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 March 31, 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: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1 Casper Street Danbury, Connecticut	**06810**
(Address of principal executive offices)	**(Zip Code)**

(818) 661-5000
(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	MNKD	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 April 26, 2024, there were 272,315,846 shares of the registrant's common stock, $0.01 par value per share, outstanding.

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended March 31, 2024

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PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
	(In thousands except per share data)	
Revenues:		
Net revenue – commercial product sales	$ 18,764	$ 17,562
Revenue – collaborations and services	24,848	11,386
Royalties – collaborations	22,651	11,678
Total revenues	66,263	40,626
Expenses:		
Cost of goods sold	3,819	5,530
Cost of revenue – collaborations and services	14,779	10,683
Research and development	10,013	5,605
Selling	11,601	13,310
General and administrative	10,728	10,542
(Gain) loss on foreign currency transaction	(1,399)	954
Total expenses	49,541	46,624
Income (loss) from operations	16,722	(5,998)
Other income (expense):		
Interest income, net	3,434	1,302
Interest expense on financing liability	(2,447)	(2,424)
Interest expense	(2,567)	(2,786)
Interest expense on liability for sale of future royalties	(4,248)	—
Other income	—	111
Total other expense	(5,828)	(3,797)
Income (loss) before income tax expense	10,894	(9,795)
Income tax expense	264	—
Net income (loss)	$ 10,630	$ (9,795)
Net income (loss) per share – basic	$ 0.04	$ (0.04)
Weighted average shares used to compute net income (loss) per share – basic	270,356	263,969
Net income (loss) per share – diluted	$ 0.04	$ (0.04)
Weighted average shares used to compute net income (loss) per share – diluted	324,733	263,969

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2024	December 31, 2023
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 193,272	$ 238,480
Short-term investments	107,457	56,619
Accounts receivable, net	19,912	14,901
Inventory	26,442	28,545
Prepaid expenses and other current assets	36,019	34,848
Total current assets	383,102	373,393
Property and equipment, net	83,620	84,220
Goodwill	1,931	1,931
Other intangible asset	1,053	1,073
Long-term investments	3,726	7,155
Other assets	7,447	7,426
Total assets	$ 480,879	$ 475,198
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,149	$ 9,580
Accrued expenses and other current liabilities	42,291	42,036
Financing liability – current	9,872	9,809
Midcap credit facility – current	20,000	20,000
Liability for sale of future royalties – current	10,537	9,756
Deferred revenue – current	7,601	9,085
Recognized loss on purchase commitments – current	2,446	3,859
Total current liabilities	99,896	104,125
Mann Group convertible note	8,829	8,829
Accrued interest – Mann Group convertible note	55	56
Financing liability – long term	94,207	94,319
Midcap credit facility – long term	8,105	13,019
Senior convertible notes	227,214	226,851
Liability for sale of future royalties – long term	137,418	136,054
Recognized loss on purchase commitments – long term	60,287	60,942
Operating lease liability	3,645	3,925
Deferred revenue – long term	67,741	69,794
Milestone liabilities	3,452	3,452
Total liabilities	710,849	721,366
Commitments and contingencies (Note 14)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2024 or December 31, 2023	—	—
Common stock, $0.01 par value – 800,000,000 shares authorized; 270,801,781 and 270,034,495 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	2,703	2,700
Additional paid-in capital	2,986,104	2,980,539
Accumulated deficit	(3,218,777)	(3,229,407)
Total stockholders' deficit	(229,970)	(246,168)
Total liabilities and stockholders' deficit	$ 480,879	$ 475,198

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
			(In thousands)		
BALANCE, JANUARY 1, 2023	263,793	$ 2,638	$ 2,964,293	$ (3,217,469)	$ (250,538)
Issuance of common stock associated with at-the-market placement	269	3	1,196	—	1,199
Issuance costs associated with at-the-market placement	—	—	(24)	—	(24)
Net issuance of common stock associated with stock options and restricted stock units	206	2	50	—	52
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	11	—	55	—	55
Stock-based compensation expense	—	—	3,655	—	3,655
Net loss	—	—	—	(9,795)	(9,795)
BALANCE, MARCH 31, 2023	264,279	$ 2,643	$ 2,969,225	$ (3,227,264)	$ (255,396)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
			(In thousands)		
BALANCE, JANUARY 1, 2024	270,034	$ 2,700	$ 2,980,539	$ (3,229,407)	$ (246,168)
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	15	—	56	—	56
Net issuance of common stock associated with stock options and restricted stock units	337	3	263	—	266
Issuance of common stock from market price stock purchase plan	416	—	1,361	—	1,361
Stock-based compensation expense	—	—	3,885	—	3,885
Net income	—	—	—	10,630	10,630
BALANCE, MARCH 31, 2024	270,802	$ 2,703	$ 2,986,104	$ (3,218,777)	$ (229,970)

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 10,630	$ (9,795)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Interest on liability for sale of future royalties	4,248	—
Stock-based compensation	3,885	3,655
Depreciation and amortization	1,361	1,058
Loss on estimated returns of acquired product	1,169	—
Write-off of inventory	1,029	2,416
Amortization of debt discount and issuance costs	501	469
Amortization of right-of-use assets	328	338
Interest on Mann Group convertible note	55	55
Other, net	49	61
(Gain) loss on foreign currency transaction	(1,399)	954
Net accretion of investments	(984)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,456)	(2,913)
Inventory	1,074	(2,641)
Prepaid expenses and other current assets	(3,274)	2,426
Other assets	(314)	—
Accounts payable	(2,431)	2,837
Accrued expenses and other current liabilities	670	(3,562)
Deferred revenue	(3,537)	8,558
Recognized loss on purchase commitments	(669)	(2,074)
Operating lease liabilities	(232)	(686)
Net cash provided by operating activities	6,703	1,156
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from held-to-maturity debt securities	21,974	22,103
Purchase of held-to-maturity debt securities	(68,399)	—
Purchase of property and equipment	(2,408)	(8,311)
Proceeds from insurance claim	396	—
Net cash (used in) provided by investing activities	(48,437)	13,792
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from market price stock purchase plan	1,361	—
Payments for taxes related to net issuance of common stock associated with restricted stock units and stock options	266	52
Principal payment on financing liability	(101)	(72)
Principal payment on MidCap credit facility	(5,000)	—
Proceeds from at-the-market-offering	—	1,198
Issuance costs associated with at-the-market offering	—	(24)
Net cash (used in) provided by financing activities	(3,474)	1,154
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(45,208)	16,102
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	238,480	69,767
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 193,272	$ 85,869

	Three Months Ended March 31,	
	2024	**2023**
	(In thousands)	
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash	$ 5,931	$ 3,700
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Reclassification of Midcap credit facility from long-term to current	5,000	11,667
Reclassification of investments from long-term to current	4,653	1,468
Non-cash construction in progress, property and equipment	1,667	2,438
Reclassification of Thirona convertible notes and interest receivable from current to long-term	—	7,726
Right-of-use asset modification	—	728
Goodwill adjustment for a net reduction in liabilities	—	430

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of Business and Significant Accounting Policies

The unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries ("MannKind," the "Company," "we" or "us"), have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the "SEC"). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024 (the "Annual Report").

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three months ended March 31, 2024 may not be indicative of the results that may be expected for the full year.

Financial Statement Estimates — The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and notes. Actual results could differ from those estimates or assumptions. Management considers many factors in selecting appropriate financial accounting policies, and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. These effects could have a material impact on the estimates and assumptions used in the preparation of the condensed consolidated financial statements. The more significant estimates include revenue recognition, including gross-to-net adjustments, stand-alone selling price considerations for recognition of collaboration revenue, assessing long-lived assets for impairment, clinical trial expenses, inventory costing and recoverability, recognized loss on purchase commitment, stock-based compensation, the determination of the provision for income taxes and corresponding deferred tax assets and liabilities, the valuation allowance recorded against net deferred tax assets, and expected cash flows from royalties received in connection with United Therapeutics' ("UT's") net revenue for the sale of Tyvaso DPI.

Business — MannKind is a biopharmaceutical company focused on the development and commercialization of innovative therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases. The Company's signature technologies—Technosphere dry-powder formulations and Dreamboat inhalation devices—offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation. The Company is currently commercializing Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, and the V-Go wearable insulin delivery device, which provides continuous subcutaneous infusion of insulin in adults that require insulin. The first product to come out of the orphan lung disease pipeline, Tyvaso DPI (treprostinil) inhalation powder, received approval from the U.S. Food and Drug Administration ("FDA") in May 2022 for the treatment of pulmonary arterial hypertension ("PAH") and for the treatment of pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). The Company's development and marketing partner, UT, began commercializing Tyvaso DPI in June 2022 and is obligated to pay the Company a 10% royalty on net sales of the product. The Company also receives a margin on supplies of Tyvaso DPI that it manufactures for UT.

Basis of Presentation — The condensed consolidated financial statements have been prepared in accordance with GAAP.

Principles of Consolidation — The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated.

Reclassifications — Certain amounts reported in the prior period have been reclassified to conform with current period presentation. The Company has presented non-cash interest accretion on financing liability on a net basis in Other, net, in the condensed consolidated statements of cash flows.

Segment Information — 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 regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating in the United States of America.

Revenue Recognition — The Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that are within the scope of Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under ASC 606, including when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company has two types of contracts with customers: (i) contracts for commercial product sales with wholesale distributors, specialty and retail pharmacies, and durable medical equipment suppliers ("DMEs") and (ii) collaboration arrangements.

Revenue Recognition — Net Revenue — Commercial Product Sales — The Company sells its products to a limited number of wholesale distributors, specialty and retail pharmacies, and DMEs in the U.S. (collectively, its "Customers"). Wholesale distributors subsequently resell the Company's products to retail pharmacies and certain medical centers or hospitals. Specialty and retail pharmacies sell directly to patients. In addition to distribution agreements with Customers, the Company enters into arrangements with payers that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at delivery for wholesale distributors and generally at delivery for specialty pharmacies. The Company recognizes revenue on product sales to a retail pharmacy as the product is dispensed to patients. Product revenues are recorded net of applicable reserves, including discounts, allowances, rebates, returns and other incentives. See *Reserves for Variable Consideration* below.

Reserves for Variable Consideration — Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payer rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payers, and other indirect customers relating to the Company's sale of its products. These reserves, as further detailed below, are based on the amounts earned, or to be claimed on the related sales, and result in a reduction of accounts receivable or establishment of a current liability. Significant judgment is required in estimating gross-to-net adjustments, including historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, claim submission time lags and inventory levels in the distribution channel.

Where appropriate, these estimates take into consideration a range of possible outcomes, which are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reduce recognized revenue to the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analysis also contemplates application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the current period estimates of gross-to-net adjustments and, therefore, the transaction price was not reduced further during the current period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net revenue from commercial product sales and earnings in the period such variances become known.

Trade Discounts and Allowances — The Company generally provides Customers with discounts which include incentives, such as prompt pay discounts, that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the

related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue and as a reduction to accounts receivable, net.

Product Returns — Consistent with industry practice, the Company generally offers Customers a right of return for unopened product that has been purchased from the Company for a period beginning six months prior to and ending 12 months after its expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to accounts receivable, net. The Company currently estimates product returns using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company's current return reserve percentage is estimated to be in the single digits. Adjustments to the returns reserve are made when changes in the Company's assumptions result in revised estimates.

Provider Chargebacks and Discounts — Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase products from the Company. Customers charge the Company for the difference between what they pay for products and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is recorded in accrued expenses and other current liabilities. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates — The Company is subject to discount obligations under Medicare and state Medicaid programs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses and other current liabilities. Estimates around Medicaid have historically required significant judgment due to timing lags in receiving invoices for claims from states. For Afrezza, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for products that have been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period. The Company's estimates include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

Payer Rebates — The Company contracts with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates, including estimates for product that has been recognized as revenue, but which remains in the distribution channel, and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities. The Company's estimates include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

Other Incentives — Other incentives which the Company offers include voluntary patient support programs, such as the Company's co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with the products that have been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses and other current liabilities.

Revenue Recognition — Revenue — Collaborations and Services — The Company enters into licensing, research or other agreements under which the Company licenses certain rights to its product candidates to third parties, conducts research or provides other services to third parties. The terms of these arrangements may include but are not limited to payment to the Company of one or more of the following: up-front license fees; development, regulatory, and commercial milestone payments; payments for commercial manufacturing and clinical supply services the Company provides; and royalties on net sales of licensed products and sublicenses of the rights. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment such as determining the performance obligation in the contract and determining the stand-alone selling price for each performance obligation identified in the contract. With respect to the Company's significant collaboration and service agreement with UT that includes a long-term commercial supply agreement (as amended, the "CSA"), the Company has identified three distinct performance obligations: (1) the license, supply of product to be used in clinical development, and continued development and approval support for Tyvaso DPI ("R&D Services and License"); (2) development activities for the next generation of the product ("Next-Gen R&D Services"); and (3) a material right associated with current and future manufacturing and supply of product ("Manufacturing Services and Product Sales"). Pre-production activities under the CSA, such as facility expansion services and other administrative services, were considered bundled services under the Manufacturing Services and Product Sales performance obligation as required by ASC 606. Following the FDA's approval of Tyvaso DPI, UT began issuing purchase orders for the supply of product, which represents distinct contracts and performance obligations under ASC 606. Revenue is recognized for the supply of product at a point in time, once control is transferred to UT. See Note 9 – *Collaboration, Licensing and Other Arrangements.*

If an arrangement has multiple performance obligations, the allocation of the transaction price is determined from observable market inputs, and the Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. Revenue is recognized based on the measurement of progress as the performance obligation is satisfied and consideration received that does not meet the requirements to satisfy the revenue recognition criteria is recorded as deferred revenue. Current deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. For further information, see Note 9 – *Collaboration, Licensing and Other Arrangements*.

The Company recognizes upfront license payments as revenue upon delivery of the license only if the license is determined to be a separate unit of accounting from the other undelivered performance obligations. The undelivered performance obligations typically include manufacturing or development services or research and/or steering committee services. If the license is not considered as a distinct performance obligation, then the license and other undelivered performance obligations would be evaluated to determine if such should be accounted for as a single unit of accounting. If concluded to be a single performance obligation, the transaction price for the single performance obligation is recognized as revenue over the estimated period of when the performance obligation is satisfied. If the license is considered to be a distinct performance obligation, then the estimated revenue is included in the transaction price for the contract, which is then allocated to each performance obligation based on the respective standalone selling prices.

Whenever the Company determines that an arrangement should be accounted for over time, the Company determines the period over which the performance obligations will be performed, and revenue will be recognized over the period the Company is expected to complete its performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

The Company's collaboration agreements typically entitle the Company to additional payments upon the achievement of development, regulatory and sales milestones. If the achievement of a milestone is considered probable at the inception of the collaboration, the related milestone payment is included with other collaboration consideration, such as upfront fees and research funding, in the Company's revenue calculation. If these milestones are not considered probable at the inception of the collaboration, the milestones will typically be recognized in one of two ways depending on the timing of when the milestone is achieved. If the milestone is improbable at inception and subsequently deemed probable of achievement, such will be added to the transaction price, resulting in a cumulative adjustment to revenue. If the milestone is achieved after the performance period has been completed and all performance obligations have been delivered, the Company will recognize the milestone payment as revenue in its entirety in the period the milestone was achieved.

The Company's collaboration agreements, for accounting purposes, represent contracts with customers and therefore are not subject to accounting literature on collaboration agreements. The Company grants licenses to its intellectual property, supplies raw materials, semi-finished goods or finished goods, provides research and development services and offers sales support for the co-promotion of products, all of which are outputs of the Company's ongoing activities, in exchange for consideration. Accordingly, the Company concluded that its collaboration agreements must generally be accounted for pursuant to ASC 606.

For collaboration agreements that allow collaboration partners to select additional optioned products or services, the Company evaluates whether such options contain material rights (i.e., have exercise prices that are discounted compared to what the Company

would charge for a similar product or service to a new collaboration partner). The exercise price of these options includes a combination of licensing fees, event-based milestone payments and royalties. When these amounts in aggregate are not offered at a discount that exceeds discounts available to other customers, the Company concludes the option does not contain a material right, and therefore is not included in the transaction price at contract inception. The Company assessed the long-term commercial supply agreement with UT (as amended, the "CSA") and determined that a material right existed for the manufacturing services performance obligation. The transaction price is allocated to the material right as well as the remaining performance obligations in accordance with ASC 606. The Company also evaluates grants of additional licensing rights upon option exercises to determine whether such should be accounted for as separate contracts.

Revenue Recognition — Royalties — The Company recognizes royalty revenue for a sales-based or usage-based royalty if it is promised in exchange for an intellectual property license. The royalty revenue is recognized as the latter of the subsequent sale of the product occurs or if the performance obligation to which the royalty has been allocated has been satisfied or partially satisfied. The Company's UT License Agreement (as defined in Note 9 – *Collaboration, Licensing and Other Arrangements*) entitles it to receive a 10% royalty on net sales of Tyvaso DPI for the license of the Company's IP that was considered to be interdependent with the development activities that supported the approval of Tyvaso DPI. Although the Company recognizes a 10% royalty on net revenue from the sale of Tyvaso DPI as revenue, it will only collect 9% of future royalties due to its sale of 1% of future royalties in December 2023 as detailed in Note 14 – *Commitments and Contingencies*.

The Company's net revenue and cost of revenue and goods sold as shown on the condensed consolidated statement of operations is comprised of revenue generated from product sales, services and royalties as shown below (in thousands):

	Three Months Ended March 31,	
	2024	2023
Net revenue:		
Product revenue [1]	$ 43,228	$ 28,726
Services [2]	384	222
Royalties [3]	22,651	11,678
Total net revenue	$ 66,263	$ 40,626

(1) Amounts represent the revenue from Afrezza and V-Go sales to wholesalers and specialty pharmacies and Tyvaso DPI to UT.
(2) Amounts represent revenue generated from the Company's collaboration arrangements, including Next-Gen R&D Services (as defined in Note 9) for UT as well as arrangements with other collaboration partners. See Note 9 – *Collaboration, Licensing and Other Arrangements*.
(3) Amounts represent royalties on UT's net revenue from Tyvaso DPI sales.

	Three Months Ended March 31,	
	2024	2023
Cost of goods sold and cost of revenue:		
Product revenue	$ 18,598	$ 16,028
Services	—	185
Total cost of goods sold and cost of revenue	$ 18,598	$ 16,213

The Company follows accounting guidance in measuring revenue and certain judgments affect the application of its revenue policy. For example, in connection with its existing collaboration agreements, the Company has recorded on its condensed consolidated balance sheets short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on the Company's current project development plan and, if the development plan should change in the future, the Company may recognize a different amount of deferred revenue over the next 12-month period.

Milestone Payments — At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its

estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration, other revenue, and earnings in the period of adjustment.

