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, 2024

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	The 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 4, 2024, the registrant had

68,377,379
shares of common stock ($0.0001 par value) outstanding.

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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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 334,678	$ 381,393
Prepaid expenses and other current assets	14,980	13,194
Accounts receivable, net	21,052	1,637
Inventory	3,111	1,208
Total current assets	373,821	397,432
Property and equipment, net	1,655	2,146
Operating lease right-of-use assets	833	1,475
Restricted cash	2,862	2,863
Inventory, non-current	6,181	8,234
Other long-term assets	1,692	1,692
Total assets	$ 387,044	$ 413,842
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 7,133	$ 12,601
Accrued expenses	35,759	17,197
Accrued interest	1,522	1,146
Operating lease liabilities, current	680	726
Current portion of revenue interest financing liability	20,194	7,111

Total current liabilities	65,288	38,781
Long-term debt, net of discount	175,729	137,842
Revenue interest financing liability	322,389	299,816
Operating lease liabilities	—	462
Other long-term liabilities	10,750	9,700
Total liabilities	574,156	486,601
Commitments and contingencies (Note 3)		
Stockholders' deficit:		
Preferred stock, $ 0.0001 par value; authorized shares — 40,000,000 at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $ 0.0001 par value; authorized shares — 400,000,000 at September 30, 2024 and December 31, 2023; issued and outstanding shares — 68,323,938 and 57,970,044 at September 30, 2024 and December 31, 2023, respectively	6	5
Treasury stock — 19 shares at September 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	1,001,442	855,921
Accumulated deficit	(1,188,560)	(928,685)

Total stockholders' deficit	(187,112)	(72,759)
Total liabilities and stockholders' deficit	$ 387,044	$ 413,842

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,	
	2024	2023	2024	2023
Product revenue, net	$ 16,352	$ —	$ 25,588	$ —
Cost of revenue	2,356	—	4,158	—
Gross profit	13,996	—	21,430	—
Operating expenses:				
Research and development	8,693	12,263	25,499	36,505
Selling, general and administrative	76,099	23,396	213,981	60,932
Total operating expenses	84,792	35,659	239,480	97,437
Loss from operations	(70,796)	(35,659)	(218,050)	(97,437)
Other (expense) income:				
Interest income	3,711	2,720	11,648	4,528
Interest expense	(18,484)	(10,107)	(53,416)	(28,939)
Other expense, net	(8)	(197)	(57)	(174)
Total other expense	(14,781)	(7,584)	(41,825)	(24,585)
Net loss and comprehensive loss	$ (85,577)	$ (43,243)	$ (259,875)	$ (122,022)
Net loss per share, basic and diluted	$ (1.32)	$ (0.76)	$ (4.29)	$ (2.48)
Weighted-average shares of common stock outstanding, basic and diluted	64,627,847	56,782,379	60,543,545	49,265,321

See accompanying notes.

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

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Capital	Deficit	Deficit
Balance at December 31, 2023	57,970,044	$ 5	19	$ 855,921	$ (928,685)	$ (72,759)
401(k) matching contribution	93,736	—	—	712	—	712
Vesting of restricted stock units	340,542	—	—	—	—	—
Stock-based compensation	—	—	—	5,626	—	5,626
ESPP shares issued	119,779	—	—	770	—	770
Net loss	—	—	—	—	(82,852)	(82,852)
Balance at March 31, 2024	58,524,101	$ 5	19	$ 863,029	$ (1,011,537)	$ (148,503)
Vesting of restricted stock units	74,492	—	—	—	—	—
Stock-based compensation	—	—	—	6,099	—	6,099
Issuance of common stock from exercises of stock options	2,432	—	—	21	—	21
Net loss	—	—	—	—	(91,446)	(91,446)
Balance at June 30, 2024	58,601,025	$ 5	19	$ 869,149	$ (1,102,983)	$ (233,829)
401(k) matching contribution	289,853	—	—	2,971	—	2,971
Vesting of restricted stock units	454,003	—	—	—	—	—
Stock-based compensation	—	—	—	5,635	—	5,635
ESPP shares issued	255,602	—	—	1,631	—	1,631
Issuance of common stock and pre-funded warrants in connection with the underwritten public offering, net	8,695,652	1	—	121,774	—	121,775

Issuance of common stock from exercises of stock options	27,803	—	—	282	—	282
Net loss	—	—	—	—	(85,577)	(85,577)
Balance at September 30, 2024	68,323,938	$ 6	19	$ 1,001,442	$ (1,188,560)	$ (187,112)

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

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Capital	Deficit	Equity (Deficit)
Balance at December 31, 2022	41,468,871	$ 3	19	$ 652,276	$ (727,093)	$ (74,814)
401(k) matching contribution	52,130	—	—	456	—	456
Vesting of restricted shares and restricted stock units	414,119	—	—	—	—	—
Stock-based compensation	—	—	—	7,048	—	7,048
ESPP shares issued	121,801	—	—	856	—	856
Issuance of common stock under ATM facility	1,514,219	1	—	14,072	—	14,073
Net loss	—	—	—	—	(37,814)	(37,814)
Balance at March 31, 2023	43,571,140	$ 4	19	$ 674,708	$ (764,907)	$ (90,195)
Vesting of restricted shares and restricted stock units	259,195	—	—	6	—	6
Stock-based compensation	—	—	—	7,253	—	7,253
Issuance of common stock in connection with underwritten public offering, net	12,793,750	1	—	141,389	—	141,390
Issuance of common stock from exercises of stock options	15,000	—	—	111	—	111
Net loss	—	—	—	—	(40,965)	(40,965)
Balance at June 30, 2023	56,639,085	$ 5	19	$ 823,467	$ (805,872)	$ 17,600
401(k) matching contribution	83,826	—	—	1,156	—	1,156
Vesting of restricted shares and restricted stock units	9,681	—	—	—	—	—

Stock-based compensation	—	—	—	6,140	—	6,140
ESPP shares issued	75,072	—	—	561	—	561
Issuance of common stock from exercises of stock options	1,421	—	—	13	—	13
Net loss	—	—	—	—	(43,243)	(43,243)
Balance at September 30, 2023	56,809,085	$ 5	19	$ 831,337	$ (849,115)	$ (17,773)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (259,875)	$ (122,022)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	602	390
Stock-based compensation	17,360	20,441
Issuance of PIK interest debt	2,724	2,684
Accrued interest on revenue interest financing liability	35,656	16,265
Amortization of debt discount	1,563	1,311
Inventory reserve	716	—
Other	4,202	1,468
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,784)	(7,813)
Accounts receivable, net	(19,415)	—
Accounts payable and accrued expenses	14,993	(3,857)
Accrued clinical trial expenses	—	661
Accrued interest	376	103
Operating right-of-use assets and lease liabilities	134	147
Inventory	(566)	(111)
Other long-term assets	—	(3,450)
Net cash used in operating activities	(203,314)	(93,783)

Cash flows from investing activities		
Cash paid for property and equipment	(130)	(1,159)
Net cash used in investing activities	(130)	(1,159)
Cash flows from financing activities		
Proceeds from issuance of common stock from exercise of stock options	303	124
Net proceeds from issuance of debt	34,650	—
Net proceeds from underwritten public offering	121,775	141,390
Net proceeds from issuance of common stock under ATM facility	—	14,073
Net cash provided by financing activities	156,728	155,587
Net (decrease) increase in cash and cash equivalents and restricted cash	(46,716)	60,645
Cash and cash equivalents and restricted cash – beginning of period	384,256	155,890
Cash and cash equivalents and restricted cash – end of period	$ 337,540	$ 216,535
Supplemental disclosure of cash flow information		
Interest paid	$ 12,478	$ 8,222
Supplemental disclosure of noncash investing and financing activities:		
Final interest payment fee	$ 1,050	$ —
Settlement of ESPP liability in common stock	$ 2,401	$ 1,417
Settlement of 401(k) liability in common stock	$ 3,683	$ 1,612

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
Notes to Unaudited Financial Statements

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.

On October 27, 2023, the U.S. Food and Drug Administration, or FDA, approved the prior approval supplements to the Company's new drug applications, or NDAs, for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. Additionally, on November 1, 2023, the FDA approved the Company's NDA for VOQUEZNA tablets. The Company initiated commercial launch for VOQUEZNA for both the Erosive GERD and *H. pylori* indications, and VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK for treatment of *H. pylori* infection in the fourth quarter of 2023. Additionally, on July 17, 2024, the FDA approved the NDA supplement, or sNDA, for VOQUEZNA 10 mg tablets for the relief of heartburn associated with Non-Erosive GERD.

Liquidity and Capital Resources

From inception to September 30, 2024, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial and approved product candidate, vonoprazan, meeting with regulatory authorities, managing the clinical trials of vonoprazan, preparing for commercialization of its initial products containing vonoprazan, commercially launching its approved products, and providing other selling, general and administrative support for these operations. The Company has a limited operating history, has generated limited revenue to date, 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. The Company has funded its operations primarily through commercial bank debt, the revenue interest financing debt and various equity offerings, including the Company's at-the-market, or ATM, offerings. In August 2024, the Company closed an underwritten public offering of

8,695,652
shares of its common stock and

2,608,922
pre-funded warrants for net proceeds of approximately $

121.8
million (see Note 7 for additional information). From inception through September 30, 2024, the Company sold

34,737,032
shares of common stock and

2,608,922
pre-funded warrants, generating net proceeds of approximately $

543.3
million, after deducting underwriting discounts, commissions and offering costs.

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 management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues 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 net product revenues, research and development expenses, and the valuation for the revenue interest financing liability. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. 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 accounts receivable, 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.

