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 June 30, 2022

Or

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

For the transition period from _____ to _____.

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**13-3607736** **(I.R.S. Employer Identification No.)**
1 Casper Street **Danbury, Connecticut** **(Address of principal executive offices)**	**06810** **(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 July 29, 2022, there were 257,338,259 shares of the registrant's common stock, $0.01 par value per share, outstanding.

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended June 30, 2022

TABLE OF CONTENTS

	Page
PART I: FINANCIAL INFORMATION	2
Item 1. Financial Statements (Unaudited)	2
Condensed Consolidated Balance Sheets: June 30, 2022 and December 31, 2021	2
Condensed Consolidated Statements of Operations: Three and six months ended June 30, 2022 and 2021	3
Condensed Consolidated Statements of Comprehensive Loss: Three and six months ended June 30, 2022 and 2021	4
Condensed Consolidated Statements of Stockholders' Deficit: Three and six months ended June 30, 2022 and 2021	5
Condensed Consolidated Statements of Cash Flows: Six months ended June 30, 2022 and 2021	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	34
Item 3. Quantitative and Qualitative Disclosures About Market Risk	41
Item 4. Controls and Procedures	41
PART II: OTHER INFORMATION	42
Item 1. Legal Proceedings	42
Item 1A. Risk Factors	42
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	72
Item 3. Defaults Upon Senior Securities	72
Item 4. Mine Safety Disclosures	72
Item 5. Other Information	72
Item 6. Exhibits	73
SIGNATURES	75

PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,507	$ 124,184
Short-term investments	118,649	79,932
Accounts receivable, net	15,030	4,739
Inventory	20,573	7,152
Prepaid expenses and other current assets	3,717	3,482
Total current assets	193,476	219,489
Property and equipment, net	37,918	36,612
Goodwill	2,900	—
Other intangible asset	1,400	—
Long-term investments	32,596	56,619
Other assets	17,507	8,441
Total assets	$ 285,797	$ 321,161
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,823	$ 6,956
Accrued expenses and other current liabilities	33,184	27,419
Financing liability — current	9,470	6,977
Deferred revenue — current	1,667	827
Recognized loss on purchase commitments — current	7,420	6,170
Total current liabilities	59,564	48,349
Senior convertible notes	224,670	223,944
Midcap credit facility	39,047	38,833
Mann Group convertible note	8,829	18,425
Accrued interest — promissory notes	86	404
Financing liability — long term	94,447	93,525
Recognized loss on purchase commitments — long term	65,996	76,659
Operating lease liability	5,928	1,040
Deferred revenue — long term	29,762	19,543
Milestone liabilities	4,524	4,838
Deposits from customer	—	4,950
Total liabilities	532,853	530,510
Commitments and contingencies (Note 15)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, $0.01 par value - 400,000,000 shares authorized, 257,276,847 and 251,477,562 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	2,573	2,515
Additional paid-in capital	2,936,667	2,918,205
Accumulated other comprehensive loss	(1,206)	—
Accumulated deficit	(3,185,090)	(3,130,069)
Total stockholders' deficit	(247,056)	(209,349)
Total liabilities and stockholders' deficit	$ 285,797	$ 321,161

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Net revenue — commercial product sales	$ 12,722	$ 9,976	$ 22,548	$ 18,075
Revenue — collaborations and services	5,868	13,304	8,034	22,641
Royalties	304	—	304	—
Total revenues	18,894	23,280	30,886	40,716
Expenses:				
Cost of goods sold	4,617	4,411	6,901	8,726
Cost of revenue — collaborations and services	8,298	5,515	17,012	8,810
Research and development	4,893	2,329	8,429	4,771
Selling, general and administrative	26,043	20,056	46,740	37,469
(Gain) loss on foreign currency translation	(4,503)	903	(6,486)	(2,935)
Loss on purchase commitments	—	339	—	339
Total expenses	39,348	33,553	72,596	57,180
Loss from operations	(20,454)	(10,273)	(41,710)	(16,464)
Other (expense) income:				
Interest income, net	516	25	893	28
Interest expense on financing liability	(2,443)	—	(4,814)	—
Interest expense on notes	(6,642)	(3,180)	(9,390)	(9,632)
Loss on extinguishment of debt, net	—	(22,130)	—	(22,130)
Other expense	—	35	—	(241)
Total other expense	(8,569)	(25,250)	(13,311)	(31,975)
Loss before provision for income taxes	(29,023)	(35,523)	(55,021)	(48,439)
Provision for income taxes	—	—	—	—
Net loss	$ (29,023)	$ (35,523)	$ (55,021)	$ (48,439)
Net loss per share - basic and diluted	$ (0.11)	$ (0.14)	$ (0.22)	$ (0.20)
Shares used to compute net loss per share - basic and diluted	253,644	249,295	252,775	247,970

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (29,023)	$ (35,523)	$ (55,021)	$ (48,439)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(130)	—	(1,206)	—
Comprehensive loss	$ (29,153)	$ (35,523)	$ (56,227)	$ (48,439)

See notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
BALANCE, JANUARY 1, 2021	242,118	$ 2,421	$ 2,866,303	$ —	$ (3,049,143)	$ (180,419)
Net issuance of common stock associated with stock options and restricted stock units	390	4	393	—	—	397
Issuance of common stock under Employee Stock Purchase Plan	293	3	387	—	—	390
Stock-based compensation expense	—	—	1,935	—	—	1,935
Issuance of common stock pursuant to conversion of the Mann Group convertible note	3,830	38	9,535	—	—	9,573
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	170	2	425	—	—	427
Issuance of common stock pursuant to conversion of the 2024 convertible notes	1,667	17	4,983	—	—	5,000
Issuance of common stock pursuant to payoff of the 2024 convertible note interest	27	—	143	—	—	143
Issuance of at-the-market placement	578	6	1,880	—	—	1,886
Issuance costs associated with at-the-market placement	—	—	(38)	—	—	(38)
Net loss	—	—	—	—	(12,916)	(12,916)
BALANCE, MARCH 31, 2021	249,073	$ 2,491	$ 2,885,946	$ —	$ (3,062,059)	$ (173,622)
Net issuance of common stock associated with stock options and restricted stock units	520	5	(550)	—	—	(545)
Stock-based compensation expense	—	—	3,926	—	—	3,926
Premium on Mann Group convertible note	—	—	22,107	—	—	22,107
Issuance of common stock from market price stock purchase	25	—	106	—	—	106
Net loss	—	—	—	—	(35,523)	(35,523)
BALANCE, JUNE 30, 2021	249,618	$ 2,496	$ 2,911,535	$ —	$ (3,097,582)	$ (183,551)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
BALANCE, JANUARY 1, 2022	251,478	$ 2,515	$ 2,918,205	$ —	$ (3,130,069)	$ (209,349)
Net issuance of common stock associated with stock options and restricted stock units	450	4	125	—	—	129
Issuance of common stock under Employee Stock Purchase Plan	233	2	738	—	—	740
Stock-based compensation expense	—	—	2,806	—	—	2,806
Issuance of common stock from market price stock purchase plan	252	3	681	—	—	684
Cumulative loss on available-for-sale securities	—	—	—	(1,076)	—	(1,076)
Net loss	—	—	—	—	(25,998)	(25,998)
BALANCE, MARCH 31, 2022	252,413	$ 2,524	$ 2,922,555	$ (1,076)	$ (3,156,067)	$ (232,064)
Issuance of common stock pursuant to conversion of Mann Group convertible note	3,838	39	9,557	—	—	9,596
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	193	2	518	—	—	520
Net issuance of common stock associated with stock options and restricted stock units	833	8	(385)	—	—	(377)
Stock-based compensation expense	—	—	4,422	—	—	4,422
Cumulative loss on available-for-sale securities	—	—	—	(130)	—	(130)
Net loss	—	—	—	—	(29,023)	(29,023)
BALANCE, JUNE 30, 2022	257,277	$ 2,573	$ 2,936,667	$ (1,206)	$ (3,185,090)	$ (247,056)

See notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (55,021)	$ (48,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,228	5,861
Interest expense on financing liability	4,814	—
Interest on milestone payment	3,912	3,663
Depreciation and amortization	2,735	1,671
Amortization of right-of-use assets	2,331	668
Interest expense on promissory notes	202	1,398
Gain on foreign currency translation	(6,486)	(2,935)
Write-off of inventory	451	—
Loss on extinguishment of debt	—	22,130
Changes in operating assets and liabilities:		
Accounts receivable, net	(10,036)	(2,087)
Inventory	(2,720)	(2,509)
Prepaid expenses and other current assets	(235)	(502)
Other assets	(441)	(202)
Accounts payable	867	1,904
Accrued expenses and other current liabilities	(134)	3,215
Deferred revenue	11,059	(13,222)
Operating lease liabilities	(2,441)	(1,554)
Recognized loss on purchase commitments	(2,928)	(3,636)
Accrued interest on Mann Group promissory notes	—	(4,919)
Customer deposits	(3,387)	5,317
Net cash used in operating activities	(50,230)	(34,178)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturity of debt securities	53,307	—
Purchase of debt securities	(68,470)	(138,920)
Acquisition of V-Go	(15,099)	—
Purchase of available-for-sale securities	(5,000)	(3,000)
Purchase of property and equipment	(2,222)	(2,030)
Net cash used in investing activities	(37,484)	(143,950)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment on financing liability	(1,399)	—
Proceeds from market price stock purchase plan	684	106
Payment of employment taxes related to vested restricted stock units and exercise of stock options	(248)	(148)
Proceeds from the Senior convertible notes	—	230,000
Issuance costs associated with Senior convertible notes	—	(7,268)
Principal payments on Mann Group promissory notes	—	(35,051)
Payment of MidCap credit facility	—	(10,000)
Payment of MidCap credit facility prepayment penalty	—	(1,000)
Milestone payment	—	(5,000)
Proceeds from at-the-market offering	—	1,886
Issuance costs associated with at-the-market offering	—	(38)
Net cash (used in) provided by financing activities	(963)	173,487
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(88,677)	(4,641)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	124,184	67,163
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 35,507	$ 62,522
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash	$ 4,341	$ 6,717
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Reclassification of investments from long-term to current	52,236	—
Payments on debt and interest through common stock issuance	10,116	15,143
Modification of operating leases	3,794	—
Addition of right-of-use asset	1,812	—
UT owned property and equipment	1,563	—
Non-cash construction in progress and property and equipment	916	1,183
Common stock issuance to settle employee stock purchase plan liability	740	390
Contingent milestone liability	610	—
Premium on Mann Group convertible note	—	22,107