Cost of Goods Sold — Cost of goods sold includes material, labor costs and manufacturing overhead. Cost of goods sold also includes a component of current period manufacturing costs in excess of costs capitalized into inventory ("excess capacity costs"). These costs, in addition to the impact of the revaluation of inventory for standard costing, and write-offs of inventory are recorded as expenses in the period in which they are incurred, rather than as a portion of inventory costs. Cost of goods sold excludes the cost of insulin purchased under the Company's Insulin Supply Agreement (the "Insulin Supply Agreement") with Amphastar Pharmaceuticals, Inc. ("Amphastar"). All insulin inventory on hand was written off and the full purchase commitment contract to purchase future insulin was accrued as a recognized loss on purchase commitments as of the end of 2016.

Cost of Revenues — Collaborations and Services — Cost of revenues for collaborations and services includes material, labor costs, manufacturing overhead, and excess capacity costs. These costs, in addition to the write-offs of inventory are recorded as expenses in the period in which they are incurred, rather than as a portion of inventory costs. Cost of revenues for collaborations and services also includes the cost of product development.

Research and Development ("R&D") — Clinical trial expenses result from obligations under contracts with vendors, consultants and clinical site agreements in addition to internal costs associated with conducting clinical trials. R&D costs are expensed as incurred. Clinical study and certain research costs are recognized over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Nonrefundable advance payments for services to be received in the future for use in R&D activities are recorded as prepaid assets and expensed in the period when the services are performed.

Cash and Cash Equivalents — The Company considers all highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash to be cash equivalents. As of March 31, 2024 and December 31, 2023, cash equivalents were comprised of money market funds, U.S. Treasury securities, corporate bonds and commercial paper with original maturities less than 90 days from the date of purchase.

Held-to-Maturity Investments — The Company's investments generally consisted of commercial paper, corporate notes or bonds and U.S. Treasury securities. As of March 31, 2024 and December 31, 2023, the Company held short-term and long-term investments of debt securities, including commercial paper and bonds. The Company assesses whether it has any intention to sell the investment before maturity, whether any declines in fair value are the result of credit losses, as well as whether there were other-than-temporary impairments associated with the available-for-sale investment. The Company intends to hold its investments until maturity; therefore, these investments are stated at amortized cost. The investments with maturities less than 12 months are included in short-term investments and investments with maturities in excess of twelve months are included in long-term investments in the condensed consolidated balance sheets. The amortization or accretion of the Company's investments is recognized as interest income in the condensed consolidated statements of operations.

Available-for-Sale Investment — In June 2021, the Company purchased a $3.0 million convertible promissory note (the "Thirona convertible note") issued by Thirona Bio, Inc. ("Thirona"). In January 2022, the Company purchased an additional $5.0 million convertible promissory note issued by Thirona. Unless earlier converted into conversion shares pursuant to the note purchase agreement, the aggregate principal of $8.0 million and accrued interest shall be due and payable by Thirona on demand by the Company at any time after the maturity date. The Thirona convertible notes were amended in February 2023 to extend the maturity date from December 31, 2022 to June 30, 2024. The Thirona convertible notes are general unsecured obligations of Thirona and accrue interest at a rate of 6% per annum. The Thirona convertible notes are classified as available-for-sale securities and are included in prepaid expenses and other current assets in the condensed consolidated balance sheets. The Company periodically assesses whether it has any intention to sell the investment, determines the fair value of its available-for-sale investments using level 3 inputs and assesses whether there were other-than-temporary impairments associated with the investment. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income until realized, while unrealized losses related to credit risk are reported through earnings in the period incurred. In June 2021, the Company and Thirona also entered into a collaboration agreement to develop a compound for the treatment of fibrotic pulmonary diseases. See Note 9 – *Collaboration, Licensing and Other Arrangements*.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consisted of cash and cash equivalents and investments. Cash and cash equivalents are held in high credit quality institutions. Cash equivalents consisted of interest-bearing money market funds and U.S. Treasury securities with original or remaining maturities of 90 days or less at the time of purchase. Investments generally consisted of commercial paper, corporate notes or bonds and U.S. Treasury securities. The cash equivalents and investments are regularly monitored by management.

Accounts Receivable and Allowance for Credit Losses — Accounts receivable are recorded at the invoiced amount and are not interest bearing. Accounts receivable are presented net of an allowance for credit losses if there are estimated losses resulting from the inability of its customers to make required payments. The Company makes ongoing assumptions relating to the collectability of its accounts receivable in its calculation of the allowance for credit losses. The allowance for expected credit losses is based primarily on past collections experience relative to the length of time receivables are past due. However, when available evidence reasonably supports an assumption that future economic conditions will differ from current and historical payment collections, an adjustment is reflected in the allowance for expected credit losses. Accounts receivable are also presented net of an allowance for product returns and trade discounts and allowances because the Company's customers have the right of setoff for these amounts against the related accounts receivable.

Pre-Launch Inventory — An improvement to the manufacturing process for the Company's primary excipient, fumaryl diketopiperazine ("FDKP") was demonstrated to be viable and management expects to realize an economic benefit in the future as a result of such process improvement. Accordingly, the Company is required to assess whether to capitalize inventory costs related to such excipient prior to validation of the improved manufacturing process and adoption of the new supplier. In doing so, management must consider a number of factors in order to determine the amount of inventory to be capitalized, including the historical experience of modifying the Company's manufacturing processes, feedback from technical experts and regulatory agencies on the changes being effected and the amount of inventory that is likely to be used in commercial production. The shelf life of the excipient will be determined as part of the validation process; in the interim, the Company must assess the available stability data to determine whether there is likely to be adequate shelf life to support anticipated future sales occurring beyond the expected adoption date of the new raw material. If management is aware of any specific material risks or contingencies other than the normal regulatory reporting process, or if the criteria for capitalizing inventory produced prior to regulatory approval are otherwise not met, the Company would not capitalize such inventory costs, choosing instead to recognize such costs as R&D expense in the period incurred.

Inventories — Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products based on management's judgment that future economic benefits are expected to be realized; otherwise, such costs are expensed as incurred as cost of goods sold. The Company uses a contract manufacturing organization outside of the U.S. for certain stages of V-Go inventory.

The Company periodically analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value and writes down such inventories, as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or may become obsolete or are forecasted to become obsolete due to expiration, the Company will record a charge to write down such unmarketable inventory to its estimated net realizable value. The Company analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. The Company performs an assessment of projected sales and evaluates the lower of cost or net realizable value and the potential excess inventory on hand at the end of each reporting period.

Property and Equipment — Property and equipment is recorded at historical cost, net of accumulated depreciation. Depreciation expense is recorded over the assets' useful lives on a straight-line basis. See Note 5 – *Property and Equipment*.

Impairment of Long-Lived Assets — Long-lived assets include property and equipment, operating lease right-of-use assets and other intangible assets. The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Assets are considered to be impaired if the carrying value is considered to be unrecoverable.

If the Company believes an asset to be impaired, the impairment recognized is the amount by which the carrying value of the asset exceeds the fair value of the asset. Fair value is determined using the market, income or cost approaches as appropriate for the asset. Any write-downs are treated as permanent reductions in the carrying amount of the asset and recognized as an operating loss.

Acquisitions — The Company first determines whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired do not constitute a business, the Company accounts for the transaction as an asset acquisition. Business combinations are accounted for by means of the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process R&D ("IPR&D") projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's condensed consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination (including the assumption of an acquiree's liability arising from an acquisition it consummated prior to the Company's acquisition) are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies have been resolved. The resulting changes in fair values are recorded in earnings. In contrast, asset acquisitions are accounted for by using a cost accumulation and allocation model. Under this model, the cost of the acquisition is allocated to the assets acquired and liabilities assumed. IPR&D projects with no alternative future

use are recorded in R&D expense upon acquisition, and contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated.

Goodwill and Other Intangible Assets — The fair value of acquired intangible assets is determined using an income-based approach referred to as the excess earnings method utilizing Level 3 fair value inputs. Market participant valuations assume a global view considering all potential jurisdictions and indications based on discounted after-tax cash flow projections, risk adjusted for estimated probability of technical and regulatory success.

The Company tests for impairment annually on a reporting unit basis, at the beginning of the Company's fourth fiscal quarter and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying amount. To the extent the carrying amount of a reporting unit is less than its estimated fair value, an impairment charge will be recorded.

Finite-lived intangible assets are amortized on a straight-line basis over the estimated useful life. Estimated useful lives are determined considering the period assets are expected to contribute to future cash flows. Finite-lived intangible assets are tested for impairment when facts or circumstances suggest that the carrying value of the asset may not be recoverable. If the carrying value exceeds the projected undiscounted pretax cash flows of the intangible asset, an impairment loss equal to the excess of the carrying value over the estimated fair value (discounted after-tax cash flows) is recognized.

Recognized Loss on Purchase Commitments — The Company reviews the terms of the long-term supply agreements and assesses the need for any accrual for estimated losses, such as lower of cost or net realizable value, that will not be recovered by future product sales. The recognized loss on purchase commitments is reduced as inventory items are received or as the liability is extinguished. See Note 14 – *Commitments and Contingencies*.

Milestone Rights Liability — In July 2013, in conjunction with the execution of a (now repaid) loan agreement with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (collectively, "Deerfield"), the Company entered into a Milestone Rights Purchase Agreement (the "Milestone Rights Agreement") pursuant to which the Company issued certain milestone rights to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÀRL (the "Original Milestone Purchasers"). The foregoing milestone rights provided the Original Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and Afrezza sales milestones, $55.0 million of which remains payable as of March 31, 2024 upon achievement of such milestones (collectively, the "Milestone Rights"). In December 2021, the Milestone Rights were purchased by Barings Global Special Situations Credit Fund 4 (Delaware), L.P. and Barings Global Special Situations Credit 4 (LUX) S.ar.l. (together the "Milestone Purchasers"). As a result, the Milestone Purchasers have assumed the obligations of the Original Milestone Purchasers and are now entitled to all rights under the Milestone Rights Agreement. The Milestone Rights liability is reported at fair value at the date of the agreement which is periodically offset against payments. See Note 10 – *Fair Value of Financial Instruments*.

The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones and discounted to present value using a selected market discount rate. The expected timing and probability of achieving the milestones was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. The Milestone Rights liability will be remeasured as the specified milestone events are achieved. Specifically, as each milestone event is achieved, the portion of the initially recorded Milestone Rights liability that pertains to the milestone event being achieved, will be remeasured to the amount of the specified related milestone payment. The resulting change in the balance of the Milestone Rights liability due to remeasurement will be recorded in the Company's condensed consolidated statements of operations as interest expense. Furthermore, the Milestone Rights liability will be reduced upon the settlement of each milestone payment. As a result, each milestone payment would be effectively allocated between a reduction of the recorded Milestone Rights liability and an expense representing a return on a portion of the Milestone Rights liability paid to the investor for the achievement of the related milestone event. See Note 7 – *Accrued Expenses and Other Current Liabilities* and Note 14 – *Commitments and Contingencies*.

Fair Value of Financial Instruments — The Company applies various valuation approaches in determining the fair value of its financial assets and liabilities within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 — Quoted prices for identical instruments in active markets.

Level 2 — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 — Significant inputs to the valuation model are unobservable.

Income Taxes — The provisions for federal, foreign, state and local income taxes are calculated on pre-tax income based on current tax law and include the cumulative effect of any changes in tax rates from those used previously in determining deferred tax assets and liabilities. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized.

For uncertain tax positions, the Company determines whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. For those tax positions where it is "not more likely than not" that a tax benefit will be sustained, no tax benefit is recognized. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense. The Company has reduced its deferred tax assets for uncertain tax positions but has not recorded liabilities for income tax expense, penalties, or interest.

Contingencies — The Company records a loss contingency for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These accruals represent management's best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation and may revise its estimates.

Stock-Based Compensation — Share-based payments to employees, including grants of restricted stock units ("RSUs"), performance-based non-qualified stock options awards ("PNQs"), restricted stock units with market conditions ("Market RSUs"), options and the compensatory elements of employee stock purchase plans, are recognized in the condensed consolidated statements of operations based upon the fair value of the awards at the grant date. RSUs are valued based on the market price on the grant date. Market RSUs are valued using a Monte Carlo valuation model and RSUs with performance conditions are evaluated for the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans.

Clinical Trial Expenses — Clinical trial expenses, which are primarily reflected in R&D expenses in the condensed consolidated statements of operations, result from obligations under contracts with vendors, consultants and clinical site agreements in addition to internal costs associated with conducting clinical trials.

Net Income (Loss) Per Share of Common Stock — Basic net income or loss per share ("EPS") is calculated by dividing net income by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the effect of potential common stock issuances resulting from assumed stock option exercises and vesting of restricted stock units, unless the effect is anti-dilutive, when applying the treasury stock method, as well as potential dilution under the if-converted method for convertible debt securities. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted EPS as they would be anti-dilutive.

Recently Issued Accounting Standards — From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company

believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condensed consolidated financial position or results of operations upon adoption.

2. Investments

Cash Equivalents — Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase that are readily convertible into cash.

Available-for-Sale Investment — The Thirona convertible notes are classified as available-for-sale securities and are included in prepaid expenses and other current assets in the condensed consolidated balance sheets. Available-for-sale investments are subsequently measured at fair value with realized gains and losses reported in other income (expense) in the condensed consolidated statements of operations. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income (loss) until realized. The Company determines the fair value of its available-for-sale investments using level 3 inputs and evaluates the fair value of its investment in Thirona by applying a scenario based method. For the three months ended March 31, 2023, the Company recognized $0.1 million of interest income on investment. No interest income on investment was recognized during the three months ended March 31, 2024. The Company's investment in Thirona is comprised of two notes with aggregate face value of $8.0 million and stated interest rate of 6%. As of March 31, 2024 and December 31, 2023, the fair value of the Company's investment in Thirona was $6.9 million. No gains or losses from credit risk or unrealized holding gains or losses were recognized during the three months ended March 31, 2024 or 2023.

Held-to-Maturity Investments — Investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. The amortization or accretion of the Company's investments is recognized in the condensed consolidated statements of operations as interest income, which was approximately $3.4 million and $1.2 million for the three months ended March 31, 2024 and 2023, respectively. No allowance for credit losses on held-to-maturity securities was required as of March 31, 2024 or December 31, 2023.

The contractual maturities of the Company's held-to-maturity investments are summarized below (in thousands):

	March 31, 2024		December 31, 2023	
	Amortized Cost Basis	Aggregate Fair Value	Amortized Cost Basis	Aggregate Fair Value
Due in one year or less[1]	$ 241,962	$ 241,970	$ 115,263	$ 115,374
Due after one year through five years	3,726	3,771	7,155	7,197
Total	$ 245,688	$ 245,741	$ 122,418	$ 122,571

(1) The investments due in one year or less include cash equivalents of $134.5 million as of March 31, 2024 and $58.6 million as of December 31, 2023.

The fair value of the cash equivalents, long-term and short-term investments are disclosed below (dollars in thousands).

		March 31, 2024			
	Investment Level	Amortized Cost (Carrying Value)	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Money market funds and other	Level 1	$ 95,389	$ —	$ —	$ 95,389
Commercial bonds and paper	Level 2	51,485	93	(71)	51,507
U.S. Treasury Securities	Level 2	98,814	56	(25)	98,845
Total cash equivalents and investments		245,688	149	(96)	245,741
Less: cash equivalents		(134,505)	—	—	(134,505)
Total Investments		$ 111,183	$ 149	$ (96)	$ 111,236

		December 31, 2023			
	Investment Level	Amortized Cost (Carrying Value)	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Money market funds	Level 1	$ 69,611	$ —	$ —	$ 69,611
Commercial bonds and paper	Level 2	43,251	135	(38)	43,348
U.S. Treasury Securities	Level 2	9,556	56	—	9,612
Total cash equivalents and investments		122,418	191	(38)	122,571
Less: cash equivalents		(58,644)	—	—	(58,644)
Total Investments		$ 63,774	$ 191	$ (38)	$ 63,927

As of March 31, 2024 and December 31, 2023, there was $0.6 million and $0.5 million, respectively, of accrued interest receivable on investments which is included in prepaid expense and other current assets in our condensed consolidated balance sheets.

3. Accounts Receivable

Accounts receivable, net consists of the following (in thousands):

	March 31, 2024	December 31, 2023
Accounts receivable – commercial		
Accounts receivable, gross	$ 17,516	$ 20,199
Wholesaler distribution fees and prompt pay discounts	(2,252)	(2,469)
Reserve for returns	(5,597)	(6,215)
Allowance for credit losses	(157)	(157)
Total accounts receivable – commercial, net	9,510	11,358
Accounts receivable – collaborations and services	10,402	3,543
Total accounts receivable, net	$ 19,912	$ 14,901

As of March 31, 2024 and December 31, 2023, the allowance for credit losses and doubtful accounts for commercial accounts receivable of $0.2 million was related to $0.2 million of accounts receivable for Zealand Pharma US, Inc. As of March 31, 2024, the Company had three wholesale distributors representing approximately 78% of commercial accounts receivable and 70% of gross sales during the three months ended March 31, 2024.

As of March 31, 2024 and December 31, 2023, there was no allowance for credit losses for accounts receivable for collaborations and services. The Company had one collaboration partner, UT, that comprised 100% of the collaboration and services net accounts receivable as of March 31, 2024 and December 31, 2023 and approximately 100% of gross revenue from collaborations and services for the three months ended March 31, 2024 and 2023.

4. Inventories

Inventories consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 5,770	$ 6,262
Work-in-process	12,310	13,646
Finished goods	8,362	8,637
Total inventory	$ 26,442	$ 28,545

Work-in-process and finished goods as of March 31, 2024 and December 31, 2023 include conversion costs and exclude the cost of insulin. All insulin inventory on hand was written off and the projected loss on the purchase commitment contract to purchase future insulin was accrued as of the end of 2016. Raw materials inventory included $0.8 million of pre-launch inventory as of March 31, 2024 and December 31, 2023, which consisted of FDKP received in November 2019.

The Company analyzed its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. The Company also performed an assessment of projected sales and evaluated the lower of cost or net realizable value and the potential excess inventory on hand as of March 31, 2024 and December 31, 2023. Inventory that was forecasted to become obsolete due to expiration as well as inventory that does not meet acceptable standards is recorded in costs of goods sold in the condensed consolidated statements of operations and a reserve for inventory in the condensed consolidated balance sheets. As a result of this assessment there were inventory write-offs of $1.0 million and $2.4 million for the three months ended March 31, 2024 and 2023, respectively.

5. Property and Equipment

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

	Estimated Useful Life (Years)	March 31, 2024	December 31, 2023
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	60,833	46,357
Machinery and equipment	3-15	62,984	60,410
Furniture, fixtures and office equipment	5-10	3,070	3,070
Computer equipment and software	3	8,677	8,658
Construction in progress	—	32,617	48,997
Total property and equipment		186,445	185,756
Less accumulated depreciation		(102,825)	(101,536)
Total property and equipment, net		$ 83,620	$ 84,220

Depreciation expense related to property and equipment was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Depreciation Expense	$ 1,341	$ 1,038

During the three months ended March 31, 2024, the Company retired $0.1 million of manufacturing equipment as it was no longer in service. The net book value for the disposed assets was *de minimis*. There were no asset retirements during the three months ended March 31, 2023.