No

ne of the Company's non-financial assets or liabilities are recorded at fair value on a

no
n-recurring basis. No transfers between levels have occurred during the periods presented.

As of September 30, 2024 and December 31, 2023, 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. Restricted cash primarily consists of cash deposited by the Company to secure corporate leased vehicles.

Accounts Receivable, Net

Accounts receivable consists of amounts due from customers, primarily wholesale distributors, net of customer allowances for prompt pay discounts, distribution service fees, and other adjustments. Our contracts with customers have standard payment terms. The Company assesses the need for an allowance for credit losses primarily based on creditworthiness, historical payment experience and general economic conditions. The Company has not experienced any credit losses to date given our limited commercial operations with any of its customers, and has not currently recognized a material allowance for credit losses.

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.

The Company is also subject to credit risk from our accounts receivable related to our product sales. The Company monitors exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit primarily to wholesale distributors. Customer creditworthiness is monitored and collateral is not required. The allowance for credit losses reflects the best estimate of expected credit losses of the accounts receivable portfolio determined on the basis of historical experience, current information, and forecasts of future economic conditions. The Company determines its allowance methodology by pooling receivable balances at the customer level. The Company considers various factors, including its previous loss history, individual credit risk associated to each customer, and the current and future conditions of the general economy. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent that any individual

debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of such customer. The Company makes concerted efforts to collect all outstanding balances due from customers; however, account balances are charged off against the allowance when management believes it is probable the receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to customers.

As of September 30, 2024,

three
customers accounted for

90
% of the accounts receivable balance, with each of these individual customers ranging from

28
% to

31
% of the accounts receivable balance. As of December 31, 2023,

three
customers accounted for

87
% of the accounts receivable balance, with each of these individual customers ranging from

28
% to

30
% of the accounts receivable balance. For the three and nine months ended September 30, 2024,

three

customers accounted for

70
% and

68
% of the product sales in both periods, with each of these individual customers ranging from

23
% to

24
% and

22
% to

24
% of the product sales, respectively.

Inventory

The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. Inventory consists of bulk active pharmaceutical ingredients that are used to manufacture vonoprazan tablets. Inventory related to indications prior to regulatory approval has been included in research and development expense in the period of purchase.

The Company states its inventory at the lower of cost or net realizable value. The Company measures inventory cost using actual cost under a first-in, first-out basis. The Company assesses recoverability of inventory each reporting period to determine any write-down to net realizable value resulting from excess or obsolete inventories. During the three and nine months ended September 30, 2024, the Company recorded approximately $

0.3
million and $

0.7
million, respectively, of charges for inventory not expected to be sold prior to its expiration date.

No

inventory adjustments or charges were recorded in the comparable prior periods.

Property and Equipment, Net

Property 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 . Equipment is depreciated over five 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 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 for the nine months ended September 30, 2024 and 2023.

Other Long-Term Assets

Other long-term assets consist of deposits relating to our co-pay and patient support programs and security deposits on our leased properties.

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.

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, in May 2022. Subsequently, in October 2022, the Company entered into a Joinder Agreement with the Initial Investors and CO Finance LVS XXXVII LLC, or the Additional Investor, together as the Investors. The net proceeds received under the transactions are recognized as short-term and long-term liabilities with interest expense based on an imputed effective rate derived from the expected future payments to the Investors. The Company recalculates the effective interest rate each period based on the current carrying value and the revised estimated future payments to the Investors. Changes in future payments to the Investors from previous estimates are included in current and future interest expense.

Revenue Recognition

Pursuant to Accounting Standards Codification 606, Revenue from Contracts with Customers, or ASC 606, the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon delivery.

Product Revenue, Net

The Company sells its product to its customers, primarily wholesale distributors, in the United States. The Company's customers subsequently resell the products to pharmacies and health care providers. In accordance with ASC 606, the Company recognizes net product revenues from sales when the customers obtain control of the Company's products, which typically occurs upon delivery to the customer.

Revenues from product sales are recorded at the net sales price, or transaction price, which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payor rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to accounts receivable, net if payable

to a customer or accrued expenses if payable to a third-party or related to product returns. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Distribution Service Fees: The Company engages with wholesalers to distribute its products to end customers. The Company pays the wholesalers a fee for services such as: Data Reporting, Inventory Management, Chargeback Administration and Service Level Commitment. The Company estimates the amount of distribution services fees to be paid to the customers based on a contractually fixed percentage of wholesaler acquisition costs and are calculated at the time of sale based on the purchase amount and the transaction price is adjusted with the amount of such estimate at the time of sale to the customer. Estimated distribution service fees are recorded within accounts receivable, net on the balance sheet.

Prompt Pay Discounts: The Company provides its customers with a percentage discount on their invoice if the customers pay within the agreed upon timeframe. The Company estimates the probability of customers paying promptly and the percentage of discount outlined in the agreement, and deducts the full amount of these discounts. Estimated prompt pay discounts are recorded within accounts receivable, net on the balance sheet.

Product Returns: The Company provides customers a return credit in the amount of the purchase price paid by customers for all products returned in accordance with the Company's returned goods policy. In the initial sales period, the Company estimates its provision for sales returns based on industry data and adjusts the transaction price with such estimate at the time of sale to the customer. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its estimate assumptions. Once the product is returned, it is destroyed. The Company does not record a right-of-return asset. Estimated product returns are recorded as accrued expenses on the balance sheet.

Chargebacks: A chargeback is the difference between the manufacturer's invoice price to the wholesaler and the contract price the wholesaler's customer has negotiated directly with the manufacturer. The wholesaler tracks these sales and "charges back" the manufacturer for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. The Company estimates the percentage of goods sold that are eligible for chargeback and adjusts the transaction price for such discount at the time of sale to the customer. Estimated chargebacks are recorded within accounts receivable, net on the balance sheet.

Administration Fees: The Company engages with Pharmacy Benefit Managers, or PBMs, to administer prescription-drug plans for people with third-party insurance through a self-insured employer, health insurance plan, labor union or government plan. The Company pays PBMs "administrative fees" for their role in providing utilization data, administering rebates, and administering claims payments. The Company estimates the amount of administration fees to be paid to PBMs and adjusts the transaction price with the amount of such estimate at the time of sale to the customer. Estimated administration fees are recorded within accrued expenses on the balance sheet.

Rebates: Rebates apply to:

- Medicaid, managed care, and supplemental rebates to all applicable states as defined by the statutory government pricing calculation requirements under the Medicaid Drug Rebate Program, and

- Medicare Part D and Commercial Managed Care rebates are paid based on the contracts with PBMs and Managed Care Organizations. Rebates are paid to these entities upon receipt of an invoice from the contracted entity which is based on the utilization of the product by the members of the contracted entity.

The Company estimates the percentage of goods sold that are eligible for rebates and adjusts the transaction price for such discounts at the time of sale to the customers. Estimated rebates are recorded as accrued expenses on the balance sheet.

Coverage Gap: The Medicare Part D coverage gap, also called the donut hole, is a period of consumer payment for prescription medication costs which lies between the initial coverage limit and the catastrophic-coverage threshold, when the patient is a member of a Medicare Part D prescription-drug program administered by the Centers for Medicare & Medicaid Services. The

Company estimates the percentage of goods sold under Coverage Gap and adjusts the transaction price for such discount at the time of sale to the customer. Estimated coverage gap accruals are recorded as accrued expenses on the balance sheet.

The Company makes significant estimates and judgments that materially affect its recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts frequently are submitted to the Company significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. The Company will adjust its estimates based on new information, including information regarding actual rebates, chargebacks, co-pays and discounts for its products, as it becomes available.

Cost of Revenue

Cost of revenue includes the cost of producing and distributing inventories that are related to product sales. This also includes royalties payable to Takeda Pharmaceutical Company Limited, or Takeda, pursuant to the Takeda License Agreement (Refer to Note 3 for further details). In addition, shipping and handling costs for product sales are recorded as incurred. Cost of revenue also includes costs related to excess or obsolete inventory adjustment charges.

In connection with the FDA approvals of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK, the Company began capitalizing inventory manufactured by or purchased from third parties. Prior to receiving FDA approvals, manufacturing costs related to inventory purchased were expensed as research and development expense and therefore are excluded from cost of revenue during the current periods. The exclusion of these previously expensed costs did not have a material impact on cost of revenue in the current periods.

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, or CROs, 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of salaries and employee-related costs, including stock-based compensation, for personnel in commercial, executive, finance, accounting, information technology, legal, medical affairs and human resources functions.

Advertising and Marketing Costs

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs for the three and nine months ended September 30, 2024 were approximately $

17.5
million and $

41.0
million, respectively, and are included in selling, general and administrative expenses. Advertising and marketing costs were not material for the three and nine months ended September 30, 2023.

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 statements 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 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 periods presented.

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.

Pre-funded Warrants

The Company issued pre-funded warrants in connection with an underwritten public offering that were accounted for as a freestanding equity-linked financial instrument that met the criteria for equity classification under ASC 480, Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging. Accordingly, the Company classified the pre-funded warrants as a component of shareholders' equity within additional paid-in capital. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated the net proceeds from the offering proportionately to the common shares and pre-funded warrants. See Note 7 for further discussion related to the offering.

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 and pre-funded warrants for the period, without consideration for other potentially dilutive securities. For the three and nine months ended September 30, 2024, basic shares outstanding includes the weighted average effect of the Company's outstanding pre-funded warrants, the exercise of which requires little or no consideration for the delivery of shares of common stock. For the

three and nine months ended September 30, 2024, the Company had

no

weighted-average unvested shares to exclude from the weighted-average number of common shares outstanding. For the three and nine months ended September 30, 2023, the Company had

no
weighted-average unvested shares and

46,131
weighted-average unvested shares, respectively, to exclude from the weighted-average number of common shares outstanding. 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 restricted stock units) 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, 2023. There were no new material accounting standards issued in the third quarter of 2024 that impacted the Company.