See notes to condensed consolidated financial statements.

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, 2021, filed with the SEC on February 24, 2022 (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 and six months ended June 30, 2022 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 accompanying 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. In addition, the ongoing COVID-19 pandemic has increased the level of judgment used by management in developing these estimates and assumptions, particularly given that the ultimate impact of the COVID-19 pandemic is uncertain and subject to change. 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, milestone rights liability, stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities, and the valuation allowance recorded against net deferred tax assets.

Business — MannKind focuses on the development and commercialization of therapeutic products for patients with endocrine and orphan lung diseases. 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 Company also collaborates with third parties to formulate their drugs on the Company's Technosphere drug delivery platform. In May 2022, the Company's partner, United Therapeutics Corporation ("United Therapeutics" or "UT"), received approval from the U.S. Food and Drug Administration ("FDA") for Tyvaso DPI (treprostinil) inhalation powder, which is indicated for the treatment of pulmonary arterial hypertension and for the treatment of pulmonary hypertension associated with interstitial lung disease. UT began commercializing Tyvaso DPI in June 2022 and is obligated to pay the Company a 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.

The Company is not currently profitable and has rarely generated positive net cash flow from operations. In addition, the Company expects to continue to incur significant expenditures for the foreseeable future in support of its manufacturing operations, sales and marketing costs for its diabetes products, and development of other product candidates in the Company's pipeline. As of June 30, 2022, the Company had capital resources of $35.5 million in cash and cash equivalents, $118.6 million in short-term investments, $32.6 million in long-term investments, an accumulated deficit of $3.2 billion and $278.8 million of total principal amount of outstanding borrowings.

In August 2019, MannKind and its wholly owned subsidiary, MannKind LLC, entered into a credit and security agreement with MidCap Financial Trust (as amended, the "MidCap Credit Facility"). The MidCap Credit Facility currently provides a secured term loan facility with a potential aggregate principal amount of up to $100.0 million, with a balance of $40.0 million borrowed as of June 30, 2022. The final $60.0 million tranche became available through June 30, 2022 after the Tyvaso DPI approval by the FDA. The Company did not exercise its right to borrow the final tranche. See Note 9 – *Borrowings*. In March 2021, the Company issued $230.0 million of 2.50% convertible senior notes due 2026 (the "Senior convertible notes") to provide additional operating capital and pay down higher cost debt.

The Company believes its resources will be sufficient to fund its operations for the next twelve months from the date of issuance of these condensed consolidated financial statements.

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. Certain prior year amounts have been reclassified for consistency with the current year presentation. Changes were made to the condensed consolidated statement of operations to disclose a single caption for interest expense on all outstanding notes. Changes were made to the condensed consolidated balance sheets to reclassify interest receivable from investments from accounts receivable, net to other assets.

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 it is entitled to 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 (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 durable medical equipment suppliers ("DME") 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.

Free Goods Program – From time to time, the Company offers programs to potential new patients that allow them to obtain free goods (prescription fills) from a pharmacy. The Company excludes such amounts related to these programs from both gross and net revenue. The cost of product associated with the free goods program is recognized as cost of goods sold in the condensed consolidated statements of operations.

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 judgments are required in making these estimates.

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 estimates detailed below as of June 30, 2022 and, therefore, the transaction price was not reduced further during the six months ended June 30, 2022. 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 — commercial product sales and earnings in the period such variances become known.

Significant judgment is required in estimating gross-to-net adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

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 have been made in the past and may be necessary in the future based on revised estimates to the Company's assumptions.

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 products that has 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 manufacturing commercial 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 our significant collaboration and service agreement with UT that includes a long-term commercial supply agreement (as amended, the "CSA"), we have 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 future commercial manufacturing and supply of product ("Manufacturing Services"). Pre-production activities under the CSA, such as facility expansion services and other administrative services, were considered bundled services under the Manufacturing Services 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 represent 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 10 – *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 10 – 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. If the revenue for a sales-based or usage-based royalty is promised in exchange for an intellectual property license, the Company recognizes revenue as the latter of the subsequent sale or usage occurs or the performance obligation to which the royalty has been allocated has been satisfied or partially satisfied.