6. Goodwill and Other Intangible Asset

Goodwill — Goodwill represents the excess of the purchase price over the identifiable tangible and intangible assets acquired plus liabilities assumed arising from business combinations. The balance of goodwill was approximately $1.9 million as of March 31, 2024 and December 31, 2023 as a result of the Company's acquisition of V-Go in May 2022. Goodwill is tested at least annually for impairment by assessing qualitative factors in determining whether it is more likely than not that the fair value of net assets is below their carrying amounts. See Note 1 – *Description of Business and Significant Accounting Policies*.

Other Intangible Asset — Other intangible asset consisted of the following (in thousands):

	Estimated Useful Life (Years)	March 31, 2024			December 31, 2023		
		Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Developed technology	15	$ 1,200	$ (147)	$ 1,053	$ 1,200	$ (127)	$ 1,073

Amortization expense related to the other intangible asset was *de minimis* for the three months ended March 31, 2024 and 2023.

The estimated annual amortization expense for the other intangible asset for the years ended December 31, 2024 through 2028 will be approximately $0.1 million per year and $0.6 million, thereafter.

The Company evaluates its other intangible asset for potential impairment when events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. See Note 1 – *Description of Business and Significant Accounting Policies*.

7. Accrued Expenses and Other Current Liabilities

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

	March 31, 2024	December 31, 2023
Salary and related expenses	$ 20,821	$ 19,506
Discounts and allowances for commercial product sales	8,800	9,541
Accrued interest	680	2,153
State income tax liability	1,825	1,561
Deferred lease liability	1,611	1,423
Professional fees	604	979
Current portion of milestone rights liability	752	752
Returns reserve for acquired product[(1)]	1,633	601
Danbury facility buildout	98	316
Other	5,467	5,204
Accrued expenses and other current liabilities	$ 42,291	$ 42,036

(1) See Note 14 – *Commitments and Contingencies.*

8. Borrowings

Carrying amount of the Company's borrowings consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Senior convertible notes	$ 227,214	$ 226,851
MidCap credit facility	28,105	33,019
Mann Group convertible note	8,829	8,829
Total debt – net carrying amount	$ 264,148	$ 268,699

The following table provides a summary of the Company's principal balance of debt and key terms:

	Amount Due		Terms		
	March 31, 2024	December 31, 2023	Annual Interest Rate	Maturity Date	Conversion Price
Senior convertible notes	$230.0 million	$230.0 million	2.50%	March 2026	$5.21 per share
MidCap credit facility	$28.3 million	$33.3 million	one-month SOFR (1% floor) plus 6.25%; cap of 8.25%	August 2025	N/A
Mann Group convertible note	$8.8 million	$8.8 million	2.50%	December 2025	$2.50 per share

In early April 2024, the Company repaid all obligations owed under the MidCap credit facility and the Mann Group convertible notes. See Note 16 – *Subsequent Events*.

The maturities of the Company's borrowings as of March 31, 2024 are as follows (in thousands):

	Amounts
Remainder of 2024	$ 15,000
2025	22,163
2026	230,000
Total principal payments	267,163
Unamortized discount and prepayment fee	(155)
Debt issuance costs	(2,860)
Total debt	$ 264,148

Senior convertible notes – In March 2021, the Company issued $230.0 million aggregate principal amount of Senior convertible notes in a private offering. The Senior convertible notes were issued pursuant to an indenture, dated March 4, 2021 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee.

The Senior convertible notes are general unsecured obligations of the Company and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased by the Company. The Senior convertible notes will bear cash interest from March 4, 2021 at an annual rate of 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021. The Senior convertible notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding December 1, 2025, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2021 (and only during such calendar quarter), if the last reported sale price of the Company's common stock, par value $0.01 per share, for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the Senior convertible notes on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period in which the trading price (as defined in the Indenture) per $1,000 principal amount of the Senior convertible notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the common stock and the conversion rate on each such trading day; (3) if the Company calls such Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date, but only with respect to the Senior convertible notes called (or deemed called) for redemption; or (4) upon the occurrence of specified corporate events as set forth in the Indenture. On or after December 1, 2025 until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, in the manner and subject to the terms and conditions provided in the Indenture.

The initial conversion rate is 191.8281 shares of common stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $5.21 per share of common stock). The initial conversion price of the Senior convertible notes represents a premium of approximately 30% to the last reported sale price of the common stock on the Nasdaq Global Market on March 1, 2021. The conversion rate for the Senior convertible notes is subject to adjustment under certain circumstances in accordance with the terms of the Indenture, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date of the Senior convertible notes or if the Company delivers a notice of redemption in respect of the Senior convertible notes, the Company will, in certain circumstances, increase the conversion rate of the Senior convertible notes for a holder who elects to convert its Senior convertible notes in connection with such a corporate event or convert its Notes called for redemption during the related redemption period (as defined in the Indenture), as the case may be.

The Company may not redeem the Senior convertible notes prior to March 6, 2024. The Company may redeem for cash all or any portion of the Senior convertible notes, at its option, on or after March 6, 2024 and prior to the 36th scheduled trading day immediately preceding the maturity date, if the last reported sale price of common stock has been at least 130% of the conversion price for the Senior convertible notes then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Senior convertible notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. If the Company elects to redeem less than all of the outstanding Senior convertible notes, at least $75.0 million aggregate principal amount of Senior convertible notes must be outstanding and not subject to redemption as of the relevant redemption notice date. No sinking fund is provided for the Senior convertible notes.

If the Company undergoes a fundamental change (as defined in the Indenture), then, subject to certain conditions and except as described in the Indenture, holders may require the Company to repurchase for cash all or any portion of their Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Senior convertible notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Indenture includes customary covenants and sets forth certain events of default after which the Senior convertible notes may be declared immediately due and payable.

If certain bankruptcy and insolvency-related events of default involving the Company (and not just any of its significant subsidiaries) occur, 100% of the principal of and accrued and unpaid interest on the Senior convertible notes will automatically become due and payable. If an event of default with respect to the Senior convertible notes, other than certain bankruptcy and insolvency-related events of default involving the Company (and not just any of its significant subsidiaries), occurs and is continuing, the trustee, by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Senior convertible notes by notice to the Company and the trustee, may, and the trustee at the request of such holders shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Senior convertible notes to be due and payable. Notwithstanding the foregoing, the Indenture provides that,

to the extent the Company so elects, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture will, for the first 365 days after the occurrence of such an event of default consist exclusively of the right to receive additional interest on the Senior convertible notes as set forth in the Indenture.

The Indenture provides that the Company shall not consolidate with or merge with or into, or sell, convey, transfer or lease all or substantially all of the consolidated properties and assets of the Company and its subsidiaries, taken as a whole, to, another person (other than any such sale, conveyance, transfer or lease to one or more of the Company's direct or indirect wholly owned subsidiaries), unless: (i) the resulting, surviving or transferee person (if not the Company) is a corporation organized and existing under the laws of the United States of America, any State thereof or the District of Columbia, and such corporation (if not the Company) expressly assumes by supplemental indenture all of the Company's obligations under the Senior convertible notes and the Indenture; and (ii) immediately after giving effect to such transaction, no default or event of default has occurred and is continuing under the Indenture.

The Company's net proceeds from the March 2021 offering were approximately $222.7 million, after deducting the initial purchasers' discounts and commissions and the estimated offering expenses payable by the Company. As of March 31, 2024, the unamortized debt issuance cost was $2.8 million.

MidCap credit facility — In August 2019, the Company entered into the MidCap credit facility and borrowed the first advance of $40.0 million ("Tranche 1") in August 2019 and the second advance of $10.0 million ("Tranche 2") in December 2020. In April 2021, $10.0 million was prepaid. Under the terms of the MidCap credit facility, a third advance of $60.0 million ("Tranche 3") became available to the Company after the Tyvaso DPI approval by the FDA through June 30, 2022 (see Note 9 – *Collaboration, Licensing and Other Arrangements*). The Company did not exercise its right to borrow Tranche 3.

In connection with an April 2021 amendment to the MidCap credit facility, the Company made a $10.0 million principal prepayment against outstanding term loans under the MidCap credit facility and paid a related $1.0 million exit fee in lieu of the unaccrued portion of the original exit fee and prepayment penalties that would otherwise have been due with respect to the partial prepayment. The prepayment penalty of $1.0 million related to the payment of $10.0 million was capitalized and amortized over the remaining life of the debt. As of March 31, 2024, the unamortized debt discount was $0.1 million and the unamortized prepayment penalty was $0.2 million.

Tranche 1 and Tranche 2 accrued interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month Secured Overnight Financing Rate ("SOFR") (subject to a one-month SOFR floor of 1.00%) plus 6.25%. Interest on each term loan advance was due and payable monthly in arrears. Principal on each term loan advance under Tranche 1 and Tranche 2 was payable in 24 equal monthly installments that began September 1, 2023.

On April 1, 2024, the Company exercised its option to prepay the existing term loans in whole in exchange for a payment of approximately $31.6 million, which included an early termination fee in an amount equal to 1.00% of principal prepaid as well as an exit fee in an amount equal to 7.00% of the initial Tranche 1 balance of $40.0 million. See Note 16 – *Subsequent Events*.

The Company's obligations under the MidCap credit facility were secured by a security interest on substantially all of its assets, including intellectual property, all of which were released as of April 2, 2024.

The MidCap credit facility, as amended, contained customary affirmative covenants and customary negative covenants limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, dispose of assets, undergo a change in control, merge or consolidate, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The Company was also required to comply with a financial covenant relating to trailing twelve month minimum Afrezza net revenue, tested on a monthly basis, unless the Company has $90.0 million or more of unrestricted cash and short-term investments. As of March 31, 2024, the Company was in compliance with the financial covenant.

The MidCap credit facility also contained customary events of default relating to, among other things, payment defaults, breaches of covenants, a material adverse change, listing of the Company's common stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments, and inaccuracies of representations and warranties. Upon an event of default, the agent and the lenders could have declared all or a portion of the Company's outstanding obligations to be immediately due and payable and exercise other rights and remedies provided for under the MidCap credit facility. During the existence of an event of default, interest on the term loans could have been increased by 2.00%.

Mann Group convertible note — In August 2019, the Company issued a $35.0 million note that is convertible into shares of the Company's common stock at $2.50 per share (the "Mann Group convertible note") as part of a restructuring of its then existing indebtedness to Mann Group.

The Mann Group convertible note accrued interest at the rate of 2.5% per year on the principal amount, payable quarterly in arrears on the first day of each calendar quarter, with a maturity date of December 31, 2025.

The principal and any accrued and unpaid interest under the Mann Group convertible note was convertible, at the option of Mann Group, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date, into shares of the Company's common stock at a conversion rate of 400 shares per $1,000 of principal and/or accrued and unpaid interest, which is equal to a conversion price of $2.50 per share. Interest on the convertible note was payable in kind by adding the amount thereof to the principal amount; provided that with respect to interest accruing from and after January 1, 2021, the Company had the option to pay any such interest on any interest payment date, if certain conditions are met, in shares of the Company's common stock at a price per shall equal to the last reported sale price on the trading day immediately prior to the payment date.

During the three months ended March 31, 2023, Mann Group converted $0.1 million of interest into 10,491 shares of common stock. During the three months ended March 31, 2024, Mann group converted $0.1 million of interest into 15,285 shares of common stock. On April 2, 2024, the Company and Mann Group agreed to discharge and terminate the Mann Group convertible note in exchange for (i) the Company's issuance to Mann Group of 1,500,000 shares of the Company's common stock and (ii) the Company's payment to Mann Group of approximately $8.9 million. See Note 16 – *Subsequent Events*.

Amortization of the premium and accretion of debt issuance costs related to all borrowings were as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Amortization of debt discount and prepayment fee	$ 85	$ 106
Amortization of debt issuance cost	363	363

9. Collaboration, Licensing and Other Arrangements

Revenue from collaborations and services were as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
UT CSA[(1)]	$ 24,464	$ 11,164
UT License Agreement [(2)]	347	185
Cipla License and Distribution Agreement	37	37
Total revenue from collaborations and services	$ 24,848	$ 11,386

(1) Amounts consist of revenue recognized for Manufacturing Services and Product Sales to UT for the periods presented.
(2) Amounts consist of revenue recognized for Next-Gen R&D Services and R&D Services and License for the periods presented.

United Therapeutics License Agreement — In September 2018, the Company and UT entered into an exclusive global license and collaboration agreement (the "UT License Agreement"), pursuant to which UT is responsible for global development, regulatory and commercial activities with respect to Tyvaso DPI. The Company is responsible for manufacturing Tyvaso DPI.

Total revenue from UT was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
UT Revenue		
UT CSA	$ 24,464	$ 11,164
UT License Agreement	347	185
Royalties — Collaborations [(1)]	22,651	11,678
Total revenue from UT	$ 47,462	$ 23,027

(1) Amounts consist of royalties associated with the UT License Agreement. The contract assets related to the royalties is included in prepaid expense and other current assets in the condensed consolidated balance sheets.

In October 2018, the Company and UT entered into the UT License Agreement for the collaboration and development of Tyvaso DPI. Pursuant to this agreement, the Company receives a 10% royalty on net sales of Tyvaso DPI. In December 2023, the Company sold a

1% royalty on future net sales of Tyvaso DPI to a royalty purchaser, with the Company retaining a 9% royalty. In August 2021, the Company and UT entered into the CSA, pursuant to which the Company is responsible for manufacturing and supplying to UT, and UT is responsible for purchasing from the Company on a cost-plus basis. In addition, UT is responsible for supplying treprostinil at its expense in quantities necessary to enable the Company to manufacture Tyvaso DPI as required by the CSA.

The activities and deliverables under the CSA and UT License Agreement resulted in distinct performance obligations which include the: (1) R&D Services and License, (2) Next-Gen R&D Services, and (3) Manufacturing Services and Product Sales.

There have been various amendments to the UT License Agreement and the CSA since inception. As amended, the term of the CSA continues until December 31, 2031 (unless earlier terminated) and is thereafter renewed automatically for additional, successive two-year terms unless (i) UT provides notice to the Company at least 24 months in advance of such renewal that UT does not wish to renew the CSA or (ii) the Company provides notice to UT at least 48 months in advance of such renewal that the Company does not wish to renew the CSA. The Company and UT each have normal and customary termination rights, including termination for material breach that is not cured within a specific timeframe or in the event of liquidation, bankruptcy or insolvency of the other party. The Company accounted for the contract modification as if it were part of the existing contract since the amendment modified the scope and price of the CSA by extending the term and increasing the occupancy rate. The effect of the modification on the transaction price and on the measure of progress is recognized as an adjustment to revenue as of the date of modification. The modification did not result in a change in the activities and deliverables under the CSA.

In December 2022, the Company and UT agreed to fund an additional $39.5 million to support capital and continuous improvement activities and $2.3 million in the development of alternative manufacturing processes. The Company determined that the capital and continuous improvements should be combined with the manufacturing services performance obligation and the alternative manufacturing processes should be combined with the Next-Gen R&D Services. The total revised anticipated cash flows of $722.3 million from the transaction was allocated to the three distinct performance obligations as follows (dollars in millions):

	Anticipated Cash Flow	Anticipated Revenue Allocation	Recognition Method	Progress Measure	Revenue Recognition
Total anticipated cash flow[1]	$ 722.3				
Distinct Performance Obligation					
R&D Services and License		$ —	Over time	Ratably	Aug 2021 - Oct 2021
Next-Gen R&D Services		$ 10.0	Over time	Input	% of completion of costs
Manufacturing Services and Product Sales[2]		$ 712.3	Point in time		Transfer of control

(1) The total anticipated cash flow includes a transaction price of $120.0 million for the contractual obligations under the CSA for the Manufacturing Services and Product Sales and the Next-Gen R&D Services performance obligations and $602.3 million for future supply of Tyvaso DPI over the remaining term of the CSA.

(2) The Manufacturing Services and Product Sales performance obligation will be recognized as control of manufactured products is transferred to UT. The modification did not result in a cumulative catch-up adjustment as a result of the revenue being deferred for the performance obligations that were affected by the modification. The allocation of the transaction price for the Manufacturing Services and Product Sales includes a material right related to the Company's estimated production of product in the amount of $220.8 million. The Company will sell product to UT under individual purchase orders, which represent distinct performance obligations. The ultimate cash flows may vary as manufacturing purchase orders are received.

In February 2024, the Company began in-house kitting of certain Tyvaso DPI stock-keeping units. The Company's obligation to perform such in-house kitting will be accounted for separately as it is distinct from Manufacturing Services and Product Sales and offered at a standalone selling price. Revenue for in-house kitting will be recognized at a point in time as services are rendered.

As of March 31, 2024, deferred revenue consisted of $74.0 million, of which $7.4 million was classified as current and $66.6 million was classified as long-term on the condensed consolidated balance sheet. As of December 31, 2023, deferred revenue consisted of $77.5 million, of which $8.9 million was classified as current and $68.6 million was classified as long-term on the condensed consolidated balance sheet. The Company determined that the revenue recognition associated with the capital improvements should be combined with the Manufacturing Services and Product Sales performance obligation.

Thirona Collaboration Agreement — In June 2021, the Company and Thirona entered into a collaboration agreement to evaluate the therapeutic potential of Thirona's compound for the treatment of fibrotic pulmonary diseases. If initial studies are promising, the Company can exercise certain rights to seek a full license to the compound for clinical development and commercialization. The

parties will perform their respective obligations and provide reasonable support for research, clinical development and regulatory strategy. The collaboration agreement was accounted for under ASC 808, Collaborative Agreements; however, no consideration was exchanged between the parties. The costs incurred by the Company were expensed as R&D in the condensed consolidated statements of operations. On February 28, 2023, the collaboration agreement was amended to extend the term through June 2024. In accordance with the amendment, the Company agreed to fund a minimum of $1.1 million to be expended on a revised development plan prepared by Thirona, of which $0.9 million has been funded through March 31, 2024.

Biomm Supply and Distribution Agreement — In May 2017, the Company and Biomm S.A. ("Biomm") entered into a supply and distribution agreement for the commercialization of Afrezza in Brazil. Under this agreement, Biomm was responsible for pursuing regulatory approvals of Afrezza in Brazil, including from the Agência Nacional de Vigilância Sanitária ("ANVISA") and, with respect to pricing matters, from the Camara de Regulação de Mercado de Medicamentos ("CMED"), both of which were received. Biomm commenced product sales in January 2020. No shipments of product were made to Biomm in 2023 or the first quarter of 2024.

Cipla License and Distribution Agreement — In May 2018, the Company and Cipla Ltd. ("Cipla") entered into an exclusive agreement for the marketing and distribution of Afrezza in India and the Company received a $2.2 million nonrefundable license fee. Under the terms of the agreement, Cipla is responsible for obtaining regulatory approvals to distribute Afrezza in India and for all marketing and sales activities of Afrezza in India. The Company is responsible for supplying Afrezza to Cipla. The Company has the potential to receive an additional regulatory milestone payment, minimum purchase commitment revenue and royalties on Afrezza sales in India once cumulative gross sales have reached a specified threshold.