2. Balance Sheet Details

Property and Equipment, Net

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

	September 30, 2024	December 31, 2023
Computer equipment and software	$ 1,537	$ 1,477
Furniture and fixtures	1,120	1,089
Leasehold improvements	160	139
Equipment	1,486	1,487
Total property and equipment, gross	4,303	4,192
Less: accumulated depreciation and amortization	(2,648)	(2,046)
Total property and equipment, net	$ 1,655	$ 2,146

Depreciation and amortization expense for the three months ended September 30, 2024 and 2023 was approximately $

0.2
million and $

0.1
million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2024 and 2023 was approximately $

0.6
million and $

0.4
million, respectively.

No

property or equipment was disposed of during the nine months ended September 30, 2024 or for the year ended December 31, 2023.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued compensation expenses	$ 14,183	$ 13,318
Accrued professional & consulting expenses	1,433	1,771
Accrued research and development expenses	2,871	1,009
Accrued revenue allowances	15,479	982
Accrued other	1,793	117
Total accrued expenses	$ 35,759	$ 17,197

Inventory

Inventory consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Finished goods	$ 1,094	$ 647
Raw materials	2,017	561
Total inventory, current	3,111	1,208
Raw materials, non-current	6,181	8,234
Total inventory	$ 9,292	$ 9,442

Raw materials consist of materials, including active pharmaceutical ingredients, to be consumed in the production of inventory related to FDA-approved products. Inventory that is used for clinical development purposes is expensed to research and development expense when consumed. Inventory, noncurrent includes inventory expected to remain on-hand beyond one year from the balance sheet date presented.

3. Commitments and Contingencies

License Agreement

O n May 7, 2019, the Company entered into 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

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 initial public offering, or 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

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, and was to expire on May 7, 2029 and became exercisable upon the consummation of the IPO. All Takeda Warrants were exercised by March 2022.

During the three and nine months ended September 30, 2024, the Company recorded $

1.6

million and $

2.6
million, respectively, of royalty expense under the Takeda License, of which $

1.6
million is included within accrued expenses as of September 30, 2024.

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 €

2.9
million, or approximately $

3.2
million, in the first 24-month period following the launch of the final product. The Company incurred $

0.3
million of expenses under the agreement during the nine months ended September 30, 2024. As of September 30, 2024, €

1.8
million, or approximately $

2.0
million, remains of the minimum purchase obligation.

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.

4. Lease Commitments

As of September 30, 2024, the Company had operating leases for office space in both Buffalo Grove, Illinois and Florham Park, New Jersey, with weighted average remaining lease terms of 0.6 years and 0.9 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 each of the three months ended September 30, 2024 and 2023 was $0.3 million. Total rent expense for each of the nine months ended September 30, 2024 and 2023 was $0.8 million. Total short-term lease costs relating to leased vehicles was approximately $2.1 million and $7.1 million for the three and nine months ended September 30, 2024, respectively, and was not material for either of the three and nine months ended September 30, 2023.

As of September 30, 2024, the future minimum annual lease payments under the operating leases were as follows (in thousands):

2024	$ 190
2025	513
Total minimum lease payments	703
Less: amount representing interest	(23)
Present value of operating lease liabilities	680
Less: operating lease liabilities, current	(680)
Operating lease liabilities, non-current	$ —
Weighted-average remaining lease term (in years)	0.86
Weighted-average incremental borrowing rate	8.25%

Operating cash flows for each of the nine months ended September 30, 2024 and 2023 included cash payments for operating leases of approximately $0.7

million.

5. Debt

Total debt consists of the following (in thousands):

	September 30, 2024	December 31, 2023
Long-term debt, current portion	$ —	$ —
Long-term debt, non-current portion	185,780	148,057
Unamortized debt discount	(10,051)	(10,215)
Total debt, net of debt discount	$ 175,729	$ 137,842

On September 17, 2021, or the Closing Date, the Company entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules, 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

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

million, all of which was funded on the Closing Date, or the First Advance, (ii) a second tranche consisting of up to an additional $

50

million, (iii) a third and fourth tranches consisting of an additional total $

50

million, which became available in May 2022.

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 was available to the Company and has been moved until May 15, 2023, rather than December 15, 2022.

On May 9, 2023, the Company entered into the Third Amendment to Loan and Security Agreement, or the Third Loan Amendment, with the lenders, pursuant to which, among other things, (i) the second tranche availability was extended from through May 15, 2023, to through December 15, 2023, and became available on October 1, 2023, (ii) the third tranche availability was extended from through September 30, 2023, to through December 15, 2023, and became available on October 1, 2023, (iii) the effective date of the performance covenants was amended to provide an option to extend the covenant trigger date to May 15, 2024, subject to the achievement of the FDA approval of vonoprazan for Erosive GERD or the EE Milestone, prior to February 15, 2024, and (iv) the warrant agreement with Hercules was amended as described below. On November 1, 2023, the EE Milestone was achieved and the covenant trigger date was extended to May 15, 2024. In connection with the Third Loan Amendment, a tranche extension amendment fee of $

150,000
and a covenant extension amendment fee of $

100,000
was paid to the Agent. These fees have been recorded as debt discount and are being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

On December 14, 2023, the Company entered into a Fourth Amendment to Loan and Security Agreement, or the Fourth Loan Amendment, with the lenders, which, among other things, (i) increases the aggregate principal amount of the term loans from $

200
million to $

300
million; (ii) provides for the possibility of accessing the remaining $

200
million commitment through five tranches referred to as the second through sixth tranches, which are available subject to certain milestones and conditions: (a) Second Tranche: $

50
million, $

40
million of which was funded on December 14, 2023, available through March 15, 2024, (b) Third Tranche: $

25
million available through June 15, 2024, (c) Fourth Tranche: $

25
million available through December 15, 2024, (d) Fifth Tranche: $

50
million available, subject to the achievement of a specified revenue milestone, or the Fifth Tranche milestone, through June 30, 2025, and (e) Sixth Tranche: $

50
million available, subject to the achievement of a specific revenue milestone, or the Sixth Tranche milestone, through December 31, 2025; (iii) extends the interest only period and the maturity date from October 2026 to December 2027, (iv) reduces the cash interest rate from

10.75
% (floating 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
% to

9.85
% (floating rate based on the greater of (a)

9.85
% or (b) US WSJ Prime +

1.35
%), provided that the cash interest rate shall be capped at

10.35
% and upon the Company achieving the Sixth Tranche milestone, the cash interest floating rated shall be decreased by

0.35
% to

9.50
%, and (v) decreases the payment-in-kind interest rate from

3.35
% per annum to

2.15
% per annum. In connection with the Fourth Loan Amendment, an amendment fee of $

250,000
was paid to the Agent and was recorded as a debt discount and is being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

On March 15, 2024, the Company drew down on the remaining $

10
million available under the Second Tranche. In addition, on June 14, 2024, the Company drew down the $

25
million available under the Third Tranche.

The Term Loan will mature on December 1, 2027 , or the Maturity Date. The Term Loan bears (i) cash interest at a variable annual rate equal to the greater of (a)

9.85
% and (b) the Prime Rate (as reported in the Wall Street Journal) plus

1.35
%, or the Interest Rate, and (ii) payment-in-kind interest at a per annum rate of interest equal to

2.15
%. The Company may make payments of interest only through the Maturity Date. After the interest-only period, the principal balance and related interest will be required to be repaid in full on 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. In connection with the Fourth Loan Amendment, the final payment fee was amended to be $

1
million plus

3.00
% of any future tranche drawdowns under the agreement, due upon final maturity. Additionally, the initial final payment fee for the first term Loan advance was amended to become payable on October 1, 2026. As of September 30, 2024, the aggregate final payment fee for the first Term Loan Advance of $

7.5
million, $

2.5
million for the second Term Loan Advance, and $

0.8
million for the third Term Loan Advance have been recorded within other long-term liabilities.

Under the Fourth Loan Amendment 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 when such prepayment occurs prior to October 1, 2026, or

0.50
% if such prepayment occurs on or after October 1, 2026. 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 financial covenants. The financial covenants under the Fourth Loan Amendment include (i) a minimum cash covenant and (ii) a performance covenant as follows:

(i) Minimum cash covenant - The Company must maintain a minimum cash balance of

20
% of the outstanding principal balance at all times. The minimum cash balance may be increased to

35
% or

50
% under performance covenant (b) below if the performance covenants (a) or (c) are not met beginning September 30, 2024 and all times thereafter.

(ii) Performance covenant - Beginning September 30, 2024 and all times thereafter the Company must satisfy any one of the following:

a. Market capitalization exceeding $

900
million;

b. Minimum cash balance exceeding (x) outstanding principal amount of term loans, multiplied by (y) (A)

50
%, prior to achieving trailing three months net product revenue of greater than $

35
million, and (B)

35
% thereafter; or

c. Trailing three months net product revenue of at least (x)

30
% of agreed upon projected net revenues for periods in the calendar year 2024 and

25
% for all periods thereafter or (y) $

120
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, 2024, the Company was in compliance with all applicable covenants under the Loan Agreement.

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. In connection with the entry into the Third Loan Amendment, the Company amended the form of warrants to be issued upon drawdowns of future tranches such that the exercise price of such warrants shall be equal to the lesser (i) of $

11.6783
, which was the trailing ten-day VWAP prior to entering into the Third Loan Amendment and (ii) the trailing ten-day VWAP preceding the date on which the Company drawdown future tranches. In connection with the entry into the Fourth Loan Amendment, the Company eliminated the warrant agreement for all future tranches. The Warrant issued with the initial tranche was not modified as part of this amendment. The exercise price and terms of the outstanding Warrant remain unchanged.