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 collaborative agreements, for accounting purposes, represent contracts with customers and therefore are not subject to accounting literature on collaborative 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 collaborative 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 CSA agreement with UT 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.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenue (in thousands)				
Product sales[1]	$ 17,417	$ 9,976	$ 28,427	$ 18,075
Services[2]	1,173	13,304	2,155	22,641
Royalties[3]	304	—	304	—
Total net revenue	$ 18,894	$ 23,280	$ 30,886	$ 40,716

(1) Amounts represent the sales of Afrezza and V-Go to wholesalers and specialty pharmacies and Tyvaso DPI to UT.

(2) Amounts represent revenue generated from our collaboration arrangements, including Next-Gen R&D Services (as defined in Note 10) for UT as well as arrangements with other collaboration partners. See Note 10 – *Collaboration, Licensing and Other Arrangements*.

(3) Amounts represent royalties on UT's net sales of Tyvaso DPI.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of revenue and goods sold (in thousands)				
Product sales	$ 12,481	$ 4,411	$ 22,967	$ 8,726
Services	434	5,515	946	8,810
Total cost of revenue and goods sold	$ 12,915	$ 9,926	$ 23,913	$ 17,536

The Company follows detailed 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 2015.

Cost of Revenues – Collaborations and Services — Cost of revenues – 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 – collaborations and services also includes the cost of product development.

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 June 30, 2022 and December 31, 2021, cash equivalents were comprised of money market funds, corporate bonds and commercial paper accounts with original maturities less than 90 days from the date of purchase.

Held-to-Maturity Investments — The Company's investments generally consist of commercial paper, corporate notes or bonds and U.S. Treasury securities. As of June 30, 2022, 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 principal and accrued interest shall be due and payable by Thirona on demand by the Company at any time after the maturity date of December 31, 2023. Interest accrues at a rate of 6% per annum. The Thirona convertible notes are general unsecured obligations of Thirona. The Thirona convertible notes are classified as available-for-sale securities and are included in other assets in the condensed consolidated balance sheet. Available-for-sale investments are subsequently measured at fair value. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income until realized. The Company assesses whether it has any intention to sell the investment, determines fair value of its available-for-sale investments using level 3 inputs as well as assesses whether there were other-than-temporary impairments associated with the available-for-sale investment. In June 2021, the Company and Thirona also entered into a collaboration agreement to develop a compound for the treatment of fibrotic lung diseases. See Note 10– *Collaboration, Licensing and Other Arrangements* for additional information.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and investments. Cash and cash equivalents are held in high credit quality institutions. Cash equivalents consist of interest-bearing money market funds and U.S. Treasury securities with maturities less than 90 days. Investments generally consist 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 regulatory approval of the new supplier and the improved manufacturing process. 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 achieving regulatory approvals for the Company's manufacturing process, feedback from 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 regulatory approval 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 approval date of the new raw material. If management is aware of any specific material risks or contingencies other than the normal regulatory review and approval 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 a research and development 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 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.

Impairment of Long-Lived 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 research and development ("IPR&D") projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's 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. See Note 2 – Acquisition.

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 will test 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 assesses whether losses on long-term purchase commitments should be accrued. Losses that are expected to arise from firm, non-cancellable, commitments for the future purchases are recognized unless recoverable. When making the assessment, the Company also considers whether it is able to renegotiate with its vendors. The recognized loss on purchase commitments is reduced as inventory items are received. If, subsequent to an accrual, a purchase commitment is successfully renegotiated, the gain is recognized in the Company's condensed consolidated statements of operations. The liability balance of the recognized loss on insulin purchase commitments as of June 30, 2022 and December 31, 2021 was $73.4 million and $82.8 million, respectively. No new contracts were identified in 2021 or in the first six months of 2022 that required a new loss on purchase commitment accrual.

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 SÁRL (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 sales milestones, $65.0 million of which remains payable 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 is now entitled to all rights under the Milestone Rights Agreement. As of June 30, 2022, $65.0 million remained payable pursuant to the Milestone Rights Agreement upon achievement of Afrezza net sales milestones with $5.0 million included in accrued expenses and other current liabilities in our condensed consolidated balance sheets, which will be paid in the third quarter of 2022.

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 9 – *Borrowings*).

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 stock options, RSUs, performance-based non-qualified stock options awards ("PNQs"), restricted stock units with market conditions ("Market RSUs") 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. 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. 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.

Clinical Trial Expenses — Clinical trial expenses, which are primarily reflected in research and development 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 excludes dilution for potentially dilutive securities and is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period. Diluted net income or loss per share reflects the potential dilution under the treasury method that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be anti-dilutive.

Recently Issued Accounting Standards — From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (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. Acquisition

On May 17, 2022, the Company entered into an Asset Purchase Agreement (the "APA") to purchase from Zealand Pharma A/S and Zealand Pharma US, Inc. (together "Zealand") certain assets and assume certain liabilities associated with the V-Go wearable insulin delivery device. The transaction closed on May 31, 2022 (the "Acquisition Date").

