***] following expiration or termination of the Agreement, upon reasonable notice and during normal working hours, Supplier may retain an independent, third-party auditor mutually agreed upon by the Parties. Upon execution of a reasonable confidentiality agreement, such auditor shall have access to the accounting records and other documents maintained by Purchaser that directly relate to this Agreement for the sole purpose of verifying Purchaser's compliance with its minimum contractual purchase obligations as set forth in Article 3.6. The auditor shall solely disclose to the Supplier whether Purchaser complied with its obligation from Article 3.6 or not and the shortfall volume, if any. No further information shall be requested by and given to the Supplier.

3.7.2 Audit Expenses. All audit expenses are at the sole cost and expense of Supplier, unless such audit results in an adjustment in favor of Supplier, in which case the reasonable costs of such auditor shall be borne by Purchaser.

3.8 Shortfall Payments. If Purchaser fails to satisfy its obligations pursuant to Article 3.6, which determination shall be made at the first Planning Meeting (as defined in Article 3.17) following the end of the applicable calendar year, [***]. Notwithstanding the foregoing, Purchaser shall not be

obligated to make any Shortfall Payment to the extent that any failure by Purchaser to meet its obligations under Article 3.6 in respect of any calendar year is attributable to actions or inactions of Supplier, including the unavailability or delay of shipments of Product, or delivery of defective Product to Purchaser.

3.9 Alternate Supplier. At any time during the Term, in the event of a Supply Failure, Purchaser shall be entitled to provide written notice to Supplier indicating that Purchaser intends to select an alternate supplier of Product, in which case Supplier shall provide written notice to Purchaser, within [***] of such notice from Purchaser indicating how it will resolve such Supply Failure.

3.9.1 Supplier Assistance. In the event of a Supply Failure Purchaser shall be entitled to select, at its sole discretion, an Alternate Supplier, and Supplier shall provide assistance and cooperation in accordance with Article 3.9.2.

3.9.2 Third Party Alternate Supplier. In the event that Supplier fails or is unable to provide a timely and mutually agreed upon remedy for a Supply Failure, then Purchaser shall be entitled to select, in its sole discretion, an alternate supplier (an "**Alternate Supplier**"). In such event Supplier shall assist and cooperate with Purchaser, for a period of up to [***] to qualify such Alternate Supplier, including, as applicable, executing such documents, providing materials, methods and information reasonably necessary for qualifying such Alternate Supplier, provided that Supplier will not provide any of its Confidential Information or its Background IP or Supplier Foreground IP, unless the Parties mutually agree on terms for the provision of such.

3.9.3 Without limiting the foregoing, Purchaser may, at any time during the Term, qualify an Alternate Supplier, provided, however, that in the absence of a Supply Failure, Supplier shall not be obligated to provide the assistance and cooperation set forth in Article 3.9.1 and Article 3.9.2 above.

3.10 Suspension of Requirements Obligation. Purchaser's requirement obligations under Article 3.6 shall cease to apply commencing on the first date of any Supply Failure, and will be reinstated after the Parties mutually agree in writing that Supplier is able to supply Product again, or at the latest if Supplier proved its ability to supply by delivering the volumes ordered in the following purchase order. Once the Supply Failure has ended, Purchaser's requirement to purchase Product shall be fully reinstated, within a commercially reasonable period of time and in no event later than [***] following the Parties' agreement that Supplier is able to resume supply, subject to Purchaser's contractual obligations with such Alternate Supplier. For the avoidance of doubt, any following purchase orders submitted by Purchaser and accepted by Supplier prior to the first date of any Supply Failure (and hence, not the purchase order in connection with which the Supply Failure occurred) shall remain binding on Purchaser, provided, however, that Purchaser may reasonably postpone any delivery dates under such purchase order(s) if Supplier is not able to supply under such purchase orders in time.

3.11 Forecasts and Purchase Orders.

3.11.1 Binding Forecast Volumes. Commencing with Phase 2 , and on the 1st business day of each calendar quarter thereafter throughout the Term, Purchaser shall provide to Supplier

[***] forecast of the campaigns to be manufactured and the Product volumes to be ordered, with the requested delivery date for such campaign per calendar year. The forecast shall be a binding purchase obligation of Purchaser (the "**Firm Commitment**") for the periods defined in Article 3.11.1.1 and 3.11.1.2, and a binding supply obligation of Supplier if the forecasted volumes do not exceed the Maximum Supply Obligation. Attached as **Exhibit C** is Purchaser's current forecast of its Product delivery requirements for calendar years 2022 through 2025. This forecast is non-binding in its entirety and is provided solely as a courtesy to Supplier.

Supplier will use commercially reasonable efforts to supply Product earlier as stated in the Firm Commitment if desired by Purchaser.

3.11.1.1 Phase 2:

Annual Campaign Size	Binding period before supply
[***]	[***]

3.11.1.2 Phase 4:

Annual Campaign Size	Binding period before supply
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

3.11.2 Binding Forecast Critical Raw Materials. Commencing with Phase 2, Supplier is entitled to purchase [***] required to produce the forecasted volumes [***] before the delivery date of annual campaigns forecasted under Article 3.11.1, irrespective whether the forecasted volumes of such campaign constitute a Firm Commitment or not. Supplier is entitled to charge Purchaser, at the point in time Supplier has to pay its suppliers for such [***], [***].

3.11.3 Forecasts Review. From time-to-time during the Term the Parties will meet to review Purchaser's latest forecast against Supplier's then-current manufacturing capacity for Product with the goal of ensuring that Supplier has the capacity to meet Purchaser's anticipated orders for Product.

3.11.4 Purchase Orders. In connection with each forecast submitted by Purchaser pursuant to Article 3.11.1, the Parties will agree on a delivery schedule for Product covering the portion of such forecast constituting a Firm Commitment. Purchaser shall include the applicable agreed upon delivery date in each of its purchase orders submitted hereunder. Purchaser shall issue purchase orders for Product with such delivery dates with a lead time of at least

[***] prior to such delivery dates. Purchase orders become binding upon Acknowledgement of Supplier.

3.11.5 Acknowledgement/Rejection of Purchase Orders. Promptly (but not later than [***]) following receipt of a purchase order that complies with the forecasting provisions of this Article 3.11, Supplier shall issue a written acknowledgement ("**Acknowledgement**") that it accepts such purchase order. Each acceptance Acknowledgement shall confirm the delivery date set forth in the purchase order or set forth a reasonable alternative delivery date (such date not to be later than [***] days after [***]). Supplier may reject any purchase order in excess of its supply obligation per the relevant Firm Commitment as set forth in Article 3.11.1, subject to Article 3.13, or otherwise not given in accordance with this Agreement. Supplier must accept any purchase orders that are consistent with the Firm Commitment.