The initial $

1.3
million fair value of the Warrant, the $

10.8
million final interest payment fees and $

4.4
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 payments under the Term Loan, including the final payment fee, as of September 30, 2024 are as follows (in thousands):

Year ending December 31:	
2024	—
2025	—
2026	7,500
2027	202,287
Total principal and interest payments	209,787
Less: payment-in-kind and final payment fee	(34,787)
Total term loan borrowings	$ 175,000

During the three months ended September 30, 2024 and 2023, the Company recognized $

6.3
million and $

4.4
million, respectively, of interest expense, including amortization of the debt discount, in connection with the Loan Agreement. During the nine months ended September 30, 2024 and 2023, the Company recognized $

16.8
million and $

12.6
million, respectively, of interest expense, including amortization of the debt discount, in connection with the Loan Agreement. As of September 30, 2024, the Company had an outstanding loan balance of $

185.8
million and accrued interest of $

1.5
million.

6. Revenue Interest Financing Liability

On May 3, 2022, the Company 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 received an additional $

160

million upon FDA approval of VOQUEZNA for treatment of Erosive GERD during the fourth quarter of 2023.

Additionally, on October 31, 2022, the Company entered into a Joinder Agreement with the Initial Investors and CO Finance LVS XXXVII LLC, or the Additional Investor, and Hercules, together as the investors. Under the terms of the Joinder Agreement, the Company received $

15

million in additional funding upon FDA approval of vonoprazan for Erosive GERD, or Approval Additional Funding, during the fourth quarter of 2023, and provides for $

25

million in additional funding for achievement of a sales milestone, or Milestone Additional Funding, and, together with the Approval Additional Funding, or the Additional Investor Funding. The Initial Investors waived their rights of first offer regarding the Additional Investor Funding and the Additional Investor and joined the Revenue Interest Financing Agreement to extend commitments for the Additional Investor 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 when the Company received FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD, which occurred on July 17, 2024. 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 GERD regulatory approval was 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.

During the year ended December 31, 2023, the Company received gross proceeds of $

175.0

million before deducting transaction costs of $

2.3

million, resulting in net proceeds of $

172.7

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. As of September 30, 2024, the effective interest rate of the revenue interest financing liability was approximately

14.26

%. Changes in future payments from previous estimates are included in the current and future interest expense. The carrying value of the revenue

interest financing liability was $

342.6
million and $

306.9
million as of September 30, 2024 and December 31, 2023, respectively.

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

Liability balance as of January 1, 2023	$ 109,525
Proceeds from the Revenue Interest Financing Agreement	175,000
Less: transaction costs	(2,325)
Less: royalty payments and payables	—
Plus: interest expense	24,727
Ending liability balance as of December 31, 2023	306,927
Less: current portion	(7,111)
Long-term liability balance as of December 31, 2023	$ 299,816

Liability balance as of January 1, 2024	$ 306,927
Proceeds from the Revenue Interest Financing Agreement	—
Less: transaction costs	—
Less: royalty payments and payables	(991)
Plus: interest expense	36,647
Ending liability balance as of September 30, 2024	342,583
Less: current portion	(20,194)
Long-term liability balance as of September 30, 2024	$ 322,389

During the three months ended September 30, 2024 and 2023, the Company recognized $

12.2
million and $

5.7
million, respectively, of interest expense in connection with the revenue interest financing liability. During the nine months ended September 30, 2024 and 2023, the Company recognized $

36.6
million and $

16.3
million, respectively, of interest expense in connection with the revenue interest financing liability.

The Company will record liabilities associated with achievement of the sales milestone when such contingent event occurs. 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 default events and achievement of the sales milestone.

7. Stockholders' Equity

Common Stock

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 had 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 ended in March 2023 . The fair value of the founder shares at the date the repurchase right was granted was recognized as stock-based compensation expense on a straight-line basis over the vesting period. As of September 30, 2024,

no
shares of common stock were subject to repurchase by the Company. The amount of recognized and unrecognized stock-based compensation related to the founder stock was immaterial for all periods presented.

Underwritten Public Offerings

In August 2024, the Company sold

8,695,652
shares of common stock at a price of $

11.50
per share and pre-funded warrants to purchase

2,608,922
shares of common stock at a price of $

11.499
per pre-funded warrant for total gross proceeds of $

130.0
million. The net purchase price after deducting the underwriting discounts and commissions and other offering expenses, was $

10.77
per share, which generated net proceeds of $

121.8
million. Certain affiliates of Frazier Life Sciences IX, L.P. (collectively, "Frazier"), a significant stockholder and Dr. James Topper, who currently serves on the Company's Board of Directors, shares voting and investment power of the securities held by Frazier. Frazier participated in the offering by purchasing pre-funded warrants on the same terms as all other investors at a purchase price of $

11.499
, which represents the per share public offering price for the

common stock less the $

0.001

per share exercise price for each pre-funded warrant. Each pre-funded warrant became exercisable upon issuance and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holders thereof immediately following such exercise would exceed a specified beneficial ownership limitation.

The pre-funded warrants were classified as a component of equity in the Company's balance sheets as they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its own shares and permit the holders to receive a fixed number of shares of common stock upon exercise. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and pre-funded warrants, of which $

28.2

million was allocated to the pre-funded warrants and recorded as a component of additional paid-in capital. As of September 30, 2024,

no

ne of the pre-funded warrants have been exercised.

In May 2023, the Company sold

12,793,750

shares of its common stock, which included the exercise in full by the underwriters of their option to purchase

1,668,750

shares, at a price of $

11.75

per share for total gross proceeds of $

150.3

million. The net purchase price after deducting underwriting discounts and commissions was $

11.08

per share, which generated net proceeds of $

141.8

million. The Company incurred an additional $

0.4

million of offering expenses in connection with this public offering.

ATM Offerings

In November 2020, the Company entered into an Open Market Sale Agreement[SM], or the Sales Agreement, with Jefferies LLC, or the Sales Agent, under which the Company may, from time to time, sell shares of common stock having an aggregate offering price of up to an amount registered under an effective registration statement through the Sales Agent.

In November 2023, the Company filed a shelf registration statement on Form S-3 which was declared effective by the SEC on November 17, 2023, which included an at-the-market prospectus pursuant to which the Company may, from time to time, sell up to an aggregate of $

150

million of the Company's common stock through the Sales Agent, or the 2023 ATM Offering. The Company is not obligated to, and cannot provide any assurances that the Company will, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by the Sales Agent or the Company at any time. For the year ended December 31, 2023, the Company sold

1,514,219

shares for net proceeds of approximately $

14.1

million after deducting $

0.4

million of issuance costs.

No

shares were sold during the three and nine months ended September 30, 2024. As of September 30, 2024, all of the available $

150

million under the 2023 ATM Offering remains available.

Common Stock Reserves

Common stock reserved for future issuance consists of the following:

	September 30, 2024

Common stock warrants including pre-funded warrants	2,700,150
Stock options and restricted stock units outstanding	8,957,196
Shares available for issuance under the 2019 Incentive Plan	1,356,384
Shares available for issuance under the ESPP Plan	1,177,618
Balance at September 30, 2024	14,191,348

Preferred Stock

The Company is authorized to issue up to

40

million shares of preferred stock. As of September 30, 2024 and December 31, 2023, there were

no

shares of preferred stock issued or outstanding.

Equity Incentive Plan

The Company's 2019 Equity Incentive Plan, or the Existing Incentive Plan, provided for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards to eligible recipients, including employees, directors or consultants of the Company. The Company had

2,231,739

shares of common stock authorized for issuance under the Existing Incentive Plan, of which,

1,400,528

stock options and

16,260

restricted stock awards were granted in 2019. As a result of the adoption of the 2019 Incentive Award Plan, or 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 or 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.

On July 14, 2023, the Company completed a voluntary, one-time stock option exchange program, or the Option Exchange, pursuant to which eligible employees were able to exchange certain outstanding stock options granted under the 2019 Plan for a lesser amount of new restricted stock units, or RSUs, issued under the 2019 Plan. Participants in the Option Exchange received one RSU for every two shares of Phathom common stock underlying the eligible options surrendered. This exchange ratio was applied on a grant by grant basis. The Option Exchange resulted in

2,406,622
options being exchanged for

1,203,341
RSUs. The Company is recognizing an additional $

2.2
million of incremental expense related to the Option Exchange to be recognized over a three-year vesting period.

As of September 30, 2024,

1,356,384
shares remain available for issuance, which reflects

3,144,137
stock options and RSUs awards granted, and

491,642
of awards cancelled or forfeited, during the nine months ended September 30, 2024 as well as an annual increase of

2,898,503
shares authorized on January 1, 2024.

Performance-Based Units

During 2020, the Company granted the initial performance-based units, or PSUs, whereby vesting depended upon the approval by the FDA of vonoprazan for *H. pylori* and then, or concurrent with, Erosive GERD. The PSU milestones were achieved upon FDA approval of vonoprazan for *H. pylori* and Erosive GERD during the fourth quarter of 2023.

No
PSUs are outstanding as of September 30, 2024.

Restricted Stock Units

The following table summarizes RSU activity under the 2019 Plan during the nine months ended September 30, 2024:

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1, 2024	2,653,892	$ 11.91
Granted	901,737	8.48
Vested	(869,037)	13.18

Forfeited	(178,230)	11.73
Unvested balance at September 30, 2024	2,508,362	$ 10.25

As of September 30, 2024, the Company had $22.4 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over a weighted-average period of 1.8 years. The total fair value of RSUs vested during the nine months ended September 30, 2024, was approximately $11.5 million.