Under the terms of the APA, the Company paid up-front consideration of $15.1 million for certain assets and assumed liabilities related to V-Go. In addition, the Company will be obligated to make one-time, sales-based milestone payments to Zealand totaling up to a maximum of $10.0 million upon the achievement of specified annual revenue milestones between $40 million and $100 million.

The total preliminary purchase consideration for V-Go was as follows (in thousands):

Fair value of consideration:		**Amount**
Cash consideration	$	15,099
Fair value of contingent consideration		610
Total	$	15,709

The transaction was accounted for using the acquisition method of accounting, which requires, among other things, the assets acquired and liabilities assumed to be recognized at their respective fair values as of the acquisition date. The excess of the purchase price over those fair values was recorded as goodwill, which will be amortized over a period of 15 years for tax purposes. The estimates and assumptions used include the projected timing and amount of future cash flows and discount rates to reflect the risk inherent in the future cash flows. The estimated fair values of assets acquired and liabilities assumed and resulting goodwill are subject to adjustment as the Company finalizes its purchase price accounting. The significant items for which a final fair value has not been determined include, but are not limited to the valuation of the intangible asset and assumed liabilities for rebates and return reserves. The Company does not expect its fair value determinations to materially change; however, there may be differences between the amounts recorded at the Acquisition Date and the final fair value analysis, which is expected to be complete no later than the second quarter of 2023.

The information below reflects the preliminary amounts of identifiable assets acquired and liabilities assumed as of the Acquisition Date (in thousands):

	Amount
Assets:	
Inventory	$ 11,152
Property and equipment	2,888
Goodwill	2,900
Intangible asset - Developed technology	1,400
Operating lease right-of-use assets	1,812
Total assets	20,152
Liabilities:	
Liabilities assumed	2,631
Operating lease liability	1,812
Total liabilities	4,443
Net assets acquired	$ 15,709

Inventory of $11.2 million consisted of raw materials, semi-finished goods and finished goods. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 inputs not observable in the market. Property and equipment and assumed liabilities were recorded at their carrying amounts which were deemed to approximate their fair values based on level 3 unobservable inputs. The fair values of the right-of-use assets and lease liabilities for assumed operating leases were assessed in accordance with ASC Topic 842, *Leases*, based on discounted cash flow from lease payments, utilizing the Company's incremental borrowing rate of 7.25%.

The fair value of the intangible asset was determined by applying the income approach based on significant level 3 unobservable inputs. The income approach estimates fair value based on the present value of cash flow that the assets could be expected to generate in the future. We developed internal estimates for expected cash flows in the present value calculation using inputs and significant assumptions that include historical revenues and earnings, long-term growth rate, discount rate, contributory asset charges and future tax rates, among others.

The fair value of the contingent milestone liability was estimated 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 2.95%, dividend yield of 0%, volatility of 65%, period of 15 years and credit risk of 12%.

The Company incurred acquisition-related costs of approximately $0.2 million for the three months ended June 30, 2022.

Supplemental Pro Forma Information (unaudited)

Net revenue for the three and six months ended June 30, 2022 was $2.1 million and loss from operations for the three and six months ended June 30, 2022 was $0.3 million since the Acquisition Date. The following unaudited pro forma summary presents consolidated information of the Company as if the acquisition had occurred on January 1, 2021 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenue	$ 24,992	$ 28,711	$ 43,082	$ 51,841
Net loss	(28,763)	(35,548)	(54,505)	(48,778)
Net loss per share - basic and diluted	$ (0.11)	$ (0.14)	$ (0.22)	$ (0.20)

These pro forma amounts have been calculated by applying the Company's accounting policies assuming transaction costs had been incurred beginning January 1, 2021. The Company did not have any other material nonrecurring pro forma adjustments directly attributable to the acquisition included in the reported pro forma revenue and loss.

3. Investments

Held-to-Maturity Investments — Investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. As of June 30, 2022, the Company held $118.6 million of short-term investments and $32.6 million of long-term investments. As of December 31, 2021, the Company held $79.9 million of short-term investments and $56.6 million of long-term investments. For the three and six months ended June 30, 2022, the Company recognized $0.5 million and $0.9 million of interest income on investments and $0.2 million and $0.5 million of amortization on certain investments. The interest income net of amortization on investments is reflected as interest income, net on the condensed consolidated statement of operations. For the three and six months ended June 30, 2021, the Company recognized a *de minimis* amount of interest income on investments. No allowance for credit losses on held-to-maturity securities was required as of June 30, 2022.