3.12 Shortage of Supply. If Supplier is unable, or anticipates that it will not be able, to supply Product as confirmed by Supplier in accordance with Article 3.11 (a "**Shortage of Supply**"), Supplier shall promptly notify Purchaser in writing of the nature of the shortage and provide its best estimate of the duration of the delay. Supplier shall, at its own cost, use commercially reasonable efforts to remedy any Shortage of Supply as soon as reasonably practicable and resume timely supplying Purchaser with ordered Product in accordance with the requirements to this Agreement.

3.13 Volumes Exceeding the Firm Commitment. If Purchaser desires volumes in excess of the Firm Commitment ("**Excess Volume**"), the Parties shall negotiate in good faith for such Excess Volume supply obligation and, if such supply of Excess Volume is agreed, Supplier shall be obligated to supply such Excess Volume upon the same terms and conditions as set forth in this Agreement; provided that Supplier in all events shall use commercially reasonable efforts to supply any Excess Volumes. Without limiting the foregoing, if following good faith negotiations Supplier does not agree to supply such Excess Volume upon the same terms and conditions as set forth in this Agreement, Purchaser may obtain such Excess Volume from a Third Party supplier and such Excess Volume will not be counted as requirement of Purchaser under Article 3.6.

If Supplier produces more Product in a campaign than as agreed in the Firm Commitment, then Purchaser shall be obliged to take up to an additional [***] of the Firm Commitment at the prices set forth in the Agreement.

3.14 Delivery Terms. The delivery terms for all Product shall be FCA Supplier Facility of the final production step Incoterms® 2020. Title and risk of loss shall pass to Purchaser upon delivery. Purchaser shall be obliged to take deliveries [***]. The Parties agree that Supplier may [***].

3.15 Acceptance or Rejection of Product.

3.15.1 Inspection Period; Acceptance. Purchaser shall have [***] after receipt of the Product and the CoC and/or CoA (an "**Inspection Period**") to inspect the Product to determine conformity with Specification, cGMP and the requirements of this Agreement. Purchaser shall provide Supplier with notice of acceptance or rejection within such period, and failure to notify Supplier of rejection during such period shall be deemed acceptance of such Product by Purchaser and all Purchaser's claims relating to any defect or non-conformity of the Product, other than latent defects, shall be waived. If Purchaser detects later on any latent defect (a defect which could not reasonably have been detected, even by conducting a thorough incoming inspection), Purchaser shall inform Supplier thereof within [***] (also an "**Inspection Period**"). If Purchaser fails to give a notice of non-conformance

within such Inspection Period, all Purchaser's claims relating to such latent defect or non-conformity of the Product shall be waived.

3.15.2 Rejection by Purchaser. If Purchaser rejects Product during the applicable Inspection Period, the Parties will engage in good faith efforts to review and resolve Purchaser's rejection. Purchaser shall only be entitled to reject Product for the following reasons: (i) Product failed to meet Specification, (ii) Supplier failed to adhere to cGMP, or (iii) Product was damaged upon delivery. Supplier will notify Purchaser within [***] of receipt of Purchaser's rejection notice whether Supplier agrees with or disputes the basis of Purchaser's rejection of Product.

3.15.3 Remedy for Purchaser's Rejection. If Supplier accepts Purchaser's basis for rejection of Product in accordance with the terms of this Agreement, Supplier shall, at Supplier's sole expense and Supplier's sole discretion, either (i) remanufacture, rework or reprocess (if possible under cGMP conditions and only if the resulting Product is immediately useable by Purchaser under the then-current regulatory approval for the Product) such rejected Product, (ii) supply replacement batches or (iii) credit the Product Price for such rejected Product plus reasonable shipping and other reasonable charges, as soon as reasonably possible and in no event later than [***] after Supplier's notice of acceptance of Purchaser rejections pursuant to Article 3.15.2.

1.1 Independent Testing. If the Parties disagree whether the Product batch conforms with the Specification, Supplier will submit a sample of such Product batch and applicable documentation to an independent, Third Party laboratory mutually agreed upon by the Parties (where such consent shall not be unreasonably withheld or delayed) in the European Union or United States. Such Third Party laboratory will determine whether such Product batch conforms to the Specification, and such determination shall be final, binding and determinative as to whether rejection of such Product batch was justified. The costs of such testing shall be borne by the Party against whom the discrepancy is resolved.

1.2 Planning Meetings. After the Effective Date, the respective Project Managers of Supplier and Purchaser, plus such other representative(s) as may be selected by each Party, shall meet in person or via telephone/video at least two (2) times each calendar year or as otherwise scheduled (each such meeting, a "**Planning Meeting**"). The first Planning Meeting in any given year shall be held in Q1 of such year. At each Planning Meeting the attendees shall review the ongoing relationship of the Parties, Purchaser's forecasts, potential Shortfall Payments, purchase orders, and Product demand in the Territory, any actual or anticipated Product shortages, consider and attempt to achieve resolution of any disputes or other matters, and addressing such other topics as the Parties may mutually agree. In the event of any actual or anticipated Product shortages, including any resulting from a Supply Failure, Purchaser may request that Supplier purchase and hold, pursuant to mutually-agreed upon terms, raw materials sufficient to produce one or more additional campaigns of Product at Purchaser's expense.

1.3 Product Packaging. Supplier shall be responsible for packaging the Product in accordance with the requirements as agreed upon between the Parties within mutually agreed upon product packaging specifications.

1.4 Raw Materials and Equipment. Supplier shall be responsible for procuring at its cost all Raw Materials, equipment, and resources needed for manufacturing the Product volumes requested in Purchaser's purchase order and thereafter accepted pursuant to Supplier's order confirmation.

ARTICLE 4PRODUCT PRICE.

4.1 Product Price. The price of Product shall be as specified in **Exhibit D** ("**Product Price**").

4.2 Product Price Adjustment. Product Price adjustments are also set forth in **Exhibit D**.

4.3 Invoicing and Payment.

4.3.1 Invoicing Event. Supplier shall submit an invoice to Purchaser after Product delivery at the address and to the attention of the person identified by Purchaser on the firm purchase order for all Product hereunder.

4.3.2 Payment Terms. Payment of undisputed amounts is due from Purchaser in full within [***] following the date of invoice. In addition, for any invoices submitted by Supplier to Purchaser on or before [***], Purchaser will use commercially reasonable efforts to remit payment to Supplier on or before [***]; provided, however, that in no event shall Purchaser's failure to remit a payment in fewer than thirty (30) days following the invoice date constitute a breach of its obligations under this Article 4.3.2.

4.3.3 Prepayment. No earlier than [***] prior to the delivery date for a particular purchase order, Supplier is entitled to invoice [***] of the purchase order value. Such invoices shall be payable as set forth in Article 4.3.2 above.