The nonrefundable licensing fee was recorded in deferred revenue and is being recognized in net revenue – collaborations over 15 years, representing the estimated period to satisfy the performance obligation. The additional milestone payments represent variable consideration for which the Company has not recognized any revenue because of the uncertainty of obtaining marketing approval.

As of March 31, 2024, the deferred revenue balance was $1.3 million, of which $0.1 million was classified as current and $1.2 million was classified as long term in the condensed consolidated balance sheets. As of December 31, 2023, the deferred revenue balance was $1.4 million, of which $0.2 million was classified as current and $1.2 million was classified as long term in the condensed consolidated balance sheets.

10. Fair Value of Financial Instruments

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement. The Company uses the exit price method for estimating the fair value of loans for disclosure purposes. Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy, as follows:

Level 1 — Quoted prices for identical instruments in active markets.

Level 2 — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 — Significant inputs to the valuation model are unobservable.

The carrying amounts reported in the condensed consolidated financial statements for cash, accounts receivable, accounts payable, and accrued expenses and other current liabilities (excluding the Milestone Rights liability) approximate their fair value due to their relatively short maturities. The fair value of the Senior convertible notes, MidCap credit facility, Mann Group convertible note, Milestone Rights liability and Financing liability are disclosed below.

Financial Liabilities — The following tables set forth the fair value of the Company's financial instruments (Level 3 in the fair value hierarchy) (in millions):

	March 31, 2024	
		Fair Value
	Carrying Value	Significant Unobservable Inputs (Level 3)
Financial liabilities:		
Senior convertible notes[(1)]	$ 227.2	$ 246.4
MidCap credit facility[(2)]	28.1	30.2
Mann Group convertible note[(3)]	8.8	17.1
Milestone rights[(4)]	3.9	12.8
Contingent milestone liability[(5)]	0.3	0.3
Financing liability[(6)]	104.1	106.7
Liability for sale of future royalties[(7)]	148.0	159.6

(1) Fair value was determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 11%, volatility of 59.9% and a Monte Carlo simulation for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $239.8 million and $253.3 million, respectively.

(2) Fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 12%. A change in yield of + or – 2% would result in a fair value of $29.7 million and $30.4 million, respectively.

(3) The fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 13% and volatility of 55.6% to the straight note and a binomial option pricing model for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $16.9 million and $17.4 million, respectively.

(4) Fair value was determined by applying a Monte Carlo simulation method for the calculation of the potential payment and the Geometric Brownian Motion forecasting model to estimate the underlying revenue. Market based inputs and other level 3 inputs were used to forecast future revenue. The key inputs used included a risk-free rate of 4.2%, dividend yield of 0%, volatility of 50%, period of 7.75 years and credit risk of 17%.

(5) Fair value was determined by using the Monte Carlo simulation method for the calculation of the potential payment and the Geometric Brownian Motion forecasting model to estimate the underlying revenue. Market based inputs and other level 3 inputs were used to forecast future revenue. The key inputs used included a risk-free rate of 4.29%, dividend yield of 0%, volatility of 43%, period of 13.75 years and credit risk of 17%.

(6) Fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 9.5%. A change in yield of + or – 2% would result in a fair value of $94.0 million and $122.4 million, respectively.

(7) At March 31, 2024, fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 11%. A change in yield of + or – 2% would result in a fair value of $139.6 million and $184.4 million, respectively. At December 31, 2023, the carrying value approximated the fair value.

	December 31, 2023	
		Fair Value
	Carrying Value	Significant Unobservable Inputs (Level 3)
Financial liabilities:		
Senior convertible notes[(1)]	$ 226.9	$ 231.3
MidCap credit facility[(2)]	33.0	35.5
Mann Group convertible note[(3)]	8.8	14.4
Milestone rights[(4)]	3.9	11.9
Contingent milestone liability[(5)]	0.3	0.3
Financing liability[(6)]	104.1	106.8

(1) Fair value was determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 11%, volatility of 62.7% and a Monte Carlo simulation for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $224.1 million and $238.9 million, respectively.

(2) Fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 12%. A change in yield of + or – 2% would result in a fair value of $35.0 million and $36.0 million, respectively.

(3) Fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 13% and volatility of 62.7% to the straight note and a binomial option pricing model for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $14.2 million and $14.7 million, respectively.

(4) Fair value was determined by applying a Monte Carlo simulation method for the calculation of the potential payment and the Geometric Brownian Motion forecasting model to estimate the underlying revenue. Market based inputs and other level 3 inputs were used to forecast

future revenue. The key inputs used included a risk-free rate of 3.88%, dividend yield of 0%, volatility of 50%, period of 8 years and credit risk of 17%.

(5) Fair value was determined by using the Monte Carlo simulation method for the calculation of the potential payment and the Geometric Brownian Motion forecasting model to estimate the underlying revenue. Market-based inputs and other level 3 inputs were used to forecast future revenue. The key inputs used included a risk-free rate of 4.01%, dividend yield of 0%, volatility of 43%, period of 15 years and credit risk of 17%.

(6) Fair value was determined by applying a discounted cash flow analysis with a hypothetical yield of 9.5%.

Milestone Rights Liability — The fair value measurement of the Milestone Rights liability is sensitive to the discount rate and the timing of achievement of milestones. The Company utilized a Monte-Carlo Simulation Method to simulate the Afrezza net sales under a neutral framework to estimate the potential payments and the Geometric Brownian Motion forecasting model to estimate the underlying revenue. The Company then discounted the future expected payments at cost of debt with a term equal to the simulated time to payout based on cumulative sales. See Note 14 – *Commitments and Contingencies*.

Contingent Milestone Liability — The acquisition of V-Go in May 2022 resulted in a contingent milestone liability which could result in obligations to the seller if certain revenue thresholds are met. The initial fair value of the contingent milestone liability was recorded as an adjustment to the purchase price. Subsequent changes in the fair value are reported in general and administrative expenses.

Financing Liability — The Sale-Leaseback Transaction in November 2021 resulted in a financing liability. See Note 14 – *Commitments and Contingencies*.

Liability for Sale of Future Royalties — The sale of a portion of our royalty rights in December 2023 resulted in a liability for sale of future royalties. See Note 14 – *Commitments and Contingencies*.

11. Common and Preferred Stock

The Company is authorized to issue 800,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. As of March 31, 2024 and December 31, 2023, 270,801,781 and 270,034,495 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

In February 2018, the Company entered into a controlled equity offering sales agreement (the "CF Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, shares of the Company's common stock having an aggregate offering price of up to $50.0 million or such other amount as may be permitted by the Sales Agreement. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at-the-market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. There were no sales under the CF Sales Agreement for the three months ended March 31, 2024. During the three months ended March 31, 2023, the Company sold 269,383 shares of common stock at a weighted average purchase price of $4.45 per share for gross proceeds of approximately $1.2 million pursuant to the CF Sales Agreement.

During the three months ended March 31, 2024, the Company received $1.4 million from the market price stock purchase plan ("MPSPP") for 416,099 shares of common stock. There were no MPSPP transactions during the three months ended March 31, 2023.

For shares of common stock issued pursuant to the Company's 2004 employee stock purchase plan ("ESPP"), see Note 13 – *Stock-Based Compensation Expense.*

12. Earnings per Common Share

The following tables summarize the components of the basic and diluted EPS computations (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2024	2023
EPS — basic:		
Net income (loss) (numerator)	$ 10,630	$ (9,795)
Weighted average common shares (denominator)	270,356	263,969
Net income (loss) per share	$ 0.04	$ (0.04)
EPS — diluted:		
Net income (loss) — basic	$ 10,630	$ (9,795)
Effect of interest and amortization expense on convertible notes	1,856	—
Adjusted net income (loss) (numerator)	$ 12,486	$ (9,795)
Weighted average common shares	270,356	263,969
Effect of dilutive securities — common shares issuable	54,377	—
Adjusted weighted average common shares (denominator)	324,733	263,969
Net income (loss) per share	$ 0.04	$ (0.04)

For the three months ended March 31, 2024, diluted net income per share excluded the weighted average effect of 5.4 million RSUs and Market RSUs and 2.1 million options and PNQs as they were antidilutive.

Common shares issuable represents incremental shares of common stock which consist of RSUs, stock options, warrants, and shares that could be issued upon conversion of the Senior convertible notes and the Mann Group convertible notes. Potentially dilutive securities outstanding which were considered antidilutive are summarized as follows (in shares):

	Three Months Ended March 31,
	2023
Senior convertible notes	44,120,463
RSUs and Market RSUs[(1)]	15,468,000
Common stock options and PNQs	8,943,899
Mann Group convertible notes	3,370,000
Total shares	71,902,362

(1) Market RSUs issued in 2020, 2021 and 2022 are included at the share delivery of 300%, 0% and 210%, respectively, in accordance with a valuation assessment obtained as of March 31, 2023.

13. Stock-Based Compensation Expense

The Company granted the following awards (in shares):

	Three Months Ended March 31,
	2024
Employee awards:	
RSUs[(1)]	267,990

(1) RSUs had a weighted average grant date fair value of $3.28 per share, of which 211,895 RSUs had a vesting period of 33.3% annually over the second, third, and fourth anniversary of the vesting determination date, 53,720 RSUs had a cliff vesting period of three years, and 2,375 RSUs had a vesting period of 25% annually over four years.

As of March 31, 2024, there was a *de minimis* amount of unrecognized stock-based compensation expense related to options and PNQs, which is expected to be recognized over a weighted average period of approximately 0.11 years, and $16.5 million and $12.1

million of unrecognized stock-based compensation expense related to RSUs and Market RSUs, respectively, which is expected to be recognized over a weighted average period of approximately 2.20 and 1.37 years, respectively.

Total stock-based compensation expense recognized in the condensed consolidated statements of operations as cost of goods sold, cost of revenue – collaborations and services, R&D and selling, general and administrative expense was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
RSUs and options	$ 3,699	$ 3,478
Employee stock purchase plan	186	177
Total	$ 3,885	$ 3,655

Employee Stock Purchase Plan

The Company provides all employees, including executive officers, the ability to purchase common stock at a discount under the ESPP. The ESPP is designed to comply with Section 423 of the Internal Revenue Code and provides all employees with the opportunity to purchase up to $25,000 worth of common stock (based on the undiscounted fair market value at the commencement of the offering period) each year at a purchase price that is the lower of 85% of the fair market value of the common stock on either the date of purchase or the commencement of the offering period. An employee may not purchase more than 5,000 shares of common stock on any purchase date. The executives' rights under the ESPP are the same as those of all other employees.

There were approximately 2.9 million shares of common stock available for issuance under the ESPP as of March 31, 2024.

14. Commitments and Contingencies

Guarantees and Indemnifications — In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal and therefore has not recorded any liability for these indemnities in the condensed consolidated balance sheets. The Company accrues for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable and the amount can be reasonably estimated. No such losses have been recorded to date.

Litigation — The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. The Company does not anticipate the final disposition of any matters will have a material adverse effect on the results of operations, financial position, or cash flows of the Company. The Company maintains liability insurance coverage to protect the Company's assets from losses arising out of or involving activities associated with ongoing and normal business operations. The Company records a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company's policy is to accrue for legal expenses in connection with legal proceedings and claims as they are incurred.

Contingencies — Milestone Rights — In July 2013, the Company entered into the Milestone Rights Agreement with the Original Milestone Purchasers, pursuant to which the Company granted the Milestone Rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, $55.0 million of which remains payable to the Milestone Purchasers as of March 31, 2024.

The Milestone Rights Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to Afrezza. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to Afrezza in violation of the terms of such agreement.

As of March 31, 2024 and December 31, 2023, the remaining Milestone Rights liability balance was $3.9 million and consisted of $0.8 million of current liability, which was presented as accrued expenses and other current liabilities, and $3.1 million of long-term liability, which was presented as milestone liabilities in our condensed consolidated balance sheets. The value of the Milestone Rights liability was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made.

Loss Contingencies — Returns Reserve for Acquired Product — During the three months ended March 31, 2024, the Company revised its previously-determined estimates for product returns associated with sales of V-Go that pre-date the Company's acquisition of the product totaling $1.2 million which is included in accrued expenses and other current liabilities in the condensed consolidated balance sheets as of March 31, 2024 and general and administrative expenses in the condensed consolidated statements of operations for three months ended March 31, 2024. Although future returns are probable, the Company cannot reasonably estimate any associated losses as of March 31, 2024.

Liability for Sale of Future Royalties — On December 27, 2023 (the "Inception Date"), the Company executed a Purchase and Sale Agreement (the "PSA") with Sagard Healthcare Partners Funding Borrower SPE 2, LP ("Sagard"). Pursuant to the PSA, Sagard paid the Company $150.0 million (the "Upfront Proceeds"), net of $0.4 million in reimbursements of Sagard's fees and expenses (the "Reimbursements"), for the purchase of a 1% royalty on future net sales of Tyvaso DPI by UT under the terms of the UT License Agreement (the "Sagard Royalty"). Sagard will also pay the Company a milestone of $50.0 million if net sales of Tyvaso DPI meet or exceed $1.9 billion for any twelve consecutive months on or prior to December 31, 2026 ("Net Sales Threshold A"), or a milestone of $45.0 million if net Sales Threshold A is not met and net sales of Tyvaso DPI meet or exceed $2.3 billion for any twelve consecutive months on or prior to September 30, 2027 ("Net Sales Threshold B"), resulting in a purchase price not to exceed $200.0 million (the "Purchase Price"). If Net Sales Thresholds A and B are not met and net sales of Tyvaso DPI meet or exceed $3.5 billion for any calendar year after September 30, 2027, no royalties will be payable to Sagard for the remainder of that year. The PSA applies to net sales of Tyvaso DPI generated during October 1, 2023 (the "Commencement Date") through December 31, 2042 (the "Termination Date") and will automatically terminate upon payment of the final royalty owed to Sagard thereafter. Upon the Termination Date, ownership of the Sagard Royalty will revert to the Company.

Given the Company's continuing involvement with the generation of Tyvaso DPI revenue under the UT License Agreement and CSA, which includes the Company's supply and manufacture of Tyvaso DPI, and the Company's retention and associated defense and maintenance obligations of the intellectual property required in the manufacture of Tyvaso DPI, the Upfront Proceeds were recorded as a liability for sale of future royalties (the "Royalty Liability") on the condensed consolidated balance sheets, and any proceeds from future milestones will be added to the Royalty Liability balance upon receipt. Although the Company is not obligated to repay any portion of the Purchase Price to Sagard, the Royalty Liability under the PSA is secured by a security interest granted to Sagard in the underlying 1% royalty rights and any proceeds therefrom. As a result of the PSA, transaction costs totaling $4.4 million (including the Reimbursements) (the "Transaction Costs") are reported net of the Royalty Liability balance and amortized to interest expense in the condensed consolidated statements of operations over the life of the PSA using the effective interest method. The Company will continue to recognize the full 10% of future royalty revenues in its condensed consolidated statements of operations, with the Sagard Royalty being non-cash revenue for the Company. As royalty payments are remitted to Sagard, the balance of the Royalty Liability will be effectively repaid as it is amortized over the life of the PSA. To amortize the Royalty Liability, the Company estimated the total amount of future royalty payments to be made to Sagard over the life of the PSA. The excess of those future estimated royalty payments over the Purchase Price proceeds received is recognized in the condensed consolidated statements of operations as non-cash interest expense over the life of the PSA utilizing an imputed effective interest rate. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate may vary during the term of the agreement depending on a number of factors, including the amount and timing of forecasted royalty payments which affects the timing and ultimate amount of reductions to the liability. The Company will evaluate the effective interest rate periodically based on its forecasted royalty payments utilizing the prospective method.

The Company periodically assesses the forecasted royalty payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments, or the timing of such payments, are materially different than original estimates, the Company will prospectively adjust the effective interest rate and amortization of the Royalty Liability. The Company's effective annual interest rate on the Royalty Liability was approximately 11.1% during the three months ended March 31, 2024, during which time the Company recorded $4.2 million in non-cash interest expense and $0.1 million amortization of the Transaction Costs in the condensed consolidated statements of operations. Non-cash revenue recognized by the Company during the period of the Commencement Date through December 31, 2023 of $2.1 million was remitted to Sagard by UT during the three months ended March 31, 2024. Non-cash revenue recognized by the Company during the three months ended March 31, 2024 of $2.3 million will be remitted to Sagard by UT during the second quarter of 2024.

The following table shows the activity within the Royalty Liability account as well as the effective interest rate (dollars in millions):

	Three Months Ended March 31, 2024
Balance, beginning of period	$ 145.8
Amortization of deferred transaction costs	0.1
Non-cash interest expense on liability for sale of future royalties	4.2
Royalty revenue remitted to Sagard by UT	(2.1)
Balance, end of period	$ 148.0
Effective interest rate	11.1%

Sale-Leaseback Transaction— In November 2021, the Company sold certain land, building and improvements located in Danbury, CT (the "Property") to an affiliate of Creative Manufacturing Properties (the "Purchaser") for a sales price of $102.3 million, subject to terms and the conditions contained in a purchase and sale agreement.

Effective with the closing of the Sale-Leaseback Transaction, the Company and the Purchaser entered into a lease agreement (the “Lease”), pursuant to which the Company leased the Property from the Purchaser for an initial term of 20 years, with four renewal options of five years each. The total annual rent under the Lease starts at approximately $9.5 million per year, subject to a 50% rent abatement during the first year of the Lease, and will increase annually by (i) 2.5% in the second through fifth year of the Lease and (ii) 3% in the sixth and each subsequent year of the Lease, including any renewal term. The Company is responsible for payment of operating expenses, property taxes and insurance for the Property. The Purchaser will hold a security deposit of $2.0 million during the Lease term. Pursuant to the terms of the Lease, the Company has four options to repurchase the Property, in 2026, 2031, 2036 and 2041, for the greater of (i) $102.3 million and (ii) the fair market value of the Property.

Effective with the closing of the Sale-Leaseback Transaction, the Company and the Purchaser also entered into a right of first refusal agreement (the “ROFR”), pursuant to which the Company has a right to re-purchase the Property from the Purchaser in accordance with terms and conditions set forth in the ROFR. Specifically, if the Purchaser receives, and is willing to accept, a bona fide purchase offer for the Property from a third-party purchaser, the Company has certain rights of first refusal to purchase the Property on the same material terms as proposed in such bona fide purchase offer.

As of March 31, 2024, the related financing liability was $104.1 million, which was recognized in the condensed consolidated balance sheet and of which $94.2 million was long-term and $9.9 million was current. As of December 31, 2023, the related financing liability was $104.1 million, of which $94.3 million was long-term and $9.8 million was current. Cash paid for interest on the financing liability totaled $2.4 million during each of the three months ended March 31, 2024 and 2023.