Available-for-Sale Investment — The Thirona convertible notes are classified as available-for-sale securities and are included in other assets in the condensed consolidated balance sheet. Available-for-sale investments are subsequently measured at fair value. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income until realized. The Company determines fair value of its available-for-sale investments using level 3 inputs. The Company evaluated the fair value of its investment in Thirona as of June 30, 2022 by applying a Monte Carlo simulation and determined that the fair value was $6.8 million. The fair value of the investment in Thirona as of December 31, 2021 was $3.0 million, which approximated carrying value. For the six months ended June 30, 2022, an unrealized holding loss of $1.2 million was recognized as other comprehensive loss in our condensed consolidated statements of comprehensive loss and condensed consolidated statements of stockholders' deficit.

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

		June 30, 2022		
	Investment Level	Amortized Cost (Carrying Value)	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial bonds and paper	Level 2	$ 105.0	$ (1.0)	$ 104.8
Money market funds	Level 1	30.5	—	30.5
U.S. Treasuries	Level 2	46.2	(0.7)	45.5
Total cash equivalents and investments		181.7	(1.7)	180.8
Less cash equivalents		(30.5)	—	(30.5)
Total Investments		$ 151.2	$ (1.7)	$ 150.3

		December 31, 2021		
	Investment Level	Amortized Cost (Carrying Value)	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial bonds and paper	Level 2	$ 115.2	$ 0.2	$ 115.0
Money market funds	Level 1	21.3	—	21.3
U.S. Treasuries	Level 2	23.9	0.1	23.8
Total cash equivalents and investments		160.4	0.3	160.1
Less cash equivalents		(23.8)	—	(23.8)
Total Investments		$ 136.6	$ 0.3	$ 136.3

As of June 30, 2022 and December 31, 2021, there was $0.4 million and $0.3 million, respectively, of interest receivable included in our condensed consolidated balance sheets as prepaid expenses and other current assets.

4. Accounts Receivable

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

	June 30, 2022	December 31, 2021
Accounts receivable – commercial		
Accounts receivable, gross	$ 14,869	$ 7,939
Wholesaler distribution fees and prompt pay discounts	(2,451)	(1,696)
Reserve for returns	(3,173)	(2,797)
Total accounts receivable – commercial, net	9,245	3,446
Accounts receivable – collaborations and services		
Accounts receivable, gross	5,785	2,060
Allowance for doubtful accounts	—	(767)
Total accounts receivable – collaborations and services, net	5,785	1,293
Total accounts receivable, net	$ 15,030	$ 4,739

As of June 30, 2022 and December 31, 2021, the allowance for doubtful accounts for accounts receivable – commercial was *de minimis*. The Company had three wholesale distributors representing approximately 76% of commercial accounts receivable as of June 30, 2022 and approximately 73% and 72% of gross sales for the three and six months ended June 30, 2022, respectively.

As of June 30, 2022, there was no allowance for credit losses for accounts receivable – collaborations and services. The Company had one collaboration partner, United Therapeutics, that comprised 99% of the collaboration and services net accounts receivable as of June 30, 2022 and approximately 88% and 90% of gross revenue from collaborations and services for the three and six months ended June 30, 2022, respectively.

5. Inventories

Inventories consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 5,789	$ 2,703
Work-in-process	6,372	2,522
Finished goods	8,412	1,927
Total inventory	$ 20,573	$ 7,152

Work-in-process and finished goods as of June 30, 2022 and December 31, 2021 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 2015. Raw materials inventory included $0.8 million of pre-launch inventory as of June 30, 2022 and December 31, 2021, which consisted of FDKP received in November 2019. The Company expects to request approval from the FDA for the new source of FDKP in 2023.

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 at June 30, 2022 and December 31, 2021. 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. For the three and six months ended June 30, 2022, there was an inventory write-off of $0.5 million as a result of this assessment. There were no inventory write-offs for the three and six months ended June 30, 2021.

6. Property and Equipment

Property and equipment consists of the following (dollars in thousands):

	Estimated Useful Life (Years)	June 30, 2022	December 31, 2021	
Land	—	$ 875	$ 875	
Buildings	39-40	17,389	17,389	
Building improvements	3-40	38,875	38,651	
Machinery and equipment	1-15	58,189	55,334	
Furniture, fixtures and office equipment	3-10	2,976	2,969	
Computer equipment and software	3	8,287	8,163	
Construction in progress	—	9,890	10,892	(1)
		136,481	134,273	
Less accumulated depreciation		(98,563)	(97,661)	
Total property and equipment, net		$ 37,918	$ 36,612	

(1) As of December 31, 2021, construction in progress included $4.7 million of equipment under construction for the manufacturing expansion for UT (the "UT Equipment"). See Note 10 – *Collaboration, Licensing and Other Arrangements.* The Company acted as agent on behalf of UT for the procurement of the UT Equipment. The Company received $5.0 million in deposit for this service, which was recognized as deposits from customer in the condensed consolidated balance sheet as of December 31, 2021. In April 2022, the Company and UT agreed that UT would hold title to the UT Equipment at all times. As such, there is no balance related to the UT Equipment included in construction in progress or deposit from customer in our consolidated condensed balance sheet as of June 30, 2022.