4.3.4 Late Interest. If Purchaser is [***] late in payment, a [***] charge may be enforced and the appropriate invoice will be issued and become due. If Purchaser is more than [***] late in payment, a [***] charge or the highest interest rate allowable under law may be enforced monthly and the appropriate invoice will be issued and become due.

4.3.5 Remedies for Nonpayment. If at any time, Purchaser fails to pay an undisputed invoice when due or if Purchaser exceeds its then existing credit limit as decided by Supplier (or if Purchaser consents to such change), Supplier may, in its own discretion, [***].

4.3.6 Currency. Payment shall be made in Euros.

4.4 Tax. The Product Price specified in this Agreement excludes any sales, use, excise, or similar taxes, and of any export and import duties, which may be levied as a result of the manufacture and shipment of the Product. Purchaser shall reimburse Supplier or Supplier's Affiliate for all applicable taxes, customs, duties, levies, tariffs or similar charges of any kind (including withholding or value added taxes) imposed by any federal, state, provincial, local, or other governmental entity for Product provided under this Agreement within [***] of receipt of Supplier's invoice for such amounts, excluding taxes based upon Supplier's income. Supplier shall reasonably cooperate with Purchaser to minimize any VAT, import or export duties or other taxes that would be imposed for Product provided hereunder. Each Party shall cooperate with the other Party, and provide assistance to an extent reasonably practicable and available documentation to secure a lower rate of withholding tax under any applicable tax treaties, to claim a refund and/or credit for any such withholding tax, or if otherwise required in response to any tax audit by regulatory authorities.

ARTICLE 5QUALITY & REGULATORY OBLIGATIONS.

5.1 Quality Control. The Quality Agreement shall stipulate the quality control and testing program Supplier has to maintain and follow for the manufacture of Product. As set forth in the Quality

Agreement, each delivery of Product to Purchaser hereunder shall be accompanied by (i) a written Certificate of Analysis (as defined in the Quality Agreement), (ii) a written Certificate of Compliance (as defined in the Quality Agreement), and (iii) for the validation campaigns only, any other documentation, including Batch Records, required with each delivery of Product by the Quality Agreement. For campaigns subsequent to the validation campaigns, Batch Records will be made available to Purchaser through electronic means via remote access.

5.2 Regulatory Applications for Final Product. As between the Parties, Purchaser (or its Affiliate or licensee) shall have the exclusive right to prepare and submit any and all regulatory applications and registrations regarding any Final Product. Any and all such regulatory applications and registrations regarding such Final Products will be owned solely by and held in the name of Purchaser (or its Affiliate or licensee, as applicable). Purchaser shall have the right to list Supplier as a manufacturer of the applicable Product on any regulatory applications or registrations regarding the Final Products to the extent required or appropriate under Applicable Law. Supplier shall have no rights in or to any such regulatory application or registration, or any approvals obtained thereon. Supplier hereby grants Purchaser the right of reference (and the right to have referenced by Purchaser's designee) the drug master files, if any, maintained by Supplier pertaining to the Product.

5.3 Adverse Event Reporting/Field Alert Report (FAR). As between the Parties, it is understood and agreed that Purchaser shall have the sole right and responsibility for reporting any adverse events or other non-compliance condition relating to the Product or Final Product to the applicable and appropriate Government or Regulatory Authorities. Supplier shall provide Purchaser all reasonable assistance in complying with such reporting requirements, at Purchaser's expense.

5.4 Delay or Withdrawal of Regulatory Approval. If Purchaser does not receive its first FDA approval to market, distribute and sell Finished Product by [***], or following such approval, Purchaser or its licensee shall withdraw or plan to withdraw, or be required by the FDA to withdraw, the Final Product from the market for any reason for a period that is, or is reasonably expected to be, greater than [***], then Purchaser may provide Supplier with written notice requesting that the Parties meet (in person or via video or teleconference) to discuss in good faith whether any adjustments are warranted to the terms and conditions of this Agreement to take into account the change in circumstances.

ARTICLE 6PROCESS DEVELOPMENTS.

6.1 The Parties acknowledge that the Background IP of Purchaser or Supplier is and will remain the separate property of Purchaser or Supplier, as the case may be and are not affected by this Agreement. Except as expressly permitted under this Agreement, neither Party shall have any claims to or rights in or to such separate Background IP of the other Party.

6.2 License to Background IP. For the Term of this Agreement, Purchaser grants to Supplier, and Supplier accepts, a fully paid up, royalty-free, worldwide and nonexclusive right to use Purchaser's Background IP, Purchaser Technology Data Package Improvements as well as Purchaser Foreground IP as necessary for the sole purpose to manufacture and supply the Product under this Agreement. Within the timetable set forth in this Agreement, Purchaser shall provide Supplier with a technology data package (the "**Purchaser Technology Data Package**") containing such Purchaser Background IP, patents, data, documents and records necessary for Supplier to manufacture the Product. Specifics to such Purchaser Technology Data Package are outlined in **Exhibit E**. Any failure on the part of Purchaser to provide the Purchaser Technology Data Package in a complete and timely manner shall not be held against Supplier with regard to meeting timelines

and will result in an automatic extension of Supplier timelines until such Purchaser Technology Data Package is complete, provided, however, that Purchaser's failure to provide the Purchaser Technology Data Package in a complete and timely manner shall not constitute a breach of this Agreement by Purchaser. If following unsuccessful completion of validation services, Supplier does not believe that the Purchaser Technology Data Package previously provided by Purchaser to Supplier contains the information necessary for Supplier to manufacture and supply the Product under this Agreement, then Supplier shall notify Purchaser in writing within [***] following unsuccessful completion of validation services, and the Parties will promptly meet to discuss and seek agreement, in good faith, on additional information, if any, to be added to the Purchaser Technology Data Package.

6.3 Purchaser Foreground IP. All results, improvements, developments, inventions, materials, processes, equipment and other know-how, whether patentable or not, resulting from or derived from or directly relating to Purchaser's activities outside this Agreement shall be the sole and exclusive property of Purchaser ("**Purchaser Technology Data Package Improvements**"). All improvements, developments, inventions, materials, processes, equipment and other know-how, whether patentable or not, resulting from or directly relating to Supplier's performance under this Agreement, which are solely related to the Product and/or its manufacturing process and which do not utilize any Supplier Background IP and/or Supplier Facility Information shall be the sole and exclusive property of Purchaser ("**Purchaser Foreground IP**"). Supplier agrees to assign and hereby assigns to Purchaser all right, title and interest in and to such Purchaser Foreground IP.