Financing liability information was as follows (dollars in thousands):

	March 31, 2024	December 31, 2023
Weighted average remaining lease term (in years)	17.6	17.8
Weighted average discount rate	9.0%	9.0%

	Three Months Ended March 31,	
	2024	2023
Interest expense on financing liability	$ 2,447	$ 2,424

The Company's remaining financing liability payments were as follows (in thousands):

	March 31, 2024
Remainder of 2024	$ 7,523
2025	10,269
2026	10,533
2027	10,849
2028	11,174
Thereafter	177,278
Total	227,626
Interest payments	(120,923)
Debt issuance costs	(2,624)
Total financing liability	$ 104,079

Commitments — In July 2014, the Company entered into the Insulin Supply Agreement with Amphastar pursuant to which Amphastar manufactures for and supplies to the Company certain quantities of recombinant human insulin for use in Afrezza. Under the terms of the Insulin Supply Agreement, Amphastar is responsible for manufacturing the insulin in accordance with the Company's specifications and agreed-upon quality standards.

In December 2023, the Company and Amphastar amended the Insulin Supply Agreement to extend the term, restructure the annual purchase commitments and include a capacity fee for certain future periods. The Company's remaining purchase commitments and estimated capacity fee liability as of March 31, 2024 were as follows (€ in millions):

	March 31, 2024	
	Remaining Purchase Commitments	Estimated Capacity Fees
Remainder of 2024	2.3	—
2025	—	1.5
2026[(1)]	4.2	2.0
2027	6.0	1.0
2028	6.0	1.0
2029	6.0	1.0
2030	6.0	1.0
2031	8.0	0.5
2032	8.0	0.5
2033	8.0	0.5
2034	4.4	0.5
Total	58.9	9.5

(1) If there is a delay in the availability of insulin with FDA approved inclusion bodies and supply does not begin in 2026 as currently expected, the Company will incur a capacity fee of €750,000 per quarter that the product is not available for purchase.

Pursuant to the amendment, the term of the Insulin Supply Agreement expires on the later of December 31, 2034 or until the completion of the total remaining purchase commitment quantities, unless terminated earlier, and can be renewed for additional, successive two-year terms upon 12 months' written notice given prior to the end of the initial term or any additional two-year term. The Company and Amphastar each have normal and customary termination rights, including termination for a material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, the Company may terminate the Insulin Supply Agreement upon two years' prior written notice to Amphastar without cause or upon 30 days' prior written notice to Amphastar if a controlling regulatory authority withdraws approval for Afrezza, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require the Company to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

The Company periodically reviews the terms of the long-term Insulin Supply Agreement and assesses the need for any accrual for estimated losses, such as lower-of-cost or net-realizable-value that will not be recovered by future product sales. The recognized loss on purchase commitments of $62.7 million and $64.8 million is included in our condensed consolidated balance sheets as of March 31, 2024 and December 31, 2023, respectively, and is reduced as inventory items are received or such liability is extinguished.

As a result of the increase in future cash flows for the excess capacity fees and extended term included in the amendment of the Insulin Supply Agreement, the Company analyzed the need for additional estimated losses and concluded that an increase in the recognized loss on purchase commitments was not required as the net realizable value of inventory resulting from the purchase commitment was in excess of the carrying value. Increases in costs associated with the amendment will be recognized through inventory as incurred.

Vehicle Leases – During the second quarter of 2018, the Company entered into a master lease agreement with Enterprise Fleet Management Inc. The monthly payment inclusive of maintenance fees, insurance and taxes is approximately $0.1 million. The lease expense is included in selling expenses in the condensed consolidated statements of operations.

Office Leases — In May 2017, the Company executed an office lease with Russell Ranch Road II LLC for the Company's corporate offices in Westlake Village, California, which was renewed in April 2022. Pursuant to the renewal, the monthly lease payments of $79,543 began in February 2023 and are subject to 3% annual increases, plus the estimated cost of maintaining the property and common areas by the landlord, and are further subject to a six-month base rent concession beginning February 2023. The Company is also entitled to a one-time allowance up to $0.9 million as reimbursement for tenant improvements or the purchase of furniture, fixtures or equipment. Of the $0.9 million allowance, an amount up to $0.7 million may be applied as an additional base rent concession. The Company has no further right to extend the lease term beyond July 31, 2028.

In May 2022, the Company assumed certain leased real property (the "Marlborough Lease") in connection with the V-Go acquisition. The Marlborough Lease pertains to certain premises in a building located in Marlborough, Massachusetts. The monthly payments of $28,895 began in June 2022, subject to approximately 3% annual increases through February 28, 2026.

The Company also acquired rights to a manufacturing service agreement where V-Go is manufactured using Company-owned equipment located at the manufacturing facility. The Company determined that this arrangement results in an embedded lease which granted the Company exclusive use of space within the manufacturing facility. The Company assessed the embedded lease cost to be $14,370 per month through February 28, 2026.

Lease information was as follows (dollars in thousands):

	March 31, 2024	December 31, 2023
Operating lease right-of-use assets[1]	$ 4,392	$ 4,685
Operating lease liability-current[2]	$ 1,611	$ 1,423
Operating lease liability-long-term	3,645	3,925
Total	$ 5,256	$ 5,348
Weighted average remaining lease term (in years)	3.8	3.7
Weighted average discount rate	7.3 %	7.3 %

(1) Operating right-of-use assets related to vehicles, offices and the manufacturing facility are included in other assets in the condensed consolidated balance sheets.
(2) Operating lease liability – current is included in accrued expenses and other current liabilities in the condensed consolidated balance sheets.

	Three Months Ended March 31,	
	2024	2023
Operating lease costs	$ 348	$ 422
Variable lease costs	10	36
Cash paid	232	323

The Company's future minimum office and vehicle lease payments were as follows (in thousands):

	March 31, 2024
Remainder of 2024	$ 1,224
2025	1,829
2026	1,213
2027	1,135
2028	643
Total	6,044
Interest expense	(788)
Total operating lease liability	$ 5,256

15. Income Taxes

During the three months ended March 31, 2024, the Company recorded income tax expense of $0.3 million related to state taxes, which was calculated using the discrete year-to-date method. The income tax provision for the three months ended March 31, 2023 resulted in no tax expense. The effective tax rate differs from the statutory tax rate of 21% primarily due to the existence of valuation allowances against net deferred tax assets and current liabilities resulting from the estimated state income tax liabilities.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded, in accordance with the applicable accounting standards, that net deferred tax assets should be fully reserved.

The Company has assessed its position with regards to uncertainty in tax positions and has not recognized a liability for unrecognized tax benefits. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the three months ended March 31, 2024, the Company did not recognize any interest or penalties. The Company’s tax years since 2019 remain subject to examination by tax authorities.

16. Subsequent Events

On April 1, 2024, the Company repaid in full all outstanding indebtedness, consisting of $28.3 million in principal and $0.2 million in accrued interest, and terminated all commitments and obligations under the MidCap credit facility that would have matured on August 1, 2025 in exchange for a payment of $31.6 million, including an exit fee of $2.8 million and a prepayment fee of $0.3 million. Additionally, unamortized debt discount and capitalized prepayment fees totaling $0.2 million were written off, resulting in a loss on extinguishment of debt of $3.3 million to be recognized in the second quarter of 2024. In connection with the repayment of outstanding indebtedness by the Company, all liens, mortgages and security interests in any assets or property securing the obligations under the MidCap credit facility were automatically terminated and released and the Company was automatically released from all guarantees.

In addition, on April 2, 2024, the Company and Mann Group agreed to discharge and terminate the Mann Group convertible note. As of April 2, 2024, the outstanding principal balance of the Mann Group convertible note plus accrued interest was $8.9 million and was convertible at Mann Group’s option into 3,554,198 shares of common stock of the Company. The Company and Mann Group agreed to terminate all outstanding indebtedness, rights and obligations under the Mann Group convertible note in exchange for (i) the Company’s issuance to Mann Group of 1,500,000 shares of the Company’s common stock and (ii) the Company’s payment to Mann Group of $8.9 million, which represented the market value of 2,054,198 shares of common stock of the Company on April 2, 2024 (eliminating any potential dilution related to these unissued shares). Termination of the Mann Group convertible note resulted in extinguishment of debt of $3.7 million to be recognized in the second quarter of 2024.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements in this report that are not strictly historical in nature are "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would," and similar expressions intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. The preceding interim condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and related notes for the year ended December 31, 2023 and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of innovative therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases. Our signature technologies—Technosphere dry-powder formulations and Dreamboat inhalation devices—offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation.

In our endocrine business unit, we currently commercialize two products: Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, and the V-Go wearable insulin delivery device, which provides continuous subcutaneous infusion of insulin in adults that require insulin. Afrezza was developed by us and received approval from the FDA in June 2014. Afrezza consists of a dry powder formulation of human insulin delivered from a small portable inhaler. V-Go received 510(k) clearance by the FDA in 2010 and has been available commercially since 2012. In May 2022, we acquired V-Go from Zealand Pharma A/S and Zealand Pharma US, Inc. (together "Zealand") and began integrating the product into our endocrine business unit. V-Go is a mechanical basal-bolus insulin delivery system that is worn like a patch and can eliminate the need for taking multiple daily injections.

The first product to come out of our orphan lung disease pipeline, Tyvaso DPI (treprostinil) inhalation powder, received FDA approval in May 2022 for the treatment of PAH and PH-ILD. Our development and marketing partner, United Therapeutics, began commercializing Tyvaso DPI in June 2022 and is obligated to pay us a royalty on net sales of the product. We also receive a margin on supplies of Tyvaso DPI that we manufacture for UT.

The lead program in our pipeline of potential treatments for orphan lung diseases is MNKD-101, a nebulized formulation of clofazimine, for the treatment of severe chronic and recurrent pulmonary infections, including nontuberculous mycobacterial (NTM) lung disease. We believe an orally inhaled formulation of clofazimine could potentially provide several clinical advantages over the current solid oral dosage form of this drug. In April 2024, the FDA cleared our investigational new drug application (IND) for MNKD-101, enabling us to initiate a Phase 3 study that will investigate its potential to treat NTM lung disease and granted Fast Track designation to our development program. This designation supplements earlier designations from the FDA granting MNKD-101 status as an orphan drug and as a qualified infectious disease product for the treatment of pulmonary NTM infections

The next most advanced program in our pipeline is MNKD-201, a dry-powder formulation of nintedanib, for the treatment of idiopathic pulmonary fibrosis (IPF). An oral dosage form of nintedanib was approved for IPF by the FDA in 2014. However, a fairly large oral dose is required in order to achieve sufficient drug levels in lung tissue. Our goal with an inhaled formulation is to deliver a therapeutic amount of nintedanib to the lungs while avoiding high levels of the drug in other tissues, where it is associated with undesirable side effects. In April 2024, the FDA cleared MNKD-201 to proceed with a first-in-human Phase 1 study of MNKD-201 for pulmonary fibrotic diseases, including IPF.

Our business is subject to significant risks, including but not limited to our ability to manufacture sufficient quantities of our products and Tyvaso DPI. Other significant risks also include the risk that our products may only achieve a limited degree of commercial success and the risks inherent in drug development, clinical trials and the regulatory approval process for our product candidates, which in some cases depends upon the efforts of our partners.

As of March 31, 2024, we had an accumulated deficit of $3.2 billion and a stockholders' deficit of $230.0 million. We had net income of $10.6 million for the three months ended March 31, 2024 and net loss of $9.8 million for the three months ended March 31, 2023. To date, we have funded our operations primarily through the sale of our equity and convertible debt securities, from the receipt of

upfront and milestone payments from collaborations, from borrowings, from sales of Afrezza and V-Go, from royalties and manufacturing revenue from UT as well as from proceeds of the sale-leaseback of our manufacturing facility in Danbury, CT and from the sale of a portion of future royalties that we receive from UT.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our critical accounting policies and estimates can be found in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report. See Note 1 – *Description of Business and Significant Accounting Policies* in the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited) for descriptions of the new accounting policies and impact of adoption.

RESULTS OF OPERATIONS

Trends and Uncertainties

Our collaboration agreement with UT entitles us to receive a 10% royalty on net sales of Tyvaso DPI, subject to the sale by us in December 2023 of a 1% royalty on future net sales to a royalty purchaser (leaving us with a 9% royalty). Our royalty revenue reflects the upward trend in demand for Tyvaso DPI in the marketplace. See Note 14 – *Commitments and Contingencies* in the condensed consolidated financial statements.

Our future success is dependent on our, and our current and future collaboration partners', ability to effectively commercialize approved products. Our future success is also dependent on our pipeline of new products. There is a high rate of failure inherent in the R&D process for new drugs. As a result, there is a high risk that the funds we invest in research programs will not generate sufficient financial returns. Products may appear promising in development but fail to reach market within the expected or optimal timeframe, or at all.

Three months ended March 31, 2024 and 2023

Revenues

The following table provides a comparison of the revenue categories for the three months ended March 31, 2024 and 2023 (dollars in thousands):

	Three Months Ended March 31,			
	2024	2023	$ Change	% Change
Net revenue – commercial product sales:				
Gross revenue from product sales	$ 30,039	$ 30,417	$ (378)	(1%)
Less: Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	11,275	12,855	$ (1,580)	(12%)
Net revenue – commercial product sales	$ 18,764	$ 17,562	$ 1,202	7%
Gross-to-net revenue adjustment percentage	38%	42%		
Revenue – collaborations and services	24,848	11,386	$ 13,462	118%
Royalties – collaborations	22,651	11,678	$ 10,973	94%
Total revenues	$ 66,263	$ 40,626	$ 25,637	63%

Afrezza — Gross revenue from sales of Afrezza increased by $0.9 million, or 4% for the three months ended March 31, 2024 compared to the same period in the prior year. The increase was driven by higher price. The gross-to-net adjustment was 31% of gross revenue, or $6.4 million, for the three months ended March 31, 2024, compared to 38% of gross revenue or $7.5 million, for the three months ended March 31, 2023. The decrease in the gross-to-net percentage was primarily attributable to a decrease in anticipated product returns (as a percentage of gross sales). As a result, net revenue from sales of Afrezza increased by $2.0 million, or 16%, for the three months ended March 31, 2024 compared to the same period in the prior year.

V-Go — Gross revenue from sales of V-Go decreased by $1.3 million, or 12%, for the three months ended March 31, 2024 compared to the same period in the prior year was primarily a result of lower demand. The gross-to-net adjustment was 53% of gross revenue, or $4.9 million, for the three months ended March 31, 2024 compared to 51% of gross revenue, or $5.4 million, for the same period in the prior year. As a result, net revenue from sales of V-Go decreased by $0.8 million, or 16%, for the three months ended March 31, 2024 compared to the same period in the prior year.

Collaborations and Services — Net revenue from collaborations and services increased by $13.5 million, or 118%, for the three months ended March 31, 2024 compared to the same period in the prior year. The increase in revenue was primarily attributable to increased manufacturing volume and related production activity for product sold to UT. Royalty revenue from UT increased by $11.0 million, or 94%, for the three months ended March 31, 2024 due to increased patient demand for Tyvaso DPI. See Note 9 – *Collaboration, Licensing and Other Arrangements*.

Commercial product gross profit

The following table provides a comparison of the commercial product gross profit categories for the three months ended March 31, 2024 and 2023 (dollars in thousands):

	Three Months Ended March 31,			
	2024	2023	$ Change	% Change
Commercial product gross profit:				
Net revenue – commercial product sales	$ 18,764	$ 17,562	$ 1,202	7%
Less: Cost of goods sold	3,819	5,530	$ (1,711)	(31%)
Commercial product gross profit:	$ 14,945	$ 12,032	$ 2,913	24%
Gross margin	80%	69%		

Commercial product gross profit increased by $2.9 million, or 24%, for the three months ended March 31, 2024 compared to the same period in the prior year. The increase in gross profit and gross margin was primarily attributable to an increase in Afrezza net revenue.

Expenses

The following table provides a comparison of the expense categories for the three months ended March 31, 2024 and 2023 (dollars in thousands):

	Three Months Ended March 31,			
	2024	2023	$ Change	% Change
Expenses:				
Cost of goods sold	$ 3,819	$ 5,530	$ (1,711)	(31%)
Cost of revenue – collaborations and services	14,779	10,683	$ 4,096	38%
Research and development	10,013	5,605	$ 4,408	79%
Selling	11,601	13,310	$ (1,709)	(13%)
General and administrative	10,728	10,542	$ 186	2%
(Gain) loss on foreign currency transaction	(1,399)	954	$ 2,353	*
Total expenses	$ 49,541	$ 46,624	$ 2,917	6%

* Not meaningful

Cost of revenue – collaborations and services increased by $4.1 million, or 38%, for the three months ended March 31, 2024 compared to the same period in the prior year. The increase was primarily attributable to increased manufacturing volume and activities. Higher manufacturing volumes resulted in efficiencies which contributed to a lower effective cost per unit.

R&D expenses increased by $4.4 million, or 79%, for the three months ended March 31, 2024 compared to the same period in the prior year. The increase was primarily attributable to increased development activities for clofazimine inhaled suspension (MNKD-101), costs for an Afrezza post-marketing clinical study (INHALE-3) which commenced in the second quarter of 2023 and personnel expenses due to increased headcount.

Selling expenses decreased by $1.7 million, or 13%, for the three months ended March 31, 2024 compared to the same period in the prior year. The decrease was primarily attributable to reduced personnel and travel expenses related to sales force restructuring activities completed during the quarter.

General and administrative expenses increased by $0.2 million, or 2%, for the three months ended March 31, 2024 compared to the same period in the prior year. This increase was primarily attributable to a loss of $1.2 million related to estimated returns associated with sales of V-Go that pre-date our acquisition of the product, partially offset by reduced personnel costs.

Under the Insulin Supply Agreement with Amphastar, payment obligations are denominated in Euros. We are required to record the foreign currency transaction impact of the U.S. dollar to Euro exchange rate associated with the recognized gain or loss on purchase commitments. The foreign currency transaction gain was $1.4 million for the three months ended March 31, 2024 compared to a loss of $1.0 million for the same period in the prior year due to the conversion of Euro to U.S. dollar exchange rates.

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the three months ended March 31, 2024 and 2023 (dollars in thousands):

	Three Months Ended March 31,			
	2024	2023	$ Change	% Change
Interest income, net	$ 3,434	$ 1,302	$ 2,132	164 %
Interest expense on financing liability	(2,447)	(2,424)	$ 23	1 %
Interest expense	(2,567)	(2,786)	$ (219)	(8 %)
Interest expense on liability for sale of future royalties	(4,248)	—	$ 4,248	*
Other income	—	111	$ (111)	*
Total other expense	$ (5,828)	$ (3,797)	$ 2,031	53 %

* Not meaningful

Interest income, net, consisting of interest and accretion on investments net of amortization, increased by $2.1 million for the three months ended March 31, 2024 compared to the same period in the prior year primarily due to higher yields on our securities portfolio as well as an increase in the underlying investments from the proceeds of the sale of 1% of our Tyvaso DPI royalties in December 2023.

Interest expense on financing liability was $2.4 million for each of the three months ended March 31, 2024 and 2023 and represented interest incurred on the sale lease-back transaction for our manufacturing facility in Danbury, CT.

Interest expense on notes decreased by $0.2 million for the three months ended March 31, 2024 compared to the same period in the prior year due primarily to principal payments made on the MidCap credit facility. See Note 8 – *Borrowings*.