Depreciation expense related to property and equipment for the three and six months ended June 30, 2022 and 2021 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Depreciation Expense	$ 727	$ 481	$ 1,326	$ 941

On November 8, 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 conditions contained in a purchase and sale agreement. Effective with the closing of this transaction, the Company entered into a 20-year lease agreement with the Purchaser (the "Sale-Leaseback Transaction"). The sale of the Property and subsequent lease did not result in the transfer of control of the Property to the Purchaser; therefore, the Sale-Leaseback Transaction qualified as a failed sale leaseback transaction whereby the lease is accounted for as a finance lease and the Property remains as a long-lived asset of the Company and is depreciated at its remaining useful life of 20 years or less. See Note 13 – *Commitments and Contingencies*.

7. 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 $2.9 million as of June 30, 2022 as a result of our 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 (dollars in thousands):

	Estimated Useful Life (Years)	June 30, 2022 Cost	Accumulated Amortization	Net Book Value
Developed technology	15	$ 1,400	$ —	$ 1,400

Amortization expense related to the other intangible asset was *de minimis* for the three and six months ended June 30, 2022.

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*.

8. Accrued Expenses and Other Current Liabilities

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

	June 30, 2022	December 31, 2021
Salary and related expenses	$ 10,481	$ 14,022
Discounts and allowances for commercial product sales	7,620	4,227
Danbury facility buildout	144	786
Deferred lease liability	1,423	1,380
Current portion of milestone rights liability	2,012	1,088
Professional fees	2,103	895
Accrued interest	6,073	2,166
Retail inventory purchase	—	875
Other	3,328	1,980
Accrued expenses and other current liabilities	$ 33,184	$ 27,419

9. Borrowings

Carrying amount of borrowings consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Senior convertible notes	$ 224,670	$ 223,944
MidCap credit facility	39,047	38,833
Mann Group convertible note	8,829	18,425
Total debt — net carrying amount	$ 272,546	$ 281,202

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

	Amount Due		Terms				
	June 30, 2022	December 31, 2021	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[1]	$40.0 million	$40.0 million	one-month LIBOR (1% floor) plus 6.25%	(1)	August 2025	(1)	N/A
Mann Group convertible note	$8.8 million	$18.4 million (plus $0.4 million accrued interest paid-in-kind)	2.50%	(2)	December 2025	(2)	$2.50 per share

(1) In April 2021, the Company prepaid $10.0 million principal balance and amended the MidCap credit facility. The interest rate prior to the amendment was one-month LIBOR (2% floor) plus 6.75% and the maturity date was in August 2024.

(2) In April 2021, the Mann Group convertible note was amended. The interest rate prior to the amendment was 7.00% and the maturity date was in November 2024.

The maturities of the Company's borrowings as of June 30, 2022 are as follows (in thousands):

	Amounts
2022	$ —
2023	6,667
2024	20,000
2025	22,163
Thereafter	230,000
Total principal payments	278,830
Unamortized discount	(954)
Debt issuance costs	(5,330)
Total debt — net carrying amount	$ 272,546

Senior convertible notes – On March 4, 2021, the Company issued $200.0 million aggregate principal amount of Senior convertible notes in a private offering. Pursuant to an option to purchase additional senior convertible notes in the purchase agreement between the Company and the initial purchasers of the Senior convertible notes, the Company issued an additional $30.0 million aggregate principal amount of Senior convertible notes on March 15, 2021. 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. 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 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 June 30, 2022, the unamortized debt issuance cost was $5.3 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 10 – *Collaboration, Licensing and Other Arrangements*). The Company did not exercise its right to borrow Tranche 3.

The MidCap credit facility has been amended several times, including in April 2021 when the parties agreed to, among other things, (i) increase the amount available under the third advance from $25.0 million to $60.0 million and extend the date through which the third advance is available to June 30, 2022, (ii) amend the conditions to the third advance of $60.0 million being available to draw, including certain milestone conditions associated with Tyvaso DPI, (iii) remove the Company's obligation to issue a warrant to purchase shares of the Company's common stock upon drawing down the third advance, (iv) extend the interest-only period until September 1, 2023 and extend the maturity date until August 1, 2025, (v) amend the financial covenant relating to trailing 12 month minimum Afrezza net revenue, (vi) decrease the minimum cash covenant, (vii) decrease the interest rate on any amounts outstanding, now or in the future, under the MidCap credit facility, (viii) permit the Company to make certain acquisitions, subject to requirements, and (ix) permit the Company to make investments of up to an additional $9.0 million so long as the Company has $90.0 million or more of unrestricted cash and short-term investments following such investment. Concurrent with entering into this amendment, 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 will be amortized over the remaining life of the debt. As of June 30, 2022, the unamortized debt discount was $0.3 million and the unamortized prepayment penalty was $0.7 million.