6.4 Supplier Foreground IP. All results, improvements, developments, inventions, materials, processes, equipment and other know-how, whether patentable or not, resulting from or derived from or directly relating to Supplier's performance under this Agreement and which utilize Supplier Background IP and/or Supplier Facility Information, or which are generally applicable inventions (i.e. not solely related to Product and its manufacturing process) shall be the sole and exclusive property of Supplier ("**Supplier Foreground IP**").

6.5 Use of Foreground IP. Unless specifically agreed upon in writing by the Parties, Supplier shall not, and shall have no obligation to, utilize in any way Supplier Background IP or Supplier Foreground IP during the performance of the services. As of the Effective Date, Supplier agrees and acknowledges that (a) [***], and (b) no Supplier Background IP or Supplier Foreground IP is or will be utilized in the manufacture of the Product absent the Parties specific written agreement, provided, however, in the event that the Parties mutually determine in the future that utilization or incorporation of such Supplier Background IP or Supplier Foreground IP is desirable, the Parties shall in good faith negotiate commercially reasonable terms upon which Supplier will use its Background and/or Foreground IP.

ARTICLE 7CONFIDENTIALITY.

7.1 Definition of Confidential Information.

7.1.1 For purposes of this Agreement, "**Confidential Information**" of a Party shall mean all confidential or proprietary information or materials disclosed by or on behalf of the Party that disclosed the information (the "**Disclosing Party**") to the Party that receives the information (the "**Receiving Party**") or its Affiliate, and shall include all Batch Records (which are expected to contain Confidential Information of each of Supplier and Purchaser) included therein, whether disclosed orally or in writing or other tangible medium, including information relating to the matters which are the subject of this Agreement.

7.1.2 The confidentiality obligations hereunder shall not apply to information which:

7.1.2.1 is now, or hereafter becomes, generally available to the public through no fault of the Receiving Party, or its Affiliate, or any entity that obtained such information or materials from the Disclosing Party;

7.1.2.2 the Receiving Party or its Affiliate already possesses, as evidenced by its written records, prior to receipt thereof from the Disclosing Party;

7.1.2.3 is obtained without restriction from a Third Party that had the legal right to disclose the same to the Receiving Party or its Affiliate; or

7.1.2.4 has been independently developed by the Receiving Party or its Affiliate without the aid, application or use of any Confidential Information of the Disclosing Party, as demonstrated by competent written records.

7.2 Obligations of Confidentiality. During the Term and for a period ending [***] after termination of this Agreement, each Party shall keep in confidence and not disclose to any Third Party or use for any purpose except as provided herein or to perform its obligations under this Agreement, any and all Confidential Information of the other Party disclosed during the Term of this Agreement. Each Party shall be responsible to the other for any breach of this Article 7 by any party to whom it is permitted to disclose the other Party's Confidential Information. Notwithstanding the foregoing, Supplier agrees that Purchaser may disclose Batch Records (including Supplier Facility Information contained within Batch Records) to Government or Regulatory Authorities in connection with Purchaser's development, manufacture, registration, marketing or sale of the Final Product. In addition, Purchaser may disclose Batch Records (including Supplier Facility Information contained within Batch Records) to Third Parties in connection with potential licensing or other strategic transactions (but excluding commercial supply arrangements) regarding Purchaser or the Final Product, including, without limitation, to underwriters, bankers, lenders, consultants and advisors in connection with potential financing activities, but excluding other CMOs; provided, however, before any such disclosure of Confidential Information to Third Parties, Purchaser shall bind such Third Parties receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement, and shall be responsible for all actions of such Third Parties, including any breach of the terms hereof.

7.3 Disclosure Pursuant to Governmental or Court Order. If a Party is compelled to disclose Confidential Information by law, stock exchange rules, or governmental order, then the compelled Party shall, prior to disclosure, provide the other Party with notice of the circumstances to allow the other Party a reasonable opportunity to contest any such disclosure and to seek, as applicable, a protective order or confidential treatment of such Confidential Information. Information shall not be deemed to be publicly available merely because more general information, or any combination thereof, may be publicly available. Notwithstanding the foregoing, either Party may disclose the terms of this Agreement in proceedings to enforce the same.

7.4 Export Compliance. The Parties shall abide by the applicable export regulations of Germany and any other country or countries. If required, the Party intending to export controlled technology or data (including a "deemed" export) shall apply for an export license or other suitable authorization from the proper authority prior to any such export and inform any Receiving Party of any further restrictions on use of the technology or data. The Parties shall not export or re-export any technical data, products, or samples received from the Disclosing Party or the direct product of such technical data in contravention of the export compliance laws of Germany or associated regulations.

ARTICLE 8REPRESENTATION & WARRANTIES.

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

8.1.1 Due Authorization. Such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

8.1.2 Enforcement of Obligations. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

8.1.3 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party.

8.2 Warranties of Supplier. Supplier hereby represents and warrants to Purchaser that:

8.2.1 All Product delivered pursuant to this Agreement will be produced in accordance with the relevant Master Batch Record, comply with the Specification and manufactured pursuant to cGMP. If Supplier has manufactured defective Product because the specifications laid down in the Purchaser Technology Data Package resulted in the respective defect of the Product, any and all warranty and liability of Supplier in that respect shall be excluded.

8.2.2 Neither Supplier nor its Affiliates will in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a), excluded from a U.S. federal healthcare program, debarred from U.S. federal contracting, or convicted or plead nolo contendere to any felony or to any violation of laws relating to fraud. If during the Term Supplier becomes aware of any non-compliance with this Section 8.2.2, Supplier shall notify Purchaser immediately. In either such event, Purchaser will have the right to terminate this Agreement upon written notice to Supplier if such non-compliance is not cured within [***] following the date Supplier first becomes aware of such non-compliance.

8.2.3 In performing its obligations under this Agreement, Supplier and its Affiliates will comply with all applicable laws, regulations, professional standards, and industry codes, ordinances and orders, as amended from time to time, including but not limited to (i) the Foreign Corrupt Practices Act of 1977 and the UK Bribery Act, (ii) the U.S. federal anti-kickback statute (42 U.S.C. §1320a-7b(b)), and state anti-kickback and other laws restricting gifts to, relationships with and information from prescribers, (iii) the federal Food and Drug Administration laws, regulations and guidance, including the federal Food, Drug and Cosmetic Act and the Prescription Drug Marketing Act, and (iv) those governing the purchase and sale of securities while in possession of material, non-public information about a company.

8.3 Warranties of Purchaser. Purchaser hereby represents and warrants that the Product and the Final Product, in particular their Production/manufacture, use, sale and distribution, and any other information provided by Purchaser to Supplier do not infringe on any German, European or foreign patent, trademark, copyright or other intellectual property or proprietary right of any third party; provided that Purchaser makes no representations and warranties as to any infringement that is attributable to use by Supplier of any proprietary manufacturing process of Supplier.