Interest expense on liability for sale of future royalties was $4.2 million for the three months ended March 31, 2024 due to imputed interest and amortization of debt issuance costs on the liability recorded in connection with the sale of 1% of our Tyvaso DPI royalties in December 2023. See Note 14 – *Commitments and Contingencies*.

Other income for the three months ended March 31, 2023 consisted primarily of a gain associated with a foreign currency hedging transaction which was entered into to mitigate our exposure to foreign currency exchange risks associated with our insulin purchase obligation under the Insulin Supply Agreement with Amphastar.

N**on-GAAP Measures**

To supplement our condensed consolidated financial statements presented under GAAP, we are presenting non-GAAP net income (loss) and non-GAAP net income (loss) per share - diluted, which are non-GAAP financial measures. We are providing these non-GAAP financial measures to disclose additional information to facilitate the comparison of past and present operations, and they are among the indicators management uses as a basis for evaluating our financial performance. We believe that these non-GAAP financial measures, when considered together with our GAAP financial results, provide management and investors with an additional understanding of our business operating results, including underlying trends.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our condensed consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of our non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. Likewise, we may determine to modify the nature of its adjustments to arrive at our non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by us in this Quarterly Report on Form 10-Q have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

The following table reconciles our financial measures as reported in our condensed consolidated statements of operations to a non-GAAP presentation as adjusted for the following select non-cash items: revenue from the 1% portion of sold royalties and interest expense on the related liability, stock-based compensation expense and gain on foreign currency transaction for the periods presented:

	Three Months Ended March 31,			
	2024		2023	
	Net Income	Diluted EPS	Net Loss	Diluted EPS
	(In thousands except per share data)			
GAAP reported	$ 10,630	$ 0.04	$ (9,795)	$ (0.04)
Select non-cash adjustments:				
Sold portion of royalty revenue [1]	(2,265)	(0.01)	—	—
Interest expense on liability for sale of future royalties	4,248	0.01	—	—
Stock compensation	3,885	0.01	3,655	0.01
(Gain) loss on foreign currency transaction	(1,399)	—	954	0.01
Non-GAAP adjusted	$ 15,099	$ 0.05	$ (5,186)	$ (0.02)
Weighted average shares used to compute net income (loss) per share – diluted	324,733		263,969	

(1) Represents the non-cash portion of the 1% royalty on net sales of Tyvaso DPI earned during the three months ended March 31, 2024 which is remitted to the royalty purchaser and recognized as royalties from collaborations in our condensed consolidated statements of operations. Our revenues from royalties from collaborations during the three months ended March 31, 2024 totaled $22.7 million, of which $2.3 million will be remitted to the royalty purchaser.

LIQUIDITY AND CAPITAL RESOURCES

Our principal sources of liquidity are our cash, cash equivalents, and investments. Our primary uses of cash include the development of our product pipeline, the manufacturing and marketing of Afrezza and V-Go, manufacturing Tyvaso DPI, the funding of general and administrative expenses, and principal and interest payments on our financing liability and debt.

To date, we have funded our operations primarily through the sale of equity and convertible debt securities, from the receipt of upfront and milestone payments from collaborations, from borrowings, from sales of Afrezza and V-Go, from royalties and manufacturing revenue from UT, from proceeds from the sale of certain assets and the sale of a portion of our future royalties that we receive from UT.

We believe we will be able to meet our liquidity needs over the next twelve months, as well as longer-term needs, based on the balance of cash, cash equivalents and investments on hand, projected sales of Afrezza and V-Go, and projected royalties and manufacturing revenue from the production and sale of Tyvaso DPI, as well as through debt or equity financing, if necessary.

As of March 31, 2024, we had $62.7 million in insulin purchase commitments and $267.1 million principal amount of outstanding debt, consisting of:

- $230.0 million aggregate principal amount of Senior convertible notes bearing interest at 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021 and maturing on March 1, 2026, unless earlier converted, redeemed or repurchased by us. The Senior convertible notes are convertible at an initial conversion price of approximately $5.21 per share of common stock. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.
- $28.3 million principal amount under the MidCap credit facility. On April 1, 2024, we exercised our option to prepay the existing term loans in whole in exchange for a payment of approximately $31.6 million, which included an early termination fee in an amount equal to 1.00% of principal prepaid as well as an exit fee in an amount equal to 7.00% of the outstanding Tranche 1 balance. See Note 16 – *Subsequent Events*.
- $8.8 million principal amount of indebtedness under the Mann Group convertible note. On April 2, 2024, we and Mann Group agreed to discharge and terminate the Mann Group convertible note in exchange for (i) the issuance to Mann Group of 1,500,000 shares of our common stock and (ii) payment to Mann Group of approximately $8.9 million, which represented the market value of 2,054,198 shares of common stock of the Company on April 2, 2024 (eliminating any potential dilution related to these unissued shares). See Note 16 – *Subsequent Events*.

With the repayment of the MidCap credit facility and the Mann Group convertible note subsequent to March 31, 2024, our Senior convertible notes are our only remaining notes outstanding. To date, we have been able to timely make our required interest payments,

but we cannot guarantee that we will be able to do so in the future. If we fail to repay, repurchase or redeem our outstanding notes when required, we will be in default under the applicable instrument for such indebtedness. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the noteholders initiating bankruptcy proceedings or causing us to cease operations altogether. We may from time to time seek to retire or purchase our outstanding debt through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material.

In July 2013, we issued the Milestone Rights pursuant to the Milestone Rights Agreement to the Original Milestone Purchasers. The Milestone Rights were subsequently assigned the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, $55.0 million of which remain payable as of March 31, 2024. See Note 14 – *Commitments and Contingencies* for further information related to the Milestone Rights.

During the three months ended March 31, 2024, we generated $6.7 million of cash for our operating activities, which primarily consisted of $55.5 million in cash receipts from customers, in addition to non-cash revenue consisting of $3.5 million net recognition of revenue that was previously deferred and $2.3 million of revenue for the 1% sold portion of our royalties, partially offset by $16.8 million of cost of goods sold, $9.8 million of selling expenses, $7.8 million of costs for research and development, $6.7 million of general and administrative expenses, and $5.8 million of net cash paid for interest.

During the three months ended March 31, 2023, we generated $1.2 million of cash from our operating activities, which consisted of $45.6 million of revenue, partially offset by $17.1 million of selling, general and administrative expenses, $19.4 million of cost of goods sold, $7.3 million of costs for research and development and $3.7 million of net cash paid for interest.

Cash used in investing activities of $48.4 million for the three months ended March 31, 2024 was primarily due to the purchase of $68.4 million of debt securities and $2.4 million of property and equipment, partially offset by the maturity of $22.0 million of debt securities.

Cash provided by investing activities of $13.8 million for the three months ended March 31, 2023 was primarily due to $22.1 million of proceeds from debt securities partially offset by $8.3 million for the purchase of property and equipment.

Cash used in financing activities of $3.5 million for the three months ended March 31, 2024 was primarily due to principal payments on the MidCap credit facility of $5.0 million partially offset by $1.4 million in proceeds from the market price stock purchase plan.

Cash provided by financing activities of $1.2 million for the three months ended March 31, 2023 was primarily due to proceeds from at-the-market offerings.

Future Liquidity Needs

We believe we will be able to meet our near-term liquidity needs based on our cash, cash equivalents and investments on hand, sales of Afrezza and V-Go, and royalties and manufacturing revenue from the production and sale of Tyvaso DPI as well as through debt or equity financing, if necessary, for our long-term liquidity needs. Although we generated a net income of $10.6 million and net cash provided by operating activities reflected in our condensed consolidated statements of cash flows was $6.7 million during the three months ended March 31, 2024, we have not generated a net income or cash flows from operating activities on a consistent basis. In addition, we expect to continue to incur expenditures for the foreseeable future in support of our manufacturing operations, sales and marketing costs for our products and development costs for other product candidates in our pipeline. As of March 31, 2024, we had capital resources comprised of $193.3 million in cash and cash equivalents, $107.5 million in short-term investments and $3.7 million in long-term investments, and total principal amount of outstanding borrowings of $267.1 million.

We believe our resources will be sufficient to fund our operations for the next twelve months from the date of issuance of our condensed consolidated financial statements included in Part I – Financial Statements (Unaudited).

Contractual Obligations

See Note 8 – *Borrowings* and Note 14 – *Commitments and Contingencies* for a discussion of material changes outside of the ordinary course of business in our contractual obligations from those disclosed within “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as contained in the Annual Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Interest on borrowings under the MidCap credit facility accrued interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month SOFR (subject to a one-month SOFR floor of 1.00%) plus 6.25%. Accordingly, our interest expense under the MidCap credit facility was subject to changes in the one-month SOFR rate.

All other debt has fixed interest rates, so the interest expense associated with such debt is not exposed to changes in market interest rates. Specifically, the interest rate on the amount borrowed under the Mann Group convertible note was fixed at 2.50% and the interest rate under the Senior convertible notes is fixed at 2.50%. See Note 8 – *Borrowings* for information about the principal amount of outstanding debt.

Foreign Currency Exchange Risk

We incur and will continue to incur significant expenditures for insulin supply obligations under our Insulin Supply Agreement with Amphastar. Such obligations are denominated in Euros. At the end of each reporting period, the recognized gain or loss on purchase commitment is converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and the Euro. For the three months ended March 31, 2024, we realized a $1.4 million currency gain, which was reflected as (gain) loss on foreign currency transaction in the accompanying condensed consolidated statements of operations.

Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If a change in the U.S. dollar to Euro exchange rate equal to 10% of the U.S. dollar to Euro exchange rate on March 31, 2024 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax income of approximately $6.3 million.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of March 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2024, our Chief Executive Officer and our Chief Financial Officer have concluded, as of such date, that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) of the Exchange Act. An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are subject to legal proceedings and claims that arise in the ordinary course of our business. As of the date hereof, we believe that the final disposition of such matters will not have a material adverse effect on our financial position, results of operations or cash flows. We maintain liability insurance coverage to protect our assets from losses arising out of or involving activities associated with ongoing and normal business operations. See Note 14 – *Commitments and Contingencies* in the condensed consolidated financial statements.

Item 1A. *Risk Factors*

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our common stock.

Summary Risk Factors

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

RISKS RELATED TO OUR BUSINESS

- The products that we or our collaboration partner are commercializing may only achieve a limited degree of commercial success.
- Manufacturing risks may adversely affect our ability to manufacture our products and Tyvaso DPI, which could reduce our gross margin and profitability.
- If our suppliers fail to deliver materials and services needed for commercial manufacturing in a timely and sufficient manner or fail to comply with applicable regulations, and if we fail to timely identify and qualify alternative suppliers, our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities could decline.
- If third-party payers do not cover our approved products, such products might not be prescribed, used or purchased, which would adversely affect our revenues.
- We may need to raise additional capital to fund our operations.
- If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.
- We expect that our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.
- We have a history of operating losses. We may incur losses and may not generate positive cash flow from operations in the future.
- We may not be able to generate sufficient cash to service all of our indebtedness and commitments
- Our business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.
- Continued testing of our products and product candidates may not yield successful results, and even if it does, we may still be unable to successfully commercialize our current or future products.
- If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.
- The long-term safety and efficacy of approved products may differ from clinical studies, which could negatively impact sales and could lead to reputational harm or other negative effects.

- Our products and product candidates may be rendered obsolete by rapid technological change.
- We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

RISKS RELATED TO GOVERNMENT REGULATION

- Our product candidates must undergo costly and time-consuming rigorous nonclinical and clinical testing and we must obtain regulatory approval prior to the sale and marketing of any product in each jurisdiction. The results of this testing or issues that develop in the review and approval by a regulatory agency may subject us to unanticipated delays or prevent us from marketing any products.
- If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined or forced to remove a product from the market, subject to criminal prosecution, or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval.
- We are subject to stringent, ongoing government regulation.
- If we or any future partner fails to comply with federal and state healthcare laws, including fraud and abuse and health information laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.
- We are subject to stringent and changing U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

RISKS RELATED TO OUR COMMON STOCK

- Our stock price is volatile.
- Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and adversely impact the market price of our common stock and other securities.

GENERAL RISK FACTORS

- Unstable market, economic and geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price.

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this Quarterly Report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. The risk factors set forth below marked with an asterisk (*) did not appear as separate risk factors in, or contains changes to the similarly titled risk factors included in, Item 1A of the Annual Report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

Risk Factors

RISKS RELATED TO OUR BUSINESS

The products that we or our collaboration partner are commercializing may only achieve a limited degree of commercial success.

Successful commercialization of therapeutic products is subject to many risks, including some that are outside our control. There are numerous examples of failures to fully exploit the market potential of therapeutic products, including by biopharmaceutical and device companies with more experience and resources than us. Products that we commercialize ourselves (including any products that we may develop or acquire in the future) and the product that is commercialized by our current collaboration partner (including future products that may be commercialized by our collaboration partner) may not gain market acceptance among physicians, patients,

third-party payers and the healthcare community. The degree of market acceptance of our or a collaboration partner's products depends on many factors, including the following:

- approved labeling claims;
- effectiveness of efforts by us and/or any current or future collaboration or marketing partner to support and educate patients and physicians about the benefits and proper administration of our products, and the perceived advantages of our products and the disadvantages of competitive products;
- willingness of the healthcare community and patients to adopt new technologies;
- ability to manufacture the product in sufficient quantities with acceptable quality and cost;
- perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits compared to competing products or therapies;
- convenience and ease of administration relative to existing treatment methods;
- coverage and reimbursement, as well as pricing relative to other treatment therapeutics and methods; and
- marketing and distribution support.

Because of these and other factors, the products described above may not gain market acceptance or otherwise be commercially successful. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations. We and our current or any future collaboration partner may need to enhance our/their commercialization capabilities in order to successfully commercialize such products in the United States or any other jurisdiction in which such product is approved for commercial sale, and we or the collaboration partner may not have sufficient resources to do so.

In order to increase adoption and sales of our products, we need to continue to develop our commercial organization, including maintaining and growing a highly experienced and skilled workforce with qualified sales representatives.

We have built a sales force that promotes Afrezza and V-Go to endocrinologists and selected primary care physicians. In order to successfully commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other commercial capabilities. The market for skilled commercial personnel is highly competitive, and we may not be able to hire all of the personnel we need on a timely basis or retain them for a sufficient period. Factors that may hinder our ability to successfully market and commercially distribute our products include:

- inability to recruit, retain and effectively manage adequate numbers of effective sales personnel;
- lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies that have more extensive product lines; and
- unforeseen delays, costs and expenses associated with maintaining our sales organization.

If we are unable to maintain an effective sales force for our products, including any other potential future approved products, we may not be able to generate sufficient product revenue in the United States. We are required to expend significant time and resources to train our sales force to educate physicians about our products. In addition, we must continually train our sales force and equip them with effective marketing materials to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our products and any additional products we may develop or acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

Similarly, if UT does not effectively engage or maintain its sales force for Tyvaso DPI, our ability to recognize royalties and manufacturing revenue from this collaboration will be adversely affected.

Manufacturing risks may adversely affect our ability to manufacture our products and Tyvaso DPI, which could reduce our gross margin and profitability.*

We use our Danbury, Connecticut facility to assemble the inhalers from their individual molded parts, formulate both the Afrezza and Tyvaso DPI inhalation powders, fill plastic cartridges with the powders, package the cartridges into secondary packaging and, beginning in 2024, assemble final kits for certain stock-keeping units. Other semi-finished goods are assembled into the final kits for commercial sale by a contract packager.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up production to commercial batch sizes. These problems include difficulties with production costs,

capacity utilization and yields. We may also experience shortages of qualified personnel, which could impact our ability to meet manufacturing requirements. In addition, there is a need to comply with strictly enforced federal, state and foreign regulations, including inspections. Our facility is inspected on a regular basis by the FDA. If the FDA makes any major observations during future inspections, the corrective actions required could be onerous and time-consuming.

Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to obtain sufficient quantities for the commercialization of drug products at the costs that we currently anticipate. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of the product or any raw material on a timely basis, and at commercially reasonable prices, sustainable compliance and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for such drug products and we would lose potential revenues.

As demand for our products increases, we may have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, we may be unable to support commercialization of Tyvaso DPI.

In addition, we rely on our contract manufacturers in Southern China to manufacture V-Go. Our contract manufacturer uses MannKind-owned custom-designed, semi-automated manufacturing equipment and production lines to meet our quality requirements. Separate contract manufacturers in China perform release testing, sterilization, inspection and packaging functions. As a result, our business is subject to risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- unexpected or unfavorable changes in regulatory requirements;
- changes and volatility in currency exchange rates;
- possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the United States; and
- difficulties in managing foreign relationships and operations generally.

These risks are likely to be exacerbated by our limited experience with V-Go and its manufacturing processes.

If our suppliers fail to deliver materials and services needed for commercial manufacturing in a timely and sufficient manner or fail to comply with applicable regulations, and if we fail to timely identify and qualify alternative suppliers, our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities could decline.

For the commercial manufacture of inhaled drug products, we need access to sufficient, reliable and affordable supplies of FDKP, the inhaler, the related cartridges and other materials. For Afrezza, we also require a supply of insulin. Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar. We must rely on all of our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with current good manufacturing practice ("cGMP") for drug products, and the molding of the inhaler and cartridges components in accordance with quality system regulations for medical devices ("QSRs").

For V-Go, we obtain parts from a small number of suppliers, including some parts and components that are purchased from single-source vendors. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. In addition, we do not have long-term supply agreements with most of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under many of our supply agreements, we have no obligation to buy any given quantity of components, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components.

Because we do not have long-standing relationships with all of our suppliers, we may not be able to convince them to continue to make components available to us unless there is demand for such components from their other customers. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our product, our quality control standards and regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components.

We may also have difficulty obtaining similar components from other suppliers that meet the requirements of the FDA or other regulatory agencies. Although we conduct our own inspections and review and/or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If a supplier fails to comply with these requirements or the comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products. If we are required to find a new or additional supplier, we will need to evaluate that supplier's ability to provide material that meets regulatory requirements, including cGMP or QSR requirements, as well as our specifications and quality requirements, which would require significant time and expense and could delay production.

As a result, our ability to purchase adequate quantities of the components for our products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture components for us, including financial difficulties or damage to their manufacturing equipment or facilities. In general, if any of our suppliers is unwilling or unable to meet its supply obligations or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

If third-party payers do not cover our approved products, such products might not be prescribed, used or purchased, which would adversely affect our revenues.

In the United States and elsewhere, sales of prescription pharmaceuticals depend in large part on the availability of coverage and adequate reimbursement to the consumer from third-party payers, such as government health administration authorities and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. The market for our approved products depends significantly on access to third-party payers' formularies, which are the lists of medications and devices for which third-party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical and device companies. Also, third-party payers may refuse to include a particular branded product in their formularies or otherwise restrict patient access to a branded product when a less costly generic equivalent or other alternative is available. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third-party payers to contain or reduce the costs of healthcare through various means. In the United States, there have been several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Inflation Reduction Act (the "IRA") limited insulin copays to $35 per month for Medicare Part D beneficiaries starting in 2023. In certain foreign markets, the pricing of prescription pharmaceuticals is subject to direct governmental control. The European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

If we or any collaboration or marketing partner is unable to obtain and maintain coverage of, and adequate third-party reimbursement for, our approved products, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our or any collaboration or marketing partner's ability to successfully commercialize such products and would impact our profitability, results of operations, financial condition, and prospects.