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 were 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, 2024 ,

1,177,618

shares of common stock remain available for issuance, which includes the

375,381

shares sold to employees during the nine months ended September 30, 2024 as well as an annual increase of

579,701

shares authorized on January 1, 2024.

The ESPP is considered a compensatory plan, and for the three and nine months ended September 30, 2024 the Company recorded related stock-based compensation of $

0.1

million and $

1.3

million, respectively, compared to $

0.1

million and $

0.4

million, respectively, for the same periods in 2023. 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,	
	2024	**2023**
Assumptions:		
Expected term (in years)	0.49	0.49
Expected volatility	105.23 %	69.73 %
Risk free interest rate	5.19 %	5.03 %
Dividend yield	—	—

The estimated weighted-average fair value of ESPP awards for the nine months ended September 30, 2024 and 2023, was $

4.03

and $

3.64

, respectively. As of September 30, 2024, the total unrecognized compensation expense related to the ESPP was $

0.6

million, which is expected to be recognized over a weighted-average period of approximately 0.3 years.

401(k) Plan

During 2020, the Company established a 401(k) savings plan. The Company's contributions to the plan are discretionary. During the three and nine months ended September 30, 2024, the Company incurred $

1.2

million and $

4.2
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 $

0.3
million and $

1.5
million, respectively, for the same periods in 2023. During the nine months ended September 30, 2024 and 2023, the Board of Directors approved employer matching contributions settled by contributing

383,589
and

135,956
, respectively, shares of common stock.

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, the Company 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 January 1, 2024	4,550,081	$ 11.75	7.50	$ 3,379
Options granted	2,242,400	8.11		
Options exercised	(30,235)	10.01		
Options cancelled	(313,412)	13.72		
Balance at September 30, 2024	6,448,834	$ 10.40	7.52	$ 51,605
Options exercisable as of September 30, 2024	2,975,481	$ 11.91	5.93	$ 20,402
Vested and expected to vest as of September 30, 2024	6,448,834	$ 10.40	7.52	$ 51,605

The estimated weighted-average fair value of employee and nonemployee director stock options granted for the nine months ended September 30, 2024 and 2023 was $ 5.55 and $ 5.38, respectively. As of September 30, 2024, the Company had $ 18.1 million of unrecognized stock-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.4 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,	
	2024	2023
Assumptions:		
Expected term (in years)	6.04	6.03
Expected volatility	74.67 %	64.10 %
Risk free interest rate	4.14 %	3.50 %
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,	
	2024	2023	2024	2023
Research and development expense	$ 1,296	$ 1,397	$ 3,876	$ 4,977
Selling, general and administrative expense	4,339	4,743	13,484	15,464
Total	$ 5,635	$ 6,140	$ 17,360	$ 20,441

8. Revenue Recognition

To date, our only source of revenue has been from the U.S. sales of VOQUEZNA products, which the Company began selling during the fourth quarter of 2023. The Company records its best estimate of chargebacks, sales discounts and other reserves to which customers are likely expected to be entitled to as contra accounts receivable charges, and within accrued expenses if payable to a third-party or related to product returns on the balance sheets. During the three and nine months ended September 30, 2024, the Company recognized $

16.4
million and $

25.6
million, respectively, of net product revenues related to sales of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK. During each of the three and nine months ended September 30, 2023, the Company had

no

net product revenues due to the launch of VOQUEZNA during the fourth quarter of 2023. Sales allowances and accruals mostly consisted of distribution fees and rebates.

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, 2023 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, 2023, or the 2023 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 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 approved products, VOQUEZNA®, VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK®, contain vonoprazan, an oral small molecule potassium-competitive acid blocker, or PCAB. PCABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan is the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years, and has shown rapid, potent, and durable anti-secretory effects. Vonoprazan has also demonstrated clinical benefits over the current standard of care as a single agent in the treatment of erosive gastroesophageal reflux disease, or Erosive GERD, also known as erosive esophagitis, and in combination with antibiotics for the treatment of *Helicobacter pylori*, or *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 positive topline data from two pivotal Phase 3 clinical trials for vonoprazan: one for the treatment of *H. pylori* infection, or PHALCON-HP, and a second for the treatment of Erosive GERD, or PHALCON-EE. These data are supplemented by the extensive existing clinical data generated by Takeda as part of its development program for vonoprazan in Japan and other markets. In September 2021, we submitted two new drug applications, or NDAs, for combination packs that contain vonoprazan for the treatment of *H. pylori* infection in adults, one in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) and the other in combination with amoxicillin alone (vonoprazan dual therapy). In May 2022, the U.S. Food and Drug Administration, or FDA, approved the NDAs for vonoprazan triple therapy, under the brand name VOQUEZNA TRIPLE PAK, and vonoprazan dual therapy, under the brand name VOQUEZNA DUAL PAK. Subsequently, on November 1, 2023, the FDA approved vonoprazan, under the brand name VOQUEZNA, as a treatment for adults for the healing of all grades of Erosive GERD, maintenance of healing of all grades of Erosive GERD, and relief of heartburn associated with Erosive GERD, as well as in combination with amoxicillin, with or without clarithromycin, for the treatment of *H. pylori* infection in adults. We initiated commercial launch for VOQUEZNA for both the Erosive GERD and *H. pylori* indications, and VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK for treatment of H. pylori infection in the fourth quarter of 2023. In addition, based on our qualified infectious disease product, or QIDP, designations for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, we received an extension of five years of new chemical entity, or NCE, exclusivity based on

the vonoprazan component in those NDAs. We believe the extended NCE exclusivity should apply to any other approved or future products containing vonoprazan we develop and for which we obtain FDA approval.

We are also continuing to develop vonoprazan as a treatment for heartburn symptoms associated with Non-Erosive GERD. In January 2023, we reported positive topline results from PHALCON-NERD-301, a Phase 3 study evaluating the safety and efficacy of vonoprazan for the daily treatment of adults with Non-Erosive GERD, and in August 2023, we announced successful completion of the 20-week extension period of PHALCON-NERD-301. Based on the results of this study, in September 2023, we submitted an NDA seeking approval of vonoprazan as a once-daily treatment for heartburn symptoms associated with Non-Erosive GERD in adults. On July 17, 2024, the FDA approved our NDA supplement, or sNDA, for VOQUEZNA 10 mg tablets for the relief of heartburn associated with Non-Erosive GERD. With this approval, patients and healthcare providers have immediate access to VOQUEZNA for Non-Erosive GERD, the largest category of GERD.

With our recent launch of VOQUEZNA for Non-Erosive GERD, we have begun generating real-world data which are being reviewed to understand consumer usage patterns and prescribing habits of healthcare providers. These insights will help assess the value and potential timing for advancing a Phase 3 program to validate the "as-needed" dosing of VOQUEZNA for active heartburn episodes, building on the positive results from our prior Phase 2 study. Additionally, we are in the final stages of obtaining FDA feedback on the Phase 2 study and program investigating VOQUEZNA as a potential treatment for Eosinophilic Esophagitis, or EoE, in adults and adolescents, with plans to initiate the program in the first half of 2025.

Our commercial launch continues to build momentum and demonstrate strong physician and patient demand. As of October 25, 2024, over 143,000 prescriptions for VOQUEZNA tablets, VOQUEZNA Triple Pak, and VOQUEZNA Dual Pak have been filled since launch. These prescriptions were written by more than 13,600 prescribers. In addition, due to increasing commercial demand, we continue to make progress in securing broad commercial coverage for VOQUEZNA with over 120 million, or over 80%, of total U.S. commercial lives now with access to VOQUEZNA tablets.

We are independently commercializing VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK in the United States. We plan to evaluate commercial partnerships for vonoprazan in Europe and Canada, expand development of vonoprazan into other indications, dosing regimens and alternative formulations and packaging, and evaluate the in-license or acquisition of 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 and approved product candidate, vonoprazan, meeting with regulatory authorities, managing our clinical trials of vonoprazan, preparing for commercialization of our initial products containing vonoprazan, commercially launching our approved products, and providing other selling, general and administrative support for our operations. Our operations to date have been funded primarily through commercial bank debt, our revenue interest financing debt and various equity offerings, including our at-the-market offerings. From inception through September 30, 2024, we sold 34,737,032 shares of our common stock and 2,608,922 pre-funded warrants, generating net proceeds of approximately $543.3 million, after deducting underwriting discounts, commissions and offering costs. As of September 30, 2024, we had cash and cash equivalents of $334.7 million. Based on our current operating plan, we believe that our existing cash and cash equivalents together with the drawdown of the remaining $125 million under our Loan and Security Agreement, as amended, or the Loan Agreement, with Hercules Capital, Inc. or Hercules, together with anticipated product revenues, are sufficient to fund operations for at least the next twelve months and we believe will be sufficient to enable us to reach cashflow positivity.

Since inception, we have incurred significant operating losses. Our net losses were $259.9 million and $122.0 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $1.2 billion. We expect to continue to incur operating losses for the foreseeable future. It could be several years, if ever, before VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK or other product candidates, if approved, generate significant revenues to offset these operating losses. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We have generated limited revenue to date, until such time as we can generate significant revenue from sales of our approved products containing vonoprazan, we expect to finance our cash needs through equity offerings, our Loan Agreement, our Revenue Interest Financing Agreement, additional debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, and this risk could be exacerbated by the impact of ongoing conflicts throughout the world and 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 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 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

Revenue

We began to recognize revenue from product sales, net of rebates, chargebacks, discounts, and other adjustments, in November 2023 in conjunction with the commercial launch of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK in the United States.