8.4 Disclaimer of Warranty. EXCEPT AS SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE. NO OTHER WARRANTY OR LIABILITY, EXPRESS OR IMPLIED, AND WHETHER ARISING BY OPERATION OF LAW OR CUSTOM, SHALL APPLY.

ARTICLE 9INDEMNIFICATION.

9.1 Purchaser's Indemnity Obligation. Purchaser shall defend, indemnify, and hold harmless Supplier (including its directors, officers, employees, Affiliates and agents) against any liability, judgments, damages, expenses or loss resulting from any Third Party actions, claims, suits, proceedings, demands, or allegations (collectively, "**Claim**") to the extent based upon the (a) development, manufacture, use, promotion, distribution or sale by Purchaser or its Affiliate, sublicensee or customer of Product or Final Products containing Product supplied by Supplier under this Agreement; (b) Purchaser's breach of any of its representations, warranties, covenants or obligations under this Agreement; (c) the negligence or willful misconduct or omission of Purchaser or any of its officers, directors, agents, representatives, employees, or subcontractors, in the performance of the Agreement; or (d) the Production, use, sale, distribution and promotion, or other disposition of any Product or product incorporating the Product, in particular related to infringement of Third Party intellectual property rights; except in each case to the extent resulting from or caused by any activities set forth in Article 9.2 for which Supplier is obligated to indemnify Purchaser.

9.2 Supplier's Indemnity Obligation. Subject to Article 10, Supplier shall defend, indemnify and hold harmless Purchaser (including its directors, officers, employees and agents) against any liability, judgments, damages, expenses or loss resulting from any Third Party Claims to the extent based upon (a) the gross negligence or willful misconduct or omission of Supplier or its officers, directors, agents, representatives, employees, or subcontractors, (b) Supplier's breach of any of its representations, warranties, covenants or obligations under this Agreement, or (c) any actual or alleged infringement or violation of any third party intellectual property to the extent resulting exclusively from practice or use of Supplier Background IP or Supplier Foreground IP; except in each case to the extent resulting from or caused by any activities set forth in Article 9.1 for which Purchaser is obligated to indemnify Supplier.

9.3 Notification of Claims; Conditions to Indemnification Obligations.

9.3.1 As a condition to a Party's right to receive indemnification under this Article 9, it shall: (a) promptly notify the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; provided, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit (at the indemnifying Party's expense); and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. The indemnified Party shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

9.3.2 In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any

indemnitee without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include using commercially reasonable efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this under this Article 9 with respect to claims or suits settled or compromised without its prior written consent.

ARTICLE 10LIABILITY.

10.1 Consequential Damages Exclusion. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY NON-CONTRACTUAL OBLIGATIONS RELATED TO IT, SUCH AS LOSS OF BUSINESS, LOSS OF PROFITS, RECALL COSTS, DEPLETION OF GOODWILL, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. Notwithstanding the foregoing, nothing in this Article 10.1 is intended to limit or restrict the indemnification rights or obligations of any Party under Article 9.1 or 9.2.

10.2 Supplier's Limitation of Liability. WITH THE EXCEPTION OF CLAIMS PURSUANT TO Article 7, OR CLAIMS RESULTING FROM SUPPLIER'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, SUPPLIER'S TOTAL LIABILITY FOR ANY AND ALL CLAIMS UNDER OR IN CONNECTION WITH THIS AGREEMENT, INCLUDING ANY THIRD PARTY CLAIMS, PRODUCT RECALL, AND SUPPLIER'S INDEMNITY OBLIGATION SET FORTH IN ARTICLE 9.2, SHALL BE LIMITED AS FOLLOWS, PROVIDED, HOWEVER, THAT THE AMOUNTS BELOW WILL BE DOUBLED FOR ANY CLAIMS ALLEGING THE SUPPLIER FOREGROUND IP OR SUPPLIER BACKGROUND IP INFRINGE ON THE INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY:

10.2.1 PER INCIDENT TO [***]; AND

10.2.2 PER CALENDAR YEAR TO [***]; AND

10.2.3 IN THE AGGREGATE TO [***].

10.2.4 ANY AND ALL CLAIMS OF EITHER PARTY UNDER OR IN CONNECTION WITH THIS AGREEMENT, INCLUDING ANY CLAIMS RELATING TO PRODUCT RECALL, BUT EXCLUDING IP INDEMNIFICATION CLAIMS PURSUANT TO ARTICLE 9.1 OR ARTICLE 9.2, AS APPLICABLE, SHALL EXPIRE [***]. INDEMNIFICATION CLAIMS RELATING TO IP PURSUANT TO ARTICLE 9.1 OR ARTICLE 9.2 SHALL EXPIRE [***].

10.3 The limitations of liability set forth herein shall not apply:

(i) death or personal injury of Purchaser caused by Supplier's negligence;
(ii) to any matter for which it would be illegal for Supplier to exclude or attempt to exclude its liability; or
(iii) for fraud or fraudulent misrepresentation.

ARTICLE 11INSURANCE.

11.1 Minimum Coverages.

11.1.1 Each Party will procure and maintain, at its own expense, (A) commercial general liability insurance including premises operations, personal injury and advertising injury including fire legal liability for bodily injury and property damage, with a per-occurrence limit of not less than [***] and an aggregate limit of not less than [***]; and (B) products and completed operations liability insurance with a per-occurrence limit of not less than [***].

11.1.2 The above coverages may be satisfied through umbrella or excess liability coverage. Each of the policies required above shall be maintained for the duration of the Agreement, and for [***] if written on a claims made or occurrence reported form, and shall be obtained from an insurance carrier rated A-VII or better with A. M. Best.

11.2 Evidence of Insurance. Upon request, each Party shall furnish to the other certificates of insurance or other suitable written documentation evidencing the insurance coverages as required in this Article 11.

ARTICLE 12TERMINATION.

12.1 Termination for Cause. If a Party breaches a material obligation under this Agreement, the other Party may notify such breaching Party in writing of such breach and require that the breaching Party cure such breach within [***] of such notice for any payment breach, or within [***] of the non-breaching Party's notice of any other breach. In the event the breaching Party shall not have cured the breach by the end of the applicable cure period, the non-breaching Party may terminate this Agreement for cause immediately upon written notice to the breaching Party; provided that, if the basis for such termination is disputed by either Party, such termination shall not be effective if and until final resolution pursuant to Article 14 that this Agreement is terminated as a result of such material breach.