We may need to raise additional capital to fund our operations.*

We may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our

ongoing activities, including the commercialization of our products and the development of our product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. The extent of our additional funding requirements will depend on a number of factors, including:

- the degree to which we are able to generate revenue from products that we or a collaboration partner commercialize;
- the costs of developing Afrezza and of commercializing Afrezza and V-Go on our own in the United States;
- the demand by any or all of the holders of our Senior convertible notes to require us to repay or repurchase such debt securities if and when required;
- our ability to repay or refinance existing indebtedness, and the extent to which our Senior convertible notes or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;
- the rate of progress and costs of our clinical studies and R&D activities;
- the costs of procuring raw materials and operating our manufacturing facility;
- our success in establishing additional strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;
- actions taken by the FDA and other regulatory authorities affecting Afrezza, V-Go, Tyvaso DPI, our product candidates or competitive products;
- the emergence of competing technologies and products and other market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal and litigation expenses; and
- the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

We have raised capital in the past through the sale of equity and debt securities and the sale of certain assets. In the future, we may pursue the sale of additional equity, debt securities and/or assets, or the establishment of other funding facilities including asset-based borrowings. There can be no assurances, however, that we will be able to raise additional capital in the future on acceptable terms, or at all. Volatility and disruptions of the global supply chain and financial markets, if sustained or recurrent, could prevent us or make it more difficult for us to access capital.

Issuances of additional debt or equity securities or the issuance of common stock upon conversion of outstanding convertible debt securities for shares of our common stock could impact the rights of the holders of our common stock and will dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We may also raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaboration, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements, borrowing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration.

We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. There can be no assurances that we will be able to raise additional capital in sufficient amounts or on favorable terms, or at all. If we are unable to raise adequate additional capital when required or in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a loss), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment for our stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets.

If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.*

We, and third parties with whom we work, employ and are increasingly dependent upon information technology systems, infrastructure, applications, websites and other resources. Our business requires collecting, receiving, manipulating, analyzing, storing, processing, generating, using, disclosing, protecting, securing, transmitting, sharing, disposing of, and making accessible (collectively "process") large amounts of data, including proprietary, confidential and sensitive data (such as personal or health-related data), intellectual property, and trade secrets (collectively, "sensitive information"). As a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents.

Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to increase, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties with whom we work may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credentials harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attached enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by artificial intelligence, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Some of our workforce works remotely, which also poses increased risks to our information technology systems and data, as employees working from home, in transit or in public locations, utilize network connections, computers and devices outside our premises or network. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to provide other products or services, or otherwise to operate our business. For example, we rely on an enterprise software system to operate and manage our business. Our business, including our ability to manufacture drug products and conduct clinical trials, therefore depends on the continuous, effective, reliable and secure operation of our information technology resources and those of third parties with whom we work, including computer hardware, software, networks, Internet servers and related infrastructure. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. In particular, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products) or the third-party information technology systems that support us and our services. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information technology systems (such as our hardware and/or software, including that of third parties with whom we work), but we may not be able to detect, mitigate, and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. We have in the past experienced security incidents. For example, like many companies, we use SolarWinds to help manage our information technology systems. A cyber-attack on SolarWinds was discovered in December 2020 and widely exploited by threat actors. Upon learning of this vulnerability, we

applied the software patch provided by SolarWinds and remediated the incident. The incident did not appear to have any negative impact on our operations or the sensitive information we may process. In addition, a ransomware attack on Ultimate Kronos Group's ("UKG") Kronos Private Cloud service was discovered in December 2021. At the time, we used UKG Pro, a product offered through UKG that is not in the Kronos Private Cloud, for human capital management. UKG is not aware of an impact on UKG Pro and the incident did not appear to have any negative impact on our operations or the sensitive information we may process. These incidents illustrate that despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standards or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our cybersecurity insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Sensitive information of the Company or our customers could also be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative artificial intelligence ("AI") technologies.

We expect that our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include the factors that will affect our funding requirements described above under "Risk Factors — We may need to raise additional capital to fund our operations." In addition, the current inflationary environment related to increased aggregate demand and supply chain constraints has the potential to adversely affect our operating expenses.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

We have a history of operating losses. We may incur losses and may not generate positive cash flow from operations in the future.*

Although we had positive cash flows from operating activities during the three months ended March 31, 2024 and the year ended December 31, 2023, we have a history of operating losses. As of March 31, 2024, we had an accumulated deficit of $230.0 billion. The accumulated deficit has resulted principally from costs incurred in our R&D programs, the write-off of assets (including goodwill, inventory and property, plant and equipment) and general operating expenses. We expect to make substantial expenditures and may incur operating losses in the future in order to continue commercializing our products and to advance development of product candidates in our pipeline.

Our losses have had, and may continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Our ability to achieve and sustain positive cash flow from operations and profitability depends heavily upon successfully commercializing

our products, and although we had positive cash flows from operations during the three months ended March 31, 2024 and the year ended December 31, 2023, we may not generate positive cash flow from operations or be profitable in the future.

We may not be able to generate sufficient cash to service all of our indebtedness and commitments.*

Our ability to make scheduled payments on our insulin purchase commitments and debt obligations will depend on our financial and operating performance, which is subject to the commercial success of our products and the commercial success of the product(s) of our collaboration partners, the extent to which we are able to successfully develop and commercialize additional products, the extent to which we enter into additional collaboration or licensing arrangements, prevailing economic and competitive conditions, and certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If we fail to pay interest on, or repay, our borrowings under the Senior convertible notes when required, we will be in default under the instrument for such debt securities, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. If our cash flows and capital resources are insufficient to fund our obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our lease obligations. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the noteholders initiating bankruptcy proceedings or causing us to cease operations altogether.

In addition, we may from time to time seek to retire or purchase our outstanding debt, including the Senior convertible notes, through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Further, any such purchases or exchanges may result in us acquiring and retiring a substantial amount of such indebtedness, which could impact the trading liquidity of such indebtedness.

Our business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we have business operations, and we could experience significant disruptions in the operations of third-party manufacturers and distributors upon whom we rely. For example, sales and demand for Afrezza were adversely affected by the global COVID-19 pandemic, and future pandemics or epidemics could adversely affect the demand for and sales of our products in the future. Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In addition, our contract manufacturers in China could be impacted by that country's recent policy of strict lockdowns in order to reduce the spread of disease. Disruptions in sales and demand for our products would be expected to occur:

- if patients are physically quarantined or are unable or unwilling to visit healthcare providers,
- if physicians restrict access to their facilities for a material period of time,
- if healthcare providers prioritize treatment of acute or communicable illnesses over chronic disease management,
- if pharmacies are closed or suffering supply chain disruptions,
- if patients lose access to employer-sponsored health insurance due to periods of high unemployment, or
- as a result of general disruptions in the operations of payers, distributors, logistics providers and other third parties that are necessary for our products to be prescribed and reimbursed.

Clinical trials of our products were delayed as a result of the COVID-19 pandemic and may be affected by a future health pandemic or epidemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the health pandemic or epidemic. Some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff would adversely impact our clinical trial operations.

A pandemic or epidemic also has the potential for disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could negatively affect our liquidity. In addition, a recession or market correction as a result of a health pandemic or epidemic could materially affect our business and the value of our common stock.

If we do not obtain regulatory approval of our products in foreign jurisdictions, we will not be able to market in such jurisdictions, which could limit our commercial revenues. We may not be able to establish additional regional partnerships or other arrangements with third parties for the commercialization of our products outside of the United States.

Although Afrezza has been approved in the United States by the FDA and in Brazil by ANVISA, we have not yet obtained approval in any other jurisdiction. Similarly, V-Go has received 510(k) clearance from the FDA, but has not received a comparable approval in any other country. In order to market our products in a foreign jurisdiction, we must obtain regulatory approval in each such foreign jurisdiction, and we may never be able to obtain such approvals. The research, testing, manufacturing, labeling, sale, import, export, marketing, and distribution of therapeutic products outside the United States are subject to extensive regulation by foreign regulatory authorities, whose regulations differ from country to country. We will be required to comply with the different regulations and policies of the jurisdictions where we seek approval for our products, and we have not yet identified all of the requirements that we will need to satisfy to submit our products for approval for other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support the approval of our products in the United States.

Our current strategy for the future commercialization of our products outside of the United States, subject to receipt of the necessary regulatory approvals, is to seek, establish and maintain regional partnerships in foreign jurisdictions where there are commercial opportunities. It may be difficult to find or maintain collaboration partners that are able and willing to devote the time and resources necessary to successfully commercialize our products. Collaborations with third parties may require us to relinquish material rights, including revenue from commercialization, agree to unfavorable terms or assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of our products in foreign jurisdictions and could have a material and adverse impact on our business, financial condition and results of operations and the market price of our common stock and other securities could decline.

Continued testing of our products and product candidates may not yield successful results, and even if it does, we may still be unable to successfully commercialize our current or future products.

We have generally sought to develop product candidates through our internal research programs. All such product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all. Further research and development on these programs will require significant financial resources. Given our limited financial resources, we may not be able to advance these programs into clinical development unless we are able to obtain specific funding for these programs or enter into collaborations with third parties.

Our research and development programs are designed to test the safety and efficacy of our product candidates through extensive nonclinical and clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or impact commercialization of any of our product candidates, including the following:

- safety and efficacy results obtained in our nonclinical and early clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing a product candidate or alter the marketing of an approved product;
- the analysis of data collected from clinical studies of our product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;
- after reviewing clinical data, we or any collaborators may abandon projects that we previously believed were promising;
- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use once approved; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions.

As a result of any of these events, we, any collaborator, the FDA, or any other regulatory authorities may suspend or terminate clinical studies or marketing of any of our products or product candidates at any time. Any suspension or termination of our clinical studies or marketing activities may harm our business, financial condition and results of operations and the market price of our common stock and other securities may decline.

If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical studies and the submission of regulatory filings. From time to time, we publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of the achievement of these milestones can vary dramatically from our estimates, in many cases for reasons beyond our control, depending on numerous factors, including:

- the rate of progress, costs and results of our clinical studies and preclinical research and development activities;
- our ability to identify and enroll patients who meet clinical study eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates or to source clinical supplies from contract manufacturers;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent to which our clinical studies compete for clinical sites and eligible subjects with clinical studies sponsored by other companies;
- actions by regulators; and
- disruptions caused by geopolitical conflicts, man-made or natural disasters or public health pandemics or epidemics or other business interruptions.

For example, in June 2023, the contract manufacturer responsible for the production of clofazimine inhalation solution, the investigational product we are developing as MNKD-101, experienced a fire in its manufacturing facility in Germany. As a result of the incident, the initiation of a Phase 3 clinical study of MNKD-101, originally planned for late 2023, is now expected to commence in the second quarter of 2024. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed development programs or otherwise fail to adhere to our projected development goals in the timeframes we expect (or within the timeframes expected by analysts or investors), our business, financial condition and results of operations may be harmed and the market price of our common stock and other securities may decline. In addition, we may be delayed or prevented from generating revenues from milestone or other payments that depend on our ability to achieve any milestone obligations specified in an out-licensing arrangement.

The long-term safety and efficacy of approved products may differ from clinical studies, which could negatively impact sales and could lead to reputational harm or other negative effects.

The effects of approved therapeutic products over terms longer than the clinical studies or in much larger populations may not be consistent with earlier clinical results. If long-term use of an approved therapeutic product results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our or any marketing or collaboration partner's ability to market and sell the product, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical studies, which may be time-consuming and expensive and may not produce favorable results.

V-Go received pre-market clearance in 2010 under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act ("FDCA"). This process typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. As a result, we currently lack significant published long-term clinical data supporting the safety and efficacy of V-Go and the benefits it offers that might have been generated in connection with other approval processes. For these reasons, adults who require insulin and their healthcare providers may be slower to adopt or recommend V-Go, we may not have comparative data that our competitors have or are generating, and third-party payers may not be willing to provide coverage or reimbursement for V-Go. Further, future studies or clinical experience may indicate that treatment with V-Go is not superior to treatment with competitive products. Such results could slow the adoption of V-Go and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. Moreover, if future results and experience indicate that V-Go causes unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability or harm to our business reputation.

We may not realize the anticipated benefits of any future acquisition or strategic transaction; we may be unable to successfully integrate new products or businesses we may acquire.

We periodically evaluate and pursue acquisition of therapeutic products. The integration of any acquired business, product or other assets into our company may be complex and time-consuming and, if such businesses, products or assets are not successfully

integrated, we may not achieve the anticipated benefits, cost-savings or growth opportunities. Potential difficulties that may be encountered in the integration process include the following:

- unanticipated liabilities related to acquired assets, companies or joint ventures;
- integrating personnel, operations and systems, while maintaining focus on producing and delivering consistent, high quality products;
- coordinating geographically dispersed organizations;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- retention of key employees;
- increases in our expenses and reductions in our cash available for operations and other uses;
- retaining existing customers and attracting new customers;
- managing inefficiencies associated with integrating the operations of our company; and
- possible write-offs or impairment charges relating to acquired assets, businesses or joint ventures.

Furthermore, these acquisitions and other arrangements, even if successfully integrated, may fail to further our business strategy as anticipated, expose us to increased competition or challenges with respect to our products or geographic markets, and expose us to additional liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair our ability to realize any benefit from our acquisitions or arrangements after we have expended resources on them.

Future acquisitions or dispositions could also result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

Our products and product candidates may be rendered obsolete by rapid technological change.

The rapid rate of scientific discoveries and technological changes could result in our approved products or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology or products less competitive, uneconomical or obsolete. Our future success may depend not only on our ability to develop our product candidates, but also our ability to improve them in order to keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

We also expect to face competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in various areas of unmet medical need. These institutions are becoming increasingly aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

Reports of side effects or safety concerns in related technology fields or in other companies' clinical studies could delay or prevent us from obtaining regulatory approval for our product candidates or negatively impact public perception of our approved products.

There are a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or potentially competitive with, our product candidates. Adverse results reported by these other companies in their clinical studies or by companies that use our proprietary formulation and inhaler technologies could delay or prevent us from obtaining regulatory approval, may subject our products to class warnings in their labels or negatively impact public perception of our product candidates, which could harm our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline.

If product liability claims are brought against us, we may incur significant liabilities and suffer damage to our reputation.

The testing, manufacturing, marketing and sales of our products and any clinical testing of our product candidates expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical studies volunteers and loss of revenues. We currently carry worldwide product liability insurance in the amount of $10.0 million as well as an errors and omissions policy in the amount of $1.0 million. Our insurance coverage may not be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will seek to obtain, or be able to obtain if desired, sufficient additional coverage. If losses from such claims exceed our liability insurance coverage, we may incur substantial liabilities that we may not have the resources to pay. If we are required to

pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities may decline.

If we lose any key employees or scientific advisors, our operations and our ability to execute our business strategy could be materially harmed.

We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all. In addition, we may be required to expand our workforce. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel on acceptable terms, if at all.

The loss of the services of any principal member of our management, commercial and scientific staff could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are "at will" and we currently do not have employment agreements with any of the principal members of our management, commercial or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

We have relationships with scientific advisors at academic and other institutions to conduct research or assist us in formulating our research, development or clinical strategy. These scientific advisors are not our employees and may have commitments to, and other obligations with, other entities that may limit their availability to us. We have limited control over the activities of these scientific advisors and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our programs could harm our business. In addition, these advisors are not prohibited from, and may have arrangements with, other companies to assist those companies in developing technologies that may compete with our products.

If our internal controls over financial reporting are not considered effective, our business, financial condition and market price of our common stock and other securities could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year.

Our management, including our Chief Executive Officer and our Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. A material weakness in our internal controls has been identified in the past, and we cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

Changes or modifications in financial accounting standards may harm our results of operations.

From time to time, the Financial Accounting Standards Board ("FASB"), either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations and presentation or classification of cash flows. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Any difficulties in adopting or implementing new accounting standards, and updating or modifying our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of collaboration revenue and other revenue sources, our operating results could be significantly affected.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), the Coronavirus Aid, Relief, and Economic Security Act and the IRA enacted many significant changes to the U.S. tax laws. Further guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U.S. tax expense.

Effective January 1, 2022, the Tax Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, it could harm our future operating results by effectively increasing our future tax obligations. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and development activities inside or outside the United States.

Our ability to use net operating loss carryforwards to offset future taxable income may be subject to limitations.

As of December 31, 2023, the Company had federal and state net operating loss carryforwards of approximately $2.0 billion and $1.3 billion available, respectively, to reduce future taxable income. $494.0 million of the federal net operating loss carryforwards do not expire and the remaining federal net operating loss carryforwards have started expiring, beginning in the current year through various future dates.

Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company’s federal and California net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. As a result of the Company's initial public offering, an ownership change within the meaning of Section 382 occurred in August 2004. As a result, federal net operating loss and credit carryforwards of approximately $105.8 million are subject to an annual use limitation of approximately $13.0 million. The annual limitation is cumulative and therefore, if not fully utilized in a year can be utilized in future years in addition to the Section 382 limitation for those years. We have completed a Section 382 analysis beginning from the date of our initial public offering through December 31, 2023, to determine whether additional limitations apply to the net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met Section 382 study ownership change threshold have been identified through December 31, 2023. There is a risk that changes in ownership may occur in tax years after December 31, 2023. If a change in ownership were to occur, our net operating loss carryforwards and other tax attributes could be further limited or restricted. If limited, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to the Company’s operations in the U.S. will not impact the Company’s effective tax rate.

In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable nexus, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

From time to time, we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. These activities may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we undertake will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If we undertake any internal restructuring activities and fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

At least for the foreseeable future, we expect that our manufacturing facility in Connecticut will be the sole location for the manufacturing of Afrezza and Tyvaso DPI. Similarly, our contract manufacturer in Southern China is the only location for the assembly of V-Go. Additional contract manufacturers in China perform release testing, sterilization, inspection and packaging functions. These facilities and the specialized manufacturing equipment we use at them would be costly to replace and could require substantial lead-time to repair or replace. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business. Natural disasters, such as interruptions in the supply of natural resources, public health pandemics or epidemics, earthquakes and extreme weather conditions, including, but not limited to, hurricanes, floods, tornados, wildfires, and winter storms, or other catastrophic events, including political and governmental changes, conflicts (including the current Russia-Ukraine war, the state of war between Israel and Hamas and attacks on commercial marine vessels in the Red Sea by Houthi rebels), explosions, actions of animal rights activists, terrorist attacks and wars, could disrupt our operations or those of our collaborators, contractors and vendors. Such conditions may be further exacerbated by the effects of climate change. We might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs or cause interruptions in our commercialization of our products.

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development work involves the controlled storage and use of hazardous materials, including chemical and biological materials. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to $1.0 million per occurrence and $2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further $20.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition.