Cost of Revenue

Cost of revenue includes the cost of producing and distributing inventories that are related to product sales. This also includes royalties payable to Takeda, pursuant to the Takeda License Agreement (Refer to Note 3 for further details). In addition, shipping and handling costs for product sales are recorded as incurred. Cost of revenue also includes costs related to excess or obsolete inventory adjustment charges.

Operating Expenses

Research and Development

To date, our research and development expenses have related to the development and regulatory approvals 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. We do not track total research and development expenses by indication.

Research and development expenses include:

- *Clinical development expenses:* external research and development expenses incurred under agreements with CROs, regulatory costs, and consultants to conduct and support our clinical trials of vonoprazan;

• *Personnel related expenses*: salaries, payroll taxes, and employee benefits;

• *Chemistry manufacturing and controls, or CMC, expenses:* costs related to the manufacturing of vonoprazan for our clinical trials;

• *Consulting, professional and other costs:* external costs related to consulting and professional services and other research costs incurred; and

• *Stock-based compensation expenses*: stock-based compensation expense recognized for those individuals involved in research and development efforts.

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Clinical development and regulatory	$ 2,640	$ 6,000	$ 8,757	$ 13,645
Personnel related	2,714	2,606	8,223	8,263
Chemistry manufacturing and controls	1,454	1,655	2,730	7,775
Consulting, professional and other costs	589	605	1,913	1,845
Stock-based compensation	1,296	1,397	3,876	4,977
Total research and development expenses	$ 8,693	$ 12,263	$ 25,499	$ 36,505

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

Selling, General and Administrative

Selling, general and administrative expenses consist of salaries and employee-related costs, including stock-based compensation, for personnel in commercial, 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 selling, general and administrative expenses will increase in the future to support our commercialization activities and research and development activities. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and 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 funds.

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. We recalculate 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 interest expense.

Beginning on December 14, 2023, interest expense under the Loan Agreement consists of (i) cash interest at a variable annual rate equal to the greater of (a) 9.85% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 1.35% and provided that the cash interest rate shall be capped at 10.35% and upon Company achieving the certain milestones, the cash interest shall be decreased by 0.35%, (ii) payment-in-kind interest at a per annum rate of interest equal to 2.15%, and (iii) amortization of the 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.

From September 17, 2021 through December 13, 2023, interest expense under the Loan Agreement consisted 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% or the Interest Rate, (ii) payment-in-kind interest at a per annum rate of interest equal to 3.35%, and (iii) amortization of the 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.

Results of Operations

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		
	2024	**2023**	**Change**
Product revenue, net	$ 25,588	$ —	$ 25,588
Cost of revenue	4,158	—	4,158
Gross profit	21,430	—	21,430
Operating expenses:			
Research and development	25,499	36,505	(11,006)
Selling, general and administrative	213,981	60,932	153,049
Total operating expenses	239,480	97,437	142,043
Loss from operations	(218,050)	(97,437)	(120,613)
Other income (expense):			
Interest income	11,648	4,528	7,120
Interest expense	(53,416)	(28,939)	(24,477)
Other expense, net	(57)	(174)	117
Total other expense	(41,825)	(24,585)	(17,240)
Net loss	$ (259,875)	$ (122,022)	$ (137,853)

Revenue. Product revenues were $25.6 million for the nine months ended September 30, 2024 related to sales of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK which were launched in the fourth quarter of 2023.

Cost of Revenue. Cost of revenue was $4.2 million for the nine months ended September 30, 2024. In periods prior to receiving FDA approval for VOQUEZNA, we recognized inventory and related costs associated with the manufacture of VOQUEZNA as research and development expense and as such, the cost of revenue and related gross profits are not necessarily indicative of future costs of revenue and gross profit. Therefore, the manufacturing costs related to the inventory purchased before FDA approval were already expensed in a prior period and are therefore excluded from the cost of revenue for the nine months ended September 30, 2024. These previously expensed costs were not material.

Research and Development Expenses. Research and development expenses were $25.5 million and $36.5 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $11.0 million consisted of reductions of $5.0 million of CMC costs related to vonoprazan, $5.0 million of regulatory and clinical study related expenses due to the wrapping up of our PHALCON-NERD-301 Phase 3 daily dosing study, and $1.0 million related to personnel-related expenses primarily for stock-based compensation.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $214.0 million and $60.9 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of $153.1 million was due to increases of $94.3 million commercial expenses related to the launch of VOQUEZNA products, which includes $53.3 million of external project spend and $41.0 million in advertising and promotional expenses in support of our commercial launch of VOQUEZNA products, $59.9 million increase in personnel-related expenses, partially offset by a decrease of $1.1 million in consulting and other professional services.

Other Income (Expense). Other expense of $41.8 million for the nine months ended September 30, 2024 consisted of $53.4 million of interest expense under the Loan Agreement and Revenue Interest Financing Agreement, partially offset by $11.6 million of interest income related to cash held in money market funds. Other expense of $24.6 million for the nine months ended September 30, 2023 consisted of $28.9 million of interest expense under the Loan Agreement and Revenue Interest Financing Agreement and $0.2 million of other expense, partially offset by $4.5 million of interest income related to cash held in money market funds. Interest expense increased due to a higher debt balance under the Loan Agreement as well as a higher liability related to our Revenue Interest Financing Agreement versus the prior period, partially offset by higher interest income due to our increased cash position.

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		
	2024	2023	Change
Product revenue, net	$ 16,352	$ —	$ 16,352
Cost of revenue	2,356	—	2,356
Gross profit	13,996	—	13,996
Operating expenses:			
Research and development	8,693	12,263	(3,570)
Selling, general and administrative	76,099	23,396	52,703
Total operating expenses	84,792	35,659	49,133
Loss from operations	(70,796)	(35,659)	(35,137)
Other income (expense):			
Interest income	3,711	2,720	991
Interest expense	(18,484)	(10,107)	(8,377)
Other expense, net	(8)	(197)	189
Total other expense	(14,781)	(7,584)	(7,197)
Net loss	$ (85,577)	$ (43,243)	$ (42,334)

Revenue. Product revenues were $16.4 million for the three months ended September 30, 2024 related to sales of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK which were launched in the fourth quarter of 2023.

Cost of Revenue. Cost of revenue was $2.4 million for the three months ended September 30, 2024. In periods prior to receiving FDA approval for VOQUEZNA, we recognized inventory and related costs associated with the manufacture of VOQUEZNA as research and development expense and as such, the cost of revenue and related gross profits are not necessarily indicative of future costs of revenue and gross profit. Therefore, the manufacturing costs related to the inventory purchased before FDA approval were already expensed in a prior period and are therefore excluded from the cost of revenue for the three months ended September 30, 2024. These previously expensed costs were not material.

Research and Development Expenses. Research and development expenses were $8.7 million and $12.3 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of $3.6 million consisted of reductions of $3.4 million of regulatory and clinical study related expenses due to the wrapping up of our PHALCON-NERD-301 Phase 3 daily dosing study, and $0.2 million of CMC costs related to vonoprazan.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $76.1 million and $23.4 million for the three months ended September 30, 2024 and 2023, respectively. The increase of $52.7 million was due to increases of $37.1 million of commercial expenses related to the launch of VOQUEZNA products, which includes $19.6 million of external project spend and $17.5 million in advertising and promotional expenses in support of our commercial launch of VOQUEZNA products, $20.1 million increase in personnel-related expenses, partially offset by a decrease of $4.5 million in consulting and other professional services.

Other Income (Expense). Other expense of $14.8 million for the three months ended September 30, 2024 consisted of $18.5 million of interest expense under the Loan Agreement and Revenue Interest Financing Agreement, partially offset by $3.7 million of

interest income related to cash held in money market funds. Other expense of $7.6 million for the three months ended September 30, 2023 consisted of $10.1 million of interest expense under the Loan Agreement and Revenue Interest Financing Agreement and $0.2 million of other expense, partially offset by $2.7 million of interest income related to cash held in money market funds. Interest expense increased due to a higher debt balance under the Loan Agreement as well as a higher liability related to our Revenue Interest Financing Agreement versus the prior period, partially offset by higher interest income due to our increased cash position.

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, 2024, we had cash and cash equivalents of $334.7 million.

Loan Agreement with Hercules

On September 17, 2021, or the Closing Date, we entered into the Loan Agreement with Hercules (in such capacity, the Agent or Hercules), as administrative agent and collateral agent and as a lender 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 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 million, all of which was funded on the Closing Date, or the First Advance, (ii) a second tranche consisting of up to an additional $50 million, (iii) a third and fourth tranches consisting of an additional total $50 million, which became available to us in May 2022.

On September 27, 2022, we 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 us has been moved until May 15, 2023, rather than December 15, 2022.