1.1 Remedies for Termination for Cause.

1.1.1 If Supplier terminates this Agreement for cause pursuant to Article 12.1, then:

1.1.1.1 Purchaser shall purchase from Supplier any and all inventories of the Product manufactured at the purchase price then in effect as well as pay Supplier for any Product volumes bindingly forecasted or ordered;

1.1.2 If Purchaser terminates this Agreement for cause pursuant to Article 12.1, then:

1.1.1.2 Purchaser shall be obligated to (i) pay for all volumes of Product delivered to Purchaser until the date of the notice of material breach giving rise to termination, and (ii) accept delivery and pay for such volumes of Product which Seller manufactured until the date of the notice of termination, provided, however, that Purchaser shall have no obligation to make the payments described in (i) and (ii) of this Article if Purchaser has terminated this Agreement due to Supplier’s failure to manufacture Product in accordance with Specification, cGMP or applicable law;

1.2 Termination for Convenience. [***].

1.3 Survival. Termination or expiration of this Agreement shall not (i) affect any other rights of either Party which may have accrued up to the date of such termination or expiration or (ii) subject to Article 12.2.2.1, relieve Purchaser of its obligation to pay to Supplier any undisputed sums due in respect of Product delivered prior to termination or expiration, including but not limited to any Raw Materials purchased and/or work in progress pursuant to a purchase order accepted by Supplier pursuant to this Agreement, so long as such Raw Materials cannot promptly be used by Supplier for its other clients. The Articles of this Agreement that by their nature would survive the expiration or termination of this Agreement shall survive the expiration or termination of this Agreement (for the time periods set forth therein), in particular Article 1, Article 6, Article 7, Article 9, Article 10, Article 11, Article 12.2, Article 12.4, Article 14, and Article 15.

ARTICLE 13FORCE MAJEURE.

13.1 Event of Force Majeure. Neither Party shall be liable to the other for its failure to perform any of its obligations under this Agreement, except for payment obligations, during any period in which such performance is delayed or rendered impracticable or impossible due to circumstances beyond its reasonable control, including without limitation earthquakes, governmental acts or regulation, fire, flood, pandemics, explosion, labor difficulties (other than those with its own employees), civil disorder, and acts of God, provided that the Party experiencing the delay promptly notifies the other Party of the delay ("**Force Majeure**").

13.2 Effect of Force Majeure. If such Force Majeure occurs, the affected Party shall notify the other Party in writing as soon as practicable of the occurrence of said Force Majeure event, the nature of and expected duration of the Force Majeure event, and the effect the Force Majeure event will have on such Party's performance of this Agreement. The affected Party will be excused from performing its obligations hereunder only during the Force Majeure event and the affected Party shall not be liable to the other Party for damages by reason of any delay or suspension of performance resulting from the Force Majeure event. The Party that invokes this Article 13.2 shall use commercially reasonable efforts to resume performance of its ongoing obligations to the other Party as soon as practicable. If the event of Force Majeure shall continue unabated for [***], then both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s); and if the Parties are not able to agree upon such modifications within [***], the Party that has not invoked this Article 13.2 may terminate this Agreement upon written notice delivered by such Party to the other Party, provided that Purchaser shall (i) purchase from Supplier any and all inventories of the Product manufactured at the Product Price then in effect, and (ii) reimburse Supplier for any actual, out-of-pocket costs and expenses incurred up to the effective date of termination, including non-cancellable Third Party costs.

ARTICLE 14GOVERNING LAW AND VENUE.

14.1 Governing Law. This Agreement and the legal relations between the Parties in connection herewith shall be governed by, and construed in accordance with, the laws of the [***], excluding the provisions of the United Nations Convention on Contracts for the International Sale of Goods and any conflict of law provisions that would require application of another choice of law.

14.2 Jurisdiction. Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof, that cannot be solved by both Parties in an amicable manner shall be finally settled by arbitration in accordance with the ICC Rules of Arbitration in force on the date when the notice of arbitration is submitted. The number of arbitrators will be three (3). The seat of arbitration will be London, England. The arbitral proceedings will be conducted in English.

ARTICLE 15MISCELLANEOUS.

15.1 Notice. All notices, consents, claims, demands or other communications given under this Agreement shall only be sufficient if in writing and sent (1) by electronic mail, conditioned upon written acknowledgment of receipt or (2) by an internationally recognized overnight courier service which provides a delivery receipt, to the Parties at the address set forth below or at such other address designated by either Party in writing. Such communications must be sent to the respective Parties at the below addresses.

For Supplier:
Evonik Operations GmbH
[***]

For Purchaser:
Phathom Pharmaceuticals, Inc.
2150 E. Lake Cook Road, Suite 800
Buffalo Grove, Illinois 60089
Attn: Vice President, Manufacturing and Supply Chain

With a copy to:
Phathom Pharmaceuticals, Inc.
100 Campus Drive, Suite 102
Florham Park, NJ 07932
Attn: General Counsel (Legal Department)
Email: [***]

15.2 Independent Parties. The Parties are not employees or legal representatives of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party.

15.3 Publicity; Use of Name. Except as required by law, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public, press, stockholders or otherwise, relating to this Agreement, to any amendment hereto or thereto or activities hereunder or thereunder without the prior written consent of the other Party. Nothing contained in this Agreement shall be construed as conferring any right to use in advertising, publicity or other promotional activities any name, trade name, trademark, or other designation (including any contraction, abbreviation, or simulation of any of the foregoing); and each Party hereto agrees not to use any designation of the other Party in any promotional activity associated with this Agreement without the express written approval of the other Party.

15.4 Severability. In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect. The Parties undertake in good faith to replace an illegal, invalid or unenforceable provision by a valid one which most closely corresponds with the economic intention of the invalid ruling.

15.5 Waiver. Any waiver (express or implied) by either Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach.

15.6 Entire Agreement. This Agreement and the exhibits attached hereto constitute the entire, final, complete and exclusive agreement between the Parties and supersede all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement. No pre-printed terms and conditions on any purchase order, order confirmation or acknowledgment, or any other writing shall have binding effect upon the Parties.

15.7 Amendment. Any amendment to this Agreement must comply with the formal requirements set forth in Article 15.10 and must specifically refer to the provision of the Agreement being amended or waived in order to be effective.

15.8 Assignment. Neither Party shall assign or transfer this Agreement or any rights or obligations hereunder, by operation of law or otherwise, without the prior written consent of the other Party, except that either Party may, without the other Party's consent (but subject to written notice), assign this Agreement in its entirety to an Affiliate (provided that the assigning Party will remain responsible and liable for such assignee's performance under this Agreement), and each Party may, without the other Party's consent (but subject to written notice), assign this Agreement in its entirety to a successor to substantially all of the business or assets of the assigning Party or its business unit responsible for performance under this Agreement. In the event of a valid assignment, this Agreement shall be binding on the successors and permitted assigns of the assigning Party, and the name of a Party appearing herein shall be deemed to include the name(s) of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Article 15.8 shall be null and void and of no legal effect.