When we purchased our facility in Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (a "responsible party") under the oversight of the Connecticut Department of Energy & Environmental Protection (formerly the Connecticut Department of Environmental Protection), which investigation and remediation is ongoing. The former site operator and responsible party will make further filings necessary to achieve closure for the environmental investigation and remediation it has conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to its prior operations at the facility. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business, financial condition and results of operations may be harmed. When we sold a portion of the property upon which our facility is located to the entity that is now our landlord, we became an additional responsible party for any environmental investigation and remediation on that portion of the property, including with respect to investigation or remediation that may be required as a result of our activities since 2001. To date, we have not identified any material environmental investigation or remediation activities that we are required to perform.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or

otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

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

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

RISKS RELATED TO GOVERNMENT REGULATION

Our product candidates must undergo costly and time-consuming rigorous nonclinical and clinical testing and we must obtain regulatory approval prior to the sale and marketing of any product in each jurisdiction. The results of this testing or issues that develop in the review and approval by a regulatory agency may subject us to unanticipated delays or prevent us from marketing any products.

Our research and development activities for product candidates, as well as the manufacturing and marketing of approved products, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulations of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

- product design, development, manufacture and testing;
- product labeling;
- product storage and shipping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

The requirements governing the conduct of clinical studies as well as the manufacturing and marketing of drug products outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical study designs. Foreign regulatory approval processes include essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot be certain if or when regulatory agencies might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical studies of our product candidates may not be completed on schedule, regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical studies may not be sufficient to support regulatory approval of our product candidates. Even if we believe the data collected from our clinical studies are sufficient, regulatory agencies have substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

Questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by regulatory agencies in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined or forced to remove a product from the market, subject to criminal prosecution, or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval.

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies.

In addition, if we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and a reformulation of our products, additional clinical studies, changes in labeling of, or indications of use for, our products and/or additional marketing applications may be required. If we encounter any of the foregoing problems, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities may decline.

We are subject to stringent, ongoing government regulation.

The FDA and comparable foreign regulatory authorities subject any approved therapeutic product to extensive and ongoing regulatory requirements concerning the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and good clinical practice guidelines for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth cGMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. In complying with cGMP and foreign regulatory requirements, we and any of our third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e.g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in significant civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business, financial condition and results of operations.

As part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. One of these studies, a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 4-17 year-old children and adolescents, is ongoing. The other required study is a long-term safety study that was originally intended to compare the incidence of pulmonary malignancy observed with Afrezza to that observed in a standard of care control group. We have an ongoing dialogue with the FDA regarding the agency's current interest in the long-term safety of Afrezza and an appropriate study design or registry to address any concerns. To date, we have not commenced a long-term safety study or budgeted any amount for it, but such a study in its original design would be anticipated to require substantial capital resources that we may not be able to obtain.

The FDA and other regulatory authorities impose significant restrictions on approved products through regulations on advertising, promotional and distribution activities. This oversight encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving the Internet. Regulatory authorities may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. Prescription drugs may be promoted only for the approved indications in accordance with the approved label. The FDA and other regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Enforcement action may include product seizures, injunctions, significant civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with such regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Failure to comply with state requirements may affect our ability to promote or sell our products in certain states.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, delay the submission or review of an application or require

additional expenditures by us. In addition, interested parties (such as individuals, advocacy groups and competing pharmaceutical companies) can file a citizen petition with the FDA to request policy change or some form of administrative action on the FDA's part, including with respect to a New Drug Application ("NDA"). For example, in July 2021, a third party submitted a citizen petition to the FDA requesting that the FDA refuse to approve Tyvaso DPI, and/or impose additional requirements in order to approve the product. This prompted the FDA to request additional information concerning Tyvaso DPI prior to granting approval in May 2022. If successful, a citizen petition can significantly delay, or even prevent, the approval of a drug product.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. We also cannot be sure that actions by foreign regulatory bodies pertaining to the safety of drugs or medical devices will not adversely affect our operations. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be denied marketing approval or lose any marketing approval that we have already obtained. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our product candidates under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business and results of operations.

Healthcare legislation may make it more difficult to receive revenues.

In both the United States and certain foreign jurisdictions, there has been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. The most recent significant healthcare legislation was the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "PPACA") enacted in March 2010, which substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly affect the healthcare industry. There have been executive, judicial and congressional challenges to certain provisions of the PPACA, although the constitutionality of the PPACA appears to now be settled. In addition, there have been proposed and enacted health reform initiatives affecting the PPACA. For example, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025, eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program, and capped the out-of-pocket cost of insulin (including Afrezza) at $35 per month for Medicare recipients beginning in 2023. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the current administration will impact the PPACA.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Presidential executive orders, Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third-party payers to contain or reduce the costs of healthcare through various means. In the United States, there have been several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While

march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. We expect that there will continue to be a number of federal and state proposals to implement similar and/or additional governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private third-party payers may take in response to any drug pricing and reimbursement reform proposals or legislation. Further, to the extent that such reforms have a material adverse effect on our ability to commercialize our products and product candidates under development, our business, financial condition and profitability may be adversely affected.

We expect that the IRA, as well as other healthcare reform measures that may be adopted in the future, are likely to have a significant effect on the pharmaceutical industry, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

If we or any future partner fails to comply with federal and state healthcare laws, including fraud and abuse and health information laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations, including those pertaining to fraud and abuse and patients' rights, are and will be applicable to our business. The number and scope of these laws, regulations and industry standards are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other, making compliance difficult. The key laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws, including without limitation the False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- The federal Physician Payments Sunshine Act under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to Centers for Medicare & Medicaid Services ("CMS") information related to payments and other transfers of value to physicians (defined to include defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact in connection with the delivery of or payment for health care benefits.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare

providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information as well as their covered subcontractors.

- Other state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security and other processing of personal data (including health information) in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities, marketing expenditures or drug pricing.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. With Afrezza approved in Brazil and as our partners pursue additional international approvals, we will be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, or any contractual obligations related to the same, we may be subject to governmental enforcement actions, investigations, litigation (including class action lawsuits) and other penalties, including significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, defense costs, exclusion from U.S. federal or state healthcare programs, additional reporting requirements and/or oversight (including if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws), bans or restrictions on our processing of personal data, indemnity obligations and the curtailment or restructuring of our operations. Any such event or consequence, including penalties, damages, fines, and curtailment or restructuring of our operations, could materially adversely affect our ability to operate our business, including our ability to run clinical trials, and our financial results and harm our reputation. Although compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly.

We are subject to stringent and changing U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.*

In the ordinary course of business, we process sensitive information (as those terms are defined above). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines (up to $7,500 per intentional violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA (like other U.S. comprehensive privacy laws) exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (EU GDPR and UK GDPR, collectively "GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and Australia's Privacy Act impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to the processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework)these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. The United States is also increasingly scrutinizing certain data transfers and may also impose certain data localization requirements, particularly if we transfer personal data to, or process personal data of residents of, high risk or sanctioned jurisdictions.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply, or may become subject to in the future.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.*

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. For example, in March 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer's price ("AMP"), for single source and innovator multiple source drugs effective January 1, 2024. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the HHS and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate AMP and best price ("BP") for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

Our business could be negatively impacted by environmental, social and corporate governance ("ESG") matters or our reporting of such matters.*

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. For example, we have not previously reported our environmental emissions and such lack of reporting may have resulted in certain investors declining to invest in our common stock. However, the SEC recently finalized rules designed to enhance and standardize climate-related disclosures. These climate disclosure rules have been challenged in court and the SEC has issued an order staying their implementation pending the outcome of judicial review. These new climate-related disclosures, if required, may significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to impact our reputation negatively and/or that harm our stock price.

Our portfolio of investment securities may require us to register with the SEC as an "investment company" in accordance with the Investment Company Act of 1940 ("'40 Act").

The rules and interpretations of the SEC and the courts relating to the definition of "investment company" are very complex. Although we are a biopharmaceutical company and we do not hold ourselves out as an investment company, the value of our investment securities relative to our total assets (exclusive of government securities and cash items) has in the past exceeded safe harbor limits prescribed in the '40 Act. If our asset mix does not continue to qualify for one of the safe harbor limits prescribed in the '40 Act, it is possible that the SEC would take the position that we would be required to register under the '40 Act and comply with the '40 Act's registration and reporting requirements, capital structure requirements, affiliate transaction restrictions, conflict of interest rules, requirements for disinterested directors, and other substantive provisions. If we were required to register as an "investment company" and be subject to the restrictions of the '40 Act, those restrictions likely would require significant changes in the way we do business and add significant administrative costs and burdens to our operations.

RISKS RELATED TO INTELLECTUAL PROPERTY

If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably.

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets and confidentiality agreements. We own a number of domestic and international patents, have a number of domestic and international patent applications pending and have licenses to additional patents. We cannot assure you that our patents and licenses will successfully preclude others from using our technologies, and we could incur substantial costs in seeking enforcement of our proprietary rights against infringement. Even if issued, the patents may not give us an advantage over competitors with alternative technologies.

For example, the coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating patients are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we are able to secure internationally. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated.

Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In the United States and certain other countries, applications are generally published 18 months after the application's priority date. Because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act ("AIA"), the United States moved to a first inventor to file system. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. As and when these different patents expire, our products could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

An issued patent is presumed valid unless it is declared otherwise by a court of competent jurisdiction. However, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions, or post grant proceedings, including, oppositions, re-examinations or other review in the United States. In some instances, we may seek re-examination or reissuance of our own patents. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. We also execute confidentiality agreements with outside collaborators. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators apply technological information to our projects that are developed independently by them or others, or apply our technology to outside projects, and there can be no assurance that any such disputes would be resolved in our favor. In addition, any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. Thus, there can be no assurance, however, that our inventions and assignment agreements and our confidentiality agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

If we become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, we would be required to devote substantial time and resources to prosecute or defend such proceedings.

Competitors may infringe our patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. A court may also decide to award us a royalty from an infringing party instead of issuing an injunction against the infringing activity. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the United States Patent and Trademark Office ("USPTO"), may be necessary to determine the priority of inventions with respect to our pre-AIA patent applications or those of our collaborators or licensors. Additionally, the AIA has greatly expanded the options for post-grant review of patents that can be brought by third parties. In particular, Inter Partes Review ("IPR"), available against any issued United States patent (pre-and post-AIA), has resulted in a higher rate of claim invalidation, due in part to the much reduced opportunity to repair claims by amendment as compared to re-examination, as well as the lower standard of proof used at the USPTO as compared to the federal courts. With the passage of time an increasing number of patents related to successful pharmaceutical products are being subjected to IPR. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. We may not prevail in any litigation, post-grant review, or interference proceedings in which we are involved and, even if we are successful, these proceedings may result in substantial costs and be a distraction to our management. Further, we may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock and other securities may decline.

If our technologies conflict with the proprietary rights of others, we may incur substantial costs as a result of litigation or other proceedings and we could face substantial monetary damages and be precluded from commercializing our products, which would materially harm our business and financial condition.

Biotechnology patents are numerous and may, at times, conflict with one another. As a result, it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner's patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry.

Patent lawsuits can be expensive and would consume time and other resources. There is a risk that a court would decide that we are infringing a third party's patents and would order us to stop the activities covered by the patents, including the commercialization of our products. In addition, there is a risk that we would have to pay the other party damages for having violated the other party's patents (which damages may be increased, as well as attorneys' fees ordered paid, if infringement is found to be willful), or that we will be required to obtain a license from the other party in order to continue to commercialize the affected products, or to design our products in a manner that does not infringe a valid patent. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms or at all, requiring cessation of activities that were found to infringe a valid patent. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Moreover, certain components of our products may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B) (a "337 action") with the International Trade Commission (the "ITC"). A 337 action can be expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party's patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100% of the value of the patented products. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms, or at all, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Although we do not believe that our products or product candidates infringe any third-party patents, if a plaintiff was to allege infringement of their patent rights, we would have to establish with the court that their patents are invalid or unenforceable in order to

avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock and other securities may decline.

In addition, patent litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline.

We may not obtain trademark registrations for our potential trade names.

We have not selected trade names for some of our product candidates in our pipeline; therefore, we have not filed trademark registrations for such potential trade names for our product candidates, nor can we assure that we will be granted registration of any potential trade names for which we do file. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere, or once registered that, prior to our being able to enter a particular market, they will not be cancelled for non-use. Nor can we give assurances, that the use of any of our trademarks will confer a competitive advantage in the marketplace.
Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.

The trading price of our common stock has been and is likely to continue to be volatile. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- our ability to obtain marketing approval for our products outside of the United States and to find collaboration partners for the commercialization of our products in foreign jurisdictions;
- future estimates of product sales, royalties, prescriptions or other operating metrics;
- our ability to successfully commercialize other products based on our Technosphere drug delivery platform;
- the progress and results of preclinical and clinical studies of our product candidates and of post-approval studies of approved products that are required by the FDA;
- general economic, political or stock market conditions, especially for emerging growth and pharmaceutical market sectors;
- geopolitical events, such as the current Russia-Ukraine and Israel-Hamas conflicts and Houthis rebel attacks on commercial marine vessels in the Red Sea;
- legislative developments;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions;
- changes in the structure of the healthcare payment systems;

- announcements by us, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing our products and product candidates;
- developments or disputes concerning our relationship with any of our current or future collaborators or third party manufacturers;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- announcements by us concerning our financial condition or operating performance;
- changes in securities analysts' estimates of our financial condition or operating performance;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- the trades of short sellers;
- our ability, or the perception of investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on The Nasdaq Global Market, and the possible delisting of our common stock if we are unable to do so;
- the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; and
- discussion of our products, competitors' products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us that appear on interactive websites that permit users to generate content anonymously or under a pseudonym. Statements attributed to company officials may, in fact, have originated elsewhere.

Any of these risks, as well as other factors, could cause the market value of our common stock and other securities to decline.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Global Market, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on The Nasdaq Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum market value of listed securities requirement, Nasdaq could determine to delist our common stock. A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We are incorporated in Delaware. Certain anti-takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders or the holders of our other securities. Our anti-takeover provisions include provisions such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and certificate of incorporation or amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended (the "Securities Act"), creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on any investment in our common stock.*

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of any investment in our common stock.

Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and adversely impact the market price of our common stock and other securities.*

We may need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities or additional convertible debt, the market price of our common stock and other securities may decline. Similarly, if our existing stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock and other securities could decrease. The perception in the public market that we or our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities.

Likewise, the issuance of additional shares of our common stock upon the exchange or conversion of the Senior convertible notes could adversely affect the market price of our common stock and other securities. Moreover, the existence of these notes may

encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities.

In addition, a substantial number of shares of our common stock is reserved for issuance upon the exercise of stock options, the vesting of restricted stock unit awards and purchases under our ESPP. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

If other biotechnology and biopharmaceutical companies or the securities markets in general encounter problems, the market price of our common stock and other securities could be adversely affected.

Public companies in general, including companies listed on The Nasdaq Stock Market, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock and other securities to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

GENERAL RISK FACTORS

Unstable market, economic and geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions can result in severely diminished liquidity and credit availability, increase in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, actual or anticipated bank failures, higher inflation, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

Other international and geopolitical events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine and the two countries are now at war. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. Additionally, in October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger conflict. Furthermore, following Hamas' attack on Israel, the Houthi movement, which controls parts of Yemen, launched a number of attacks on commercial marine vessels in the Red Sea. The Red Sea is an important maritime route for international trade and as such disruptions to these trade routes can have an impact on global supply chains. As a result of such disruptions, we may experience in the future extended lead times, delays in supplier deliveries, and increased freight costs. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In January 2024, we elected to pay quarterly interest under the Mann Group convertible note of approximately $0.1 million by issuing the Mann Group 15,285 shares of common stock. See Note 8 – *Borrowings*.

We relied on an exemption from registration provided by Section 3(a)(9) or 4(a)(2) of the Securities Act of 1933, as amended, for the issuance of the shares described above.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 2, 2017).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 13, 2017).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 27, 2020).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 30, 2023).
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 27, 2020).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5 and 3.6.
4.2	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).
4.3	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.4	Form of Warrant to Purchase Stock issued to MidCap Financial Trust on August 6, 2019 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.5	Indenture, dated as of March 4, 2021, by and between MannKind Corporation and U.S. Bank National Association, as Trustee (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 5, 2021).
4.6	Form of Global Note, representing MannKind Corporation's 2.50% Convertible Senior Notes due 2026 (included as Exhibit A to the Indenture filed as Exhibit 4.15) (incorporated by reference to Exhibit 4.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 5, 2021).
10.1*	Offer Letter, dated March 25, 2024, by and between MannKind Corporation and Chris Prentiss (incorporated by reference to Exhibit 10.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 26, 2024).
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
32.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Inline Interactive Data Files pursuant to Rule 405 of Regulation S-T.
104	The cover page has been formatted in Inline XBRL.

* Indicates management contract or compensatory plan.

SIGNATURE

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

Dated: May 8, 2024

MANNKIND CORPORATION

By: /s/ MICHAEL E. CASTAGNA
Michael E. Castagna
Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

By: /s/ CHRISTOPHER B. PRENTISS
Christopher B. Prentiss
Chief Financial Officer

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Michael E. Castagna, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024 of MannKind Corporation;

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.

/s/ Michael E. Castagna

Michael E. Castagna
Chief Executive Officer and Director

Date: May 8, 2024

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Christopher B. Prentiss, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024 of MannKind Corporation;

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.

/s/ Christopher B. Prentiss

Christopher B. Prentiss
Chief Financial Officer

Date: May 8, 2024

Exhibit 32.1

CERTIFICATION OF
CHIEF EXECUTIVE OFFICER
PURSUANT TO
RULE 13a-14(b) OR 15d-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AND SECTION 1350 OF

CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (18 U.S.C. § 1350)[1]

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended March 31, 2024, as filed with the Securities and Exchange Commission on or about the date hereof, to which this certification is attached as Exhibit 32.1 (the "Report") and pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Michael E. Castagna, Chief Executive Officer of MannKind Corporation (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

In Witness Whereof, the undersigned has set his hand hereto as of the 8th day of May, 2024.

/s/ Michael E. Castagna
Michael E. Castagna
Chief Executive Officer

[1] This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not deemed filed for purposes of Section 18 of the Exchange Act or the Securities Act of 1933, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION OF
CHIEF FINANCIAL OFFICER
PURSUANT TO
RULE 13a-14(b) OR 15d-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AND SECTION 1350 OF

CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (18 U.S.C. § 1350)[1]

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended March 31, 2024, as filed with the Securities and Exchange Commission on or about the date hereof, to which this certification is attached as Exhibit 32.2 (the "Report") and pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Christopher B. Prentiss, Chief Financial Officer of MannKind Corporation (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

In Witness Whereof, the undersigned has set his hand hereto as of the 8th day of May, 2024.

/s/ Christopher B. Prentiss
Christopher B. Prentiss
Chief Financial Officer

[1] This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not deemed filed for purposes of Section 18 of the Exchange Act or the Securities Act of 1933, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language contained in such filing.