On May 9, 2023, we entered into the Third Amendment to Loan and Security Agreement, or the Third Loan Amendment, with the lenders, pursuant to which, among other things, (i) the second tranche availability was extended from through May 15, 2023, to through December 15, 2023, and became available on October 1, 2023, (ii) the third tranche availability was extended from through September 30, 2023, to through December 15, 2023, and became available on October 1, 2023, (iii) the effective date of the Performance Covenants was amended to provide an option to extend the covenant trigger date to May 15, 2024, subject to the achievement of the FDA approval of vonoprazan for Erosive GERD or the EE Milestone, prior to February 15, 2024, and (iv) the warrant agreement with Hercules was amended as described below. On November 1, 2023, the EE Milestone was achieved and the covenant trigger date was extended to May 15, 2024. In connection with the Third Loan Amendment, a tranche extension amendment fee of $150,000 and a covenant extension amendment fee of $100,000 was paid to the Agent. These fees have been recorded as debt discount and are being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

On December 14, 2023, we entered into a Fourth Amendment to Loan and Security Agreement, or the Fourth Loan Amendment, with the lenders, which, among other things, (i) increases the aggregate principal amount of the term loans from $200 million to $300 million; (ii) provides for the possibility of accessing the $200 million commitment through five additional tranches referred to as tranches 2 through 6, which are available subject to certain milestones and conditions: (a) Tranche 2: $50 million, $40 million of which was funded on December 14, 2023, available through March 15, 2024, (b) Tranche 3: $25 million available through June 15, 2024, (c) Tranche 4: $25 million available through December 15, 2024, (d) Tranche 5: $50 million available, subject to the achievement of a specified revenue milestone, through June 30, 2025, and (e) Tranche 6: $50 million available, subject to the achievement of a specified revenue milestone, through December 31, 2025; (iii) extends the interest only period and the maturity date from October 2026 to December 2027, (iv) reduces the cash interest rate from 10.75% (floating 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% to 9.85% (floating rate based on the greater of (a) 9.85% or (b) US WSJ Prime + 1.35%), provided that the cash interest rate shall be capped at 10.35% and upon us achieving the certain milestones, the cash interest shall be decreased by 0.35%, and (v) decreases the payment-in-kind interest rate from 3.35% per annum to 2.15% per annum. In connection with the Fourth Loan Amendment, an amendment fee of $250,000 was paid to the Agent and was recorded as a debt discount and being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

On March 15, 2024, we drew down the remaining $10 million available under the Second Tranche. In addition, on June 14, 2024, we drew down the $25 million available under the Third Tranche.

The Term Loan will mature on December 1, 2027, or the Maturity Date. The Term Loan bears (i) cash interest at a variable annual rate equal to the greater of (a) 9.85% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 1.35%, or the Interest Rate, and (ii) payment-in-kind interest at a per annum rate of interest equal to 2.15%. We may make payments of interest only through the Maturity Date. After the interest-only period, the principal balance and related interest will be required to be repaid in full on the Maturity Date.

In addition, we are 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. In connection with the Fourth Loan Amendment, the final payment fee was amended to be $1 million plus 3.00% of any future tranche drawdowns under the agreement, due upon final maturity. Additionally, the initial final payment fee for the first term Loan advance was amended to become payable on October 1, 2026. As of September 30, 2024, the aggregate final payment fee for the first Term Loan Advance of $7.5 million, $2.5 million for the second Term Loan Advance, and $0.8 million for the third Term Loan Advance have been recorded within other long-term liabilities.

Under the Fourth Loan Amendment, we 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 when such prepayment occurs prior to October 1, 2026, or 0.50% if such prepayment occurs on or after October 1, 2026. After repayment, no Term Loan amounts may be borrowed again.

The Loan Agreement contains customary closing fees, prepayment fees and provisions, events of default, and representations, warranties and covenants, including financial covenants. The financial covenants under the Fourth Loan Amendment include (i) a minimum cash covenant and (ii) a performance covenant as follows:

(i) Minimum cash covenant - We must maintain a minimum cash balance of 20% of the outstanding principal balance at all times. The minimum cash balance may be increased to 35% or 50% under performance covenant (b) below if the performance covenants (a) or (c) are not met beginning September 30, 2024 and all times thereafter.

(ii) Performance covenant - Beginning September 30, 2024 and all times thereafter we must satisfy any one of the following:

a. Market capitalization exceeding $900 million;

b. Minimum cash balance exceeding (x) outstanding principal amount of term loans, multiplied by (y) (A) 50%, prior to achieving trailing three months net product revenue of greater than $35 million, and (B) 35% thereafter; or

c. Trailing three months net product revenue of at least (x) 30% of agreed upon projected net revenues for periods in the calendar year 2024 and 25% for all periods thereafter or (y) $120 million.

Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by us may be declared immediately due and payable by Hercules, as collateral agent.

As of September 30, 2024, we were in compliance with all applicable covenants under the Loan Agreement.

As collateral for the obligations, we granted 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, or 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 is 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. In connection with the entry into the Third Loan Amendment, we amended the form of warrants to be issued upon drawdowns of future tranches such that the exercise price of such warrants shall be equal to the lesser (i) of $11.6783, which was the trailing ten-day VWAP prior to entering into the Third Loan Amendment and (ii) the trailing ten-day VWAP preceding the date on which we drawdown future tranches. In connection with the entry into the Fourth Amendment, we eliminated the warrant agreement for all future tranches. The Warrant issued with the initial tranche was not modified as part of this amendment. The exercise price and terms of the outstanding Warrant remain unchanged.

The initial $1.3 million fair value of the Warrant, the $10.8 million final interest payment fees and $4.4 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.

Revenue Interest Financing Agreement

On May 3, 2022, we 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, together with NQ and Sagard, or the Initial Investors, pursuant to which we could 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 received an additional $160 million upon FDA approval of vonoprazan for treatment of Erosive GERD in the fourth quarter of 2023. Additionally, on October 31, 2022, we entered into a Joinder and Waiver Agreement with the Initial Investors and CO Finance LVS XXXVII LLC, or the Additional Investor, and Hercules in its capacity as administrative agent and collateral agent for itself and the lenders under that certain Loan Agreement, or the Joinder Agreement, in respect of the Revenue Interest Financing Agreement. Under the terms of the Joinder Agreement, we received $15 million in additional funding upon FDA approval of vonoprazan for Erosive GERD, or Approval Additional Funding, in the fourth quarter of 2023 and provides for $25 million in additional funding for achievement of a sales milestone, or Milestone Additional Funding, and, together with the Approval Additional Funding, or the Additional Investor Funding. The Initial Investors waived their right of first offer for any Additional Investor 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 Initial Investors and the Additional Investor, 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 upon FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD, which occurred on July 17, 2024. 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 GERD regulatory approval was 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 we previously paid pursuant to the agreement.

At-the-Market-Offerings

In November 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 an amount registered under an effective registration statement through the Sales Agent.

In November 2023, we filed a shelf registration statement on Form S-3 which was declared effective by the SEC on November 17, 2023, which included an at-the-market prospectus pursuant to which we may, from time to time, sell up to an aggregate of $150 million of our common stock through the Sales Agent, or the 2023 ATM Offering. 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. For the year ended December 31, 2023, we sold 1,514,219 shares for net proceeds of approximately $14.1 million after deducting $0.4 million of issuance costs. No shares were sold during the three and nine months ended September 30, 2024. As of September 30, 2024, all of the available $150 million under the 2023 ATM Offering remains available.

Underwritten Public Offerings

On August 20, 2024, we completed an underwritten public offering, in which we sold 8,695,652 shares of our common stock at a price of $11.50 per share and pre-funded warrants to purchase 2,608,922 shares of our common stock at a price of $11.499 per pre-funded warrant for total gross proceeds of $130.0 million. The net purchase price after deducting the underwriting discounts and commissions and other offering expenses, was $10.77 per share or net proceeds of $121.8 million.

On May 23, 2023, we completed an underwritten public offering, in which we sold 12,793,750 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 1,668,750 shares, at a price of $11.75 per share for total gross proceeds of $150.3 million. The net purchase price after deducting underwriting discounts and commissions was $11.08 per share, which generated net proceeds of $141.8 million. We incurred an additional $0.4 million of offering expenses in connection with this 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 $125 million under our Loan Agreement with Hercules together with anticipated product revenues, are sufficient to fund operations for at least the next twelve months and we believe will be sufficient to enable us to reach cashflow positivity. 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 inaccurate, and we could deplete our capital resources sooner than we expect and not reach cashflow positivity based on the amount and timing of product sales and operating expenses, among other factors. 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:

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payers 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 payers;
- 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;
- the costs and timing of manufacturing for vonoprazan or any future product candidates, including commercial scale manufacturing for any approved product candidates;
- the costs, timing and outcome of regulatory review of future vonoprazan applications or such applications for 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;
- 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;
- 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, the Loan Agreement, the Revenue Interest Financing Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt

financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Including our existing cash and cash equivalents, we believe that we have sufficient working capital on hand to fund operations such that there is no substantial doubt as to our ability to continue as a going concern at the date the financial statements were issued. There can be no assurance that we will be successful in acquiring additional funding, that our projections of future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. Based on our current operating plan, we believe that our existing cash and cash equivalents together with the drawdown of the remaining $125 million under our Loan Agreement with Hercules together with anticipated product revenues, are sufficient to fund operations for at least the next twelve months and we believe will be sufficient to enable us to reach cashflow positivity.

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,		
	2024	**2023**	**Change**
Net cash provided by (used in):			
Operating activities	$ (203,314)	$ (93,783)	$ (109,531)
Investing activities	(130)	(1,159)	1,029
Financing activities	156,728	155,587	1,141
Net (decrease) increase in cash	$ (46,716)	$ 60,645	$ (107,361)

Operating Activities

Net cash used in operating activities was approximately $203.3 million and $93.8 million for the nine months ended September 30, 2024 and 2023, respectively. The net cash used in operating activities for the nine months ended September 30, 2024 was due to approximately $197.0 million spent on ongoing research and development and selling, general and administrative activities and a $6.3 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $15.5 million increase in accounts payable and accrued expenses (including interest, operating lease assets and liabilities), and a $21.8 million increase in accounts receivable, inventory, and prepaid assets and other current assets in support of our growth and launch of our first commercial products. The net cash used in operating activities for the nine months ended September 30, 2023 was due to approximately $79.5 million spent on ongoing research and development and general and administrative activities and a $14.3 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $3.1 million decrease in accounts payable and accrued expenses (including interest and clinical trial expenses), and a $11.2 million increase in prepaid assets and other current assets, inventory, operating right-of-use assets and lease liabilities and other long-term assets.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024 and 2023, was related to payments for acquiring property and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was $156.7 million primarily related to $34.7 million of net proceeds from the issuance of debt under our Loan Agreement and $121.8 million of net proceeds from issuance of common stock and pre-funded warrants in connection with the underwritten public offering completed in August 2024. Net cash provided by financing activities for the nine months ended September 30, 2023 was $155.6 million related to net proceeds from the sale of our common stock.