15.9 English Language. The English language version of this Agreement shall be controlling on both Parties, and all matters relating to interpretation or enforcement of this Agreement shall be in English. All information, documents, reports, notices and communications to be provided by one Party to the other Party hereunder shall be provided in the English language.

15.10 Counterparts; Evidence of Signature. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall constitute together the same instrument. Any such counterparts executed and/or transmitted electronically, including scanned signed documents or digital signatures, shall bind the Parties to the same extent as documents with original signatures.

The Parties hereto have each caused this Agreement to be signed and delivered by its duly authorized officer or representative as of the Effective Date.

[*Signature page to follow*]

Phathom Pharmaceuticals, Inc.

By: /s/ Azmi Nabulsi
Name: Azmi Nabulsi
Title: COO

Evonik Operations GmbH

By: /s/ [***]
Name: [***]
Title: SVP Health Care

By: /s/ [***]
Name: [***]
Title: Senior Legal Counsel

EXHIBIT A DEFINITIONS

"**Affiliate**" shall mean with respect to a Party, any person, corporation, company, partnership or other entity that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" shall mean direct or indirect ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity.

"**Applicable Law**" shall mean the applicable provisions of any national, regional, state and local laws, treaties, statutes, rules, regulations, guidance, or ordinances of or from any Governmental or Regulatory Authority of the European Union, United States, or other territory, in each instance only to the extent applicable to the performance of the Parties' obligations hereunder including, without limitation, the manufacture or use of the Product.

"**Background IP**" means any and all (1) proprietary information and know-how and expertise whether patented or patentable including, without limitation, specifications, processes, formulations, procedures, instructions, technology and any other technical information which may be contained in drawings, photographs, samples, models and other documentation or communicated orally; (2) patent applications, patents and other intellectual property rights; (3) material, including without limitation, samples of products and models; and (4) software and other creation being subject to copyrights; which a Party owns or controls prior to the Effective Date, or thereafter acquires or independently develops outside the scope of this Agreement. In the case of Supplier, Supplier Background IP also includes Supplier Facility and Supplier Facility Information. In the case of Purchaser, Purchaser Background IP also includes Purchaser Technology Data Package.

"**Batch Record**" shall have the meaning set forth in the Quality Agreement.

"**Claim**" shall have the meaning set forth in Article 9.1.

"**Confidential Information**" shall have the meaning set forth in Article 7.1.

"**Disclosing Party**" shall have the meaning set forth in Article 7.1.

"**Current Good Manufacturing Practice**" or "**cGMP**" means all then-current applicable laws, regulations and recognized good manufacturing practices that apply to the manufacture of any therapeutically active material that provides pharmacological activity in a pharmaceutical product, and govern the standards of manufacture of any product intended for human use, including, as applicable: (i) 21 C.F.R. Parts 210 and 211, as amended, in the United States, (ii) the EU good manufacturing practices set forth in Eudralex Volume 4: The Rules Governing Medicinal Products in the European Union Volume 4: Good Manufacturing Practices, Medicinal Products for Human and Veterinary Use – Part II – Basic Requirements for Active Substances used as Starting Materials, (iii) the Guideline ICH Tripartite Guidance Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients and (iv) applicable guidance published by the FDA or the EMA; and; in each case as may be modified or supplemented during the Term.

"**Effective Date**" shall have the meaning set forth in the preamble of this Agreement.

"**FDA**" means the United States Food and Drug Administration, or any successor thereto, having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, drug delivery systems, and devices in the United States of America.

"**Final Product**" shall have the meaning set forth in the recitals of this Agreement.

"**Force Majeure**" shall have the meaning set forth in Article 13.1.

"**Government or Regulatory Authority**" means any supranational, national, regional, state or local government, court, governmental agency, authority, board, bureau, instrumentality or regulatory body which are relevant to the development and manufacture of the Product.

"**Invention**" shall mean any creation, discovery and invention (whether or not patentable) conceived, created, developed or reduced to practice by Supplier in connection with its performance of the contractual obligations hereunder.

"**Master Batch Record**" shall have the meaning set forth in the Quality Agreement.

"Maximum Supply Obligation" shall have the meaning set forth in Article 3.2.5.

"**Product**" shall have the meaning set forth in the recitals, and as further described in **Exhibit B**.

"**Product Price**" shall have the meaning set forth in Article 4.1.

"**Production**" or "**Produce**" means the synthesis, manufacturing, purification, packaging, testing and release of the Product by Supplier to Purchaser.

"**Project Manager**" shall have the meaning set forth in Article 3.3.

"**Purchaser Foreground IP**" shall have the meaning as set forth in Article 6.3.

"**Purchaser Technology Data Package**" shall have the meaning set forth in Article 6.2.

"**Purchaser Technology Data Package Improvements**" shall have the meaning set forth in Article 6.3.

"**Quality Agreement**" means the quality agreement between Purchaser and Supplier relating to the manufacture of Product (whether executed by the Parties prior to, concurrently with, or after entry into this Agreement), as the same may be amended or modified from time to time by agreement of the Parties. The Quality Agreement describes the relationship of the Parties hereunder and the responsibilities of each Party regarding quality systems practices and activities concerning the manufacture of the Product.

"**Raw Material**" shall mean the chemicals, compounds, water, solvents, reagents and other materials and supplies, including disposable manufacturing materials and labeling and packaging materials, used in manufacturing the Product.

"**Receiving Party**" shall have the meaning set forth in Article 7.1.

"**Shortfall Payment**" shall have the meaning set forth in Article 3.8.

"**Specification**" shall have the meaning as set forth in Article 3.1.

"**Supplier Facility**" shall mean the specific premises of Supplier located at [***] for Phase 1, Phase 2 and Phase 4 and additionally the specific premises of Supplier's Affiliate and subcontractor [***] for Phase 3 and Phase 4.

"**Supplier Facility Information**" means Supplier's Confidential Information relating to (a) layout and design of Supplier Facility(ies); (b) equipment and other assets including information revealing the make,

model or other identifying features of any laboratory or process equipment utilized by Supplier in the performance of this Agreement; (c) any and all nomenclature, identifiers and facility capabilities of Supplier and (d) location and address of Supplier Facilities.

"**Supply Failure**" means that after the second campaign following successful completion of the validation campaign of the relevant Supplier Facility Supplier has, in any given [***] period, failed to deliver at least [***] of Product ordered by Purchaser pursuant to the relevant Purchase Order(s) within [***] following the delivery date set forth in the applicable Acknowledgement and after expiry of a [***] grace period to be granted by Purchaser to Supplier to remedy such failure; for reasons solely attributable to Supplier, its Affiliates or subcontractors, and in particular other than Force Majeure.

"**Supplier Foreground IP**" shall have the meaning as set forth in Article 6.4.

"**Term**" shall have the meaning as set forth in Article 2.2.

"**Third Party**" shall mean any other person, company or other business entity other than Purchaser or Supplier, or an Affiliate of either of them.

EXHIBIT B - PRODUCT SPECIFICATION

[***]

EXHIBIT C – INDICATIVE NON-BINDING PRODUCT VOLUMES

[***]

EXHIBIT D – PRICE AND PRICE ADJUSTMENTS

[***]

EXHIBIT E - PURCHASER TECHNOLOGY DATA PACKAGE

[***]

EXHIBIT F – PRODUCT VOLUMES

[***]

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment"), dated as of September 26, 2022, is entered into by and among PHATHOM PHARMACEUTICALS, INC., a Delaware corporation, each of its Subsidiaries from time to time party to the Loan Agreement (as defined below) as borrower (individually or collectively, as the context may require, "Borrower"), the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively, referred to as the "Lenders"), and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (together with its successors and assigns, in such capacity, the "Agent").

A. Borrower, Lenders and Agent are parties to that certain Loan and Security Agreement, dated as of September 17, 2021 (as amended, restated, supplemented or otherwise modified from time to time prior to the date of this Amendment, the "Loan Agreement").

B. Borrower, Lenders and Agent desire to modify the terms of the Loan Agreement as set forth in this Amendment, subject to the terms and conditions hereof.

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement (as amended by this Amendment).

(b) **Rules of Construction**. The rules of construction in Section 1.2 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan Agreement.

(a) Upon satisfaction of the conditions set forth in Section 3 hereof, the Loan Agreement is hereby amended as follows:

(i) New Definitions. The following definition is added to Section 1.1 of the Loan Agreement in its proper alphabetical order:

> "PDUFA Action Date" means the Prescription Drug User Fee Act ("PDUFA") target action date for Borrower's new drug application for the use of vonoprazan as a treatment for adults for the healing of all grades of erosive esophagitis ("EE") and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn.

(ii) Amended and Restated Definition. The following definition in Section 1.1 of the Loan Agreement is hereby amended in its entirety and replaced with the following:

> "Initial Performance Covenant Test Date" means the date on which the outstanding principal amount of the Term Loan Advances is first greater than $100,000,000; provided that the Initial Performance Covenant Test Date shall begin only on or after November 15, 2023 (i.e. the date Borrower's 2023 third fiscal quarter reporting is due under Section 7.1(b) hereof).

(iii) Tranche II Term Loan Commitment. Clause (ii) of Section 2.1(a) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

(ii) *Tranche II*. Subject to the terms and conditions of this Agreement and satisfaction of the Clinical Milestone, on or prior to (A) February 15, 2023, or (B) in the event that the PDUFA Action Date is extended beyond January 11, 2023, May 15, 2023, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of $5,000,000 (or if less than $5,000,000 the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(ii)) in an aggregate principal amount up to $50,000,000.

(b) **References Within Loan Agreement**. Each reference in the Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder", or words of like import, shall mean and be a reference to the Loan Agreement as amended by this Amendment. This Amendment shall be a Loan Document.

SECTION 3 Conditions of Effectiveness. The effectiveness of this Amendment (the "Second Amendment Effective Date") shall be subject to Agent's receipt of the following documents, in form and substance satisfactory to Agent, or, as applicable, the following conditions being met:

(a) this Amendment, executed by Agent, each Lender and Borrower;

(b) Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 6(d), and (ii) all other fees, costs and expenses, if any, due and payable as of the date hereof under the Loan Agreement; and

(c) on the Second Amendment Effective Date, immediately after giving effect to the amendment of the Loan Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Second Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce Agent and Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; *provided, further,* that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date, and (a) that no Event of Default has occurred and is continuing; (b) that there has not been and there does not exist a Material Adverse Effect; (c) Lenders have and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lenders, pursuant to the Loan Documents or otherwise granted to or held by Lenders; (d) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (e) the execution, delivery and performance of this Amendment by Borrower will not violate any law, rule, regulation, order, contractual obligation or organizational document of Borrower and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this 4,

each reference in Section 5 of the Loan Agreement to "this Agreement," and the words "hereof", "herein", "hereunder", or words of like import in such Section, shall mean and be a reference to the Loan Agreement as amended by this Amendment.

SECTION 5 Release. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby to the extent possible under applicable law fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

SECTION 6 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Secured Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3 of the Loan Agreement, (3) reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Loan Agreement, including without limitation any Term Loan Advances funded on or after the Second Amendment Effective Date, as of the date hereof, and with effect from (and including) the Second Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Loan Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement, and (5) agrees that the Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Secured Obligations under or in connection with the Loan Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to the Lenders unless Agent shall have received notice from such Lender prior to the date hereof specifying its objection thereto.

(c) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. Borrower agrees to pay to Agent on the date hereof the out-of-pocket costs and expenses of Agent and each Lender party hereto, and the fees and disbursements of counsel to Agent and each Lender party hereto (including allocated costs of internal counsel) in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the date hereof.

(e) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(f) **Governing Law.** THIS AMENDMENT AND THE OTHER LOAN DOCUMENTS SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF CALIFORNIA, EXCLUDING CONFLICT OF LAWS PRINCIPLES THAT WOULD CAUSE THE APPLICATION OF LAWS OF ANY OTHER JURISDICTION.

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(h) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(j) **Electronic Execution of Certain Other Documents**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments,

assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:
PHATHOM PHARMACEUTICALS, INC.
Signature:
Print Name: Title: Molly Henderson Chief Financial and Business Officer

AGENT:

HERCULES CAPITAL, INC.

Signature: ____

Print Name: Seth Meyer
Title: Chief Financial Officer

[LENDERS:]

HERCULES CAPITAL, INC.

Signature: ____

Print Name: Seth Meyer
Title: Chief Financial Officer

HERCULES CAPITAL IV, L.P.
By: Hercules Technology SBIC Management, LLC, its General Partner
By: Hercules Capital, Inc., its Manager

Signature: ____

Print Name: Seth Meyer
Title: Chief Financial Officer

HERCULES PRIVATE CREDIT FUND 1 L.P.
By: Hercules Adviser LLC, its Investment Adviser

By: ____ Name: Seth Meyer
Title: Authorized Signatory

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Private Global Venture Growth Fund GP I LLC, its general partner

By: Hercules Adviser LLC, its sole member

Signature: ____

Print Name: Seth Meyer

Title: Chief Financial Officer

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, 2022

/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, Molly Henderson, 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, 2022

/s/ Molly Henderson
Molly Henderson
Chief Financial and Business Officer
(Principal Financial and Accounting 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, 2022 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, 2022

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

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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Molly Henderson, as Chief Financial and Business 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, 2022

/s/ Molly Henderson
Molly Henderson
Chief Financial and Business Officer
(Principal Financial and Accounting 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.