Contractual Obligations and Commitments

There were no material changes outside the ordinary course of our business during the nine months ended September 30, 2024 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 2023 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, revenues 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 2023 Form 10-K. There have not been any material changes to the critical accounting policies discussed therein during the nine months ended September 30, 2024.

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 $1.235 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 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 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, 2024, 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 2023 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 our third fiscal quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Other than as set forth below, there have been no material changes to the risk factors disclosed in Part I, Item 1A, "Risk Factors" of our 2023 Form 10-K.

If the scope of any patent protection or non-patent regulatory exclusivity we obtain is not sufficiently broad, or if we lose or fail to obtain any of our patent protection or non-patent regulatory exclusivity, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our in-licensed pending and future patent applications may not result in patents being issued which protect vonoprazan or any future product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own in the future or license currently issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any future patents that we own or license, now or in the future, may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether vonoprazan or any future product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our future patents or the patents of our current and future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our future patents or the patents of our current and future licensors may not cover vonoprazan or any future product candidates or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our predecessors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our in-licensed patents and patent applications has been found. There is also no assurance that there is not prior art of which we, our predecessors or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our in-licensed patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize vonoprazan or any future product candidates and compete directly with us, without payment to us. It is possible that defects of form in the preparation or filing of our or our current and future licensors' patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our future patents or future patent applications or our current and future licensors' patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents.

Any loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of vonoprazan or any future product candidates, which could materially and adversely impact our business. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the

eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our future patents and future patent applications or the patents and patent applications of our current and future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize vonoprazan or any future product candidates.

In addition to patent exclusivity, the successful commercialization of our products also depends, in part, on our ability to obtain and maintain periods of non-patent exclusivity during which time the FDA is precluded from accepting new drug applications, or NDAs, submitted under Section 505(b)(2) of the FDCA or abbreviated new drug applications, or ANDAs, for certain competitive products. In May 2021, FDA granted qualified infectious disease product, or QIDP, designations to vonoprazan tablets in combination with both amoxicillin capsules and clarithromycin tablets, and with amoxicillin capsules alone, respectively, for the treatment of H. pylori infection. On May 3, 2022, the FDA approved our NDAs for these products, branded as VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, respectively. Because these approvals were for QIDP-designated drugs containing the active moiety, vonoprazan, which had not previously been approved, the FDA granted five-years of NCE exclusivity, which was extended by an additional five-years pursuant to the GAIN Act, resulting in a total of ten-years of NCE exclusivity, until May 3, 2032.

In November 2023, we received approval for VOQUEZNA, which also contains vonoprazan. NCE exclusivity protects against the submission and the FDA's acceptance of a 505(b)(2) NDA or ANDA referencing that NCE for the duration of the exclusivity period, and the FDA interprets this form of exclusivity to attach to the active moiety such that the submission and the FDA's acceptance of ANDAs and 505(b)(2) NDAs for a drug with that active moiety may not occur until the innovator's exclusivity has expired, whether or not FDA has approved other versions of the drugs entitled to exclusivity, and regardless of the specific listed drug product to which the ANDA or 505(b)(2) application refers. Consequently, we believe that VOQUEZNA, because it contains vonoprazan, should benefit from the same extended period of NCE exclusivity granted in connection with our NDAs for VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PACK, until May 3, 2032.

The FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," referred to as the Orange Book, identifies that VOQUEZNA benefits from the same five-year period of NCE exclusivity as VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, but does not currently identify the GAIN Act extension of an additional five-years of NCE exclusivity to which we believe it is entitled. We informally requested that the FDA correct the VOQUEZNA listings to reflect the same extended NCE exclusivity period as VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. However, the FDA has not yet updated those listings. Based on feedback from the FDA, we plan to evaluate our alternatives, which may include pursuing a citizen petition or legal or other actions at the appropriate time. If the FDA ultimately concludes that the GAIN Act extension of NCE exclusivity granted in connection with our VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK NDAs does not extend to our VOQUEZNA NDA, there is the potential we could be subject to competition earlier than we currently anticipate given that our regulatory exclusivity would no longer extend beyond the current expected expiry of our vonoprazan drug patents in 2030 (assuming the grant of patent term extension). If this occurs, it would have a material adverse effect on our business and financial condition.

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

Director and Officer Trading Arrangements:

Rule 10b5-1 Trading Plans

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended September 30, 2024, none of our officers or directors adopted , modified or terminated any such trading arrangements.

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	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as filed with the Secretary of the State of Delaware on May 26, 2023	8-K	5/30/23	3.1	
3.3	Amended and Restated Bylaws, effective as of December 13, 2023	8-K	12/15/23	3.1	
4.1	Form of Common Stock Certificate	S-1/A	10/15/19	4.1	
4.2	Warrant to purchase stock issued to Silicon Valley Bank, dated May 14, 2019	S-1	9/30/19	4.3	
4.3	Warrant to purchase stock issued to WestRiver Innovation Lending Fund VIII, L.P., dated May 14, 2019	S-1	9/30/19	4.4	
4.4	Warrant to purchase stock issued to Hercules Capital, dated September 17, 2021	10-Q	11/8/21	10.2	
4.5	First Amendment to Warrant to purchase stock issued to Hercules Capital, dated May 9, 2023	10-Q	5/10/23	4.5	
4.6	Form of Warrant to purchase stock issuable pursuant to the Loan and Security Agreement, as amended, by and between the Registrant and Hercules Capital, Inc.	10-Q	5/10/23	4.6	
4.7	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	
4.8	Form of Pre-Funded Warrant to purchase common stock	8-K	8/19/24	4.1	
10.1†	Letter Agreement to Vonoprazan Commercial Supply Agreement, dated September 4, 2024, by and among Evonik Operations GmbH 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
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* 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.

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

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 7, 2024

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

Date: November 7, 2024

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

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE PHATHOM PHARMACEUTICALS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO PHATHOM PHARMACEUTICALS, INC. IF PUBLICLY DISCLOSED.

4 September 2024

Phathom Pharmaceuticals, Inc
100 Campus Drive, Suite 102
Florham Park, NJ 07932

Theresa Ledbetter
Evonik Corporation
Director, Key Account Management and Sales
Drug Substance

Re: **Letter Agreement ("Letter Agreement") regarding Vonoprazan Commercial Supply Agreement** made by and among Phathom Pharmaceuticals, Inc., a Delaware corporation located at 100 Campus Drive, Suite 102, Florham Park, NJ 07932 ("Purchaser"), Evonik Operations GmbH, a limited liability company located at Rodenbacher Chaussee 4, 63457 Hanau (Wolfgang), Germany ("Evonik GmbH" or "Supplier") and Evonik Corporation, an Alabama corporation with offices located at 2 Turner Place, Piscataway, NJ 08854 ("Evonik US" or "Supplier") **effective as of August 1, 2022, as it has been amended to date (the "Agreement")**

We are writing to confirm that pursuant to Section 15.7 of the Agreement, the Parties have agreed to modify the Agreement as set forth herein. As used in this Letter Agreement, capitalized terms have the meanings assigned to them in the Agreement and references to "Sections" shall be to Sections of the Agreement. The Parties agree as follows:

1. Section 3.11.2 of the Agreement entitles Supplier to order [***] quantity [***] months in advance of Product delivery based on Purchaser's forecast, irrespective of whether the forecasted volumes of such campaign constitute a Firm Commitment. Notwithstanding the foregoing, Purchaser and Supplier hereby agree, on a one- time basis, to extend this time period to [***] months in order to allow for Supplier to purchase [***] to satisfy both December 2025 [***] demand from Purchaser's August 2024 Forecast (see attached document titled 'Evonik Forecast – 08-08-24.xlsx') and verbal communication for November 2026 demand [***]. If, at the time the November 2026 demand becomes a Firm Commitment the Product volume is lower than [***], the Parties agree this will be managed as outlined in Section 3.11.2 of the Agreement or in accordance with an alternate approach as mutually agreed by the Parties.

2. Except for the potential payment contemplated by Section 3.11.2 for a reduction from ordered quantity to Firm Commitment, Purchaser shall not be required to provide Supplier a Prepayment earlier than outlined in Section 4.3.3 of the Agreement.

Except as expressly provided in this Letter Agreement, all other terms, conditions, and provisions of the Agreement shall continue in full force and effect as provided therein. This Letter Agreement shall be governed by and construed in accordance with the laws of the state of New Jersey without regard to the conflict of law provisions thereof.

This Letter 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.

IN WITNESS WHEREOF, the Parties have confirmed their acceptance of the contents of this Letter Agreement.

Evonik Operations GmbH Evonik Operations GmbH

By: /s/ Tim Pohlman By: /s/ Marcus Andresen
Name: Tim Pohlmann Name: Marcus Andresen
Title: Sr. Director CDMO Project Business Title: Senior Legal Counsel

Evonik Corporation Phathom Pharmaceuticals, Inc.

By: /s/ Stefan Randl By: /s/ Jay Buchanan
Name: Stefan Randl Name: Jay Buchanan
Title: VP PL Drug Substance Title: VP, Manufacturing & Supply Chain

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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 7, 2024

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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 7, 2024

/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, 2024 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 7, 2024

/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, 2024 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 7, 2024

/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.