Tranche 1 and Tranche 2 accrue interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month LIBOR (subject to a one-month LIBOR floor of 1.00%) plus 6.25%. Interest on each term loan advance is due and payable monthly in arrears. Principal on each term loan advance under Tranche 1 and Tranche 2 are payable in 24 equal monthly installments beginning September 1, 2023, until paid in full on August 1, 2025. The Company has the option to prepay its existing term loans, in whole or in part, subject to early termination fees in an amount equal to 3.00% of principal prepaid if prepayment occurs on or prior to April 22, 2022; 2.00% of principal prepaid if prepayment occurs on or after April 23, 2022 through and including April 22, 2023; and 1.00% of principal prepaid if prepayment occurs on or after April 23, 2023 through the maturity date.

The Company's obligations under the MidCap credit facility are secured by a security interest on substantially all of its assets, including intellectual property.

The MidCap credit facility, as amended, contains 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 must also 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 June 30, 2022, the Company was in compliance with the financial covenants.

The MidCap credit facility also contains 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 may declare 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 be increased by 2.00%.

Mann Group promissory notes — 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") and issued a non-convertible note to Mann Group in an aggregate principal amount of $35.1 million (the "Mann Group non-convertible note" and, together with the Mann Group convertible note, the "Mann Group promissory notes") as part of a restructuring of its then existing indebtedness to Mann Group.

The Mann Group promissory notes originally accrued interest at the rate of 7.00% per year on the principal amount, payable quarterly in arrears on the first day of each calendar quarter beginning October 1, 2019. In April 2021, the Company repaid the entire principal amount of $35.1 million outstanding under the Mann Group non-convertible note, together with all accrued and unpaid interest thereon. On the same date, the Company and Mann Group amended the Mann Group convertible note, pursuant to which the parties agreed to (i) reduce the interest rate from 7.0% to 2.5% effective on April 22, 2021, and (ii) extend the maturity date from November 3, 2024 to December 31, 2025.

The amendment to the Mann Group convertible note resulted in a debt extinguishment with a substantial premium based on the fair value post extinguishment. The fair value in excess of the face amount of $18.4 million contributed to a loss on extinguishment of $22.1 million in the consolidated statement of operations for the year ended December 31, 2021 and resulted in a corresponding debt premium of $22.1 million which was recognized as additional paid-in capital in the consolidated balance sheet as of December 31, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company. The Company wrote off a *de minimis* amount of debt issuance cost.

The principal and any accrued and unpaid interest under the Mann Group convertible note may be converted, 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. The conversion rate will be subject to adjustment under certain circumstances described in the Mann Group convertible note. Interest on the convertible note will be 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 may, at its option, elect 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 quarter ended June 30, 2022, Mann Group converted $10.0 million of principal and capitalized interest into 4,000,000 shares of common stock. In addition, the Company paid quarterly interest by issuing the Mann Group 31,541 shares of common stock.

Amortization of debt discount and debt issuance cost related to all borrowings for the three and six months ended June 30, 2022 and 2021 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Amortization of debt discount	$ 106	$ 86	$ 212	$ 146
Amortization of debt issuance cost	363	363	726	488

Milestone Rights — As of June 30, 2022 and December 31, 2021, the remaining Milestone Rights liability balance was $5.9 million, which was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. As of December 31, 2021, the $5.9 million liability consisted of a $1.1 million current liability which was presented as accrued expenses and other current liabilities and a $4.8 million long-term liability which was presented in milestone liabilities in our condensed consolidated balance sheets. During the second quarter of 2022, the Company achieved an Afrezza net sales milestone specified by the Milestone Rights. The carrying value of the Milestone Rights liability related to the $5.0 million payment, which will be made in the third quarter of 2022, is approximately $1.1 million and represents the fair value as determined in 2013 (the most recent measurement date).

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.

10. Collaboration, Licensing and Other Arrangements

Revenue from collaborations and services for the three and six months ended June 30, 2022 and 2021 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
UT CSA Agreement(1)	$ 4,695	$ —	$ 5,879	$ —
UT License Agreement(2)	698	12,163	1,556	21,163
Vertice Pharma Co-Promotion Agreement	325	856	325	1,147
Cipla License and Distribution Agreement	36	37	73	73
Other	114	83	201	83
Receptor CLA	—	165	—	175
Total revenue from collaborations and services	$ 5,868	$ 13,304	$ 8,034	$ 22,641

(1) Amount consists of revenue recognized for Manufacturing Services and sales of product 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 the manufacturing of Tyvaso DPI.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
UT Revenue (in thousands)				
UT CSA Agreement	$ 4,695	$ —	$ 5,879	$ —
UT License Agreement	698	12,163	1,556	21,163
Royalties	304	—	304	—
Total revenue from UT	$ 5,697	$ 12,163	$ 7,739	$ 21,163

Under the terms of the UT License Agreement, the Company received an upfront payment of $45.0 million in October 2018 and four $12.5 million milestone payments between April 2019 and November 2020. The Company is also entitled to receive low double-digit royalties on net sales of Tyvaso DPI as well as a manufacturing margin on commercial supplies of the product. UT, at its option, may expand the scope of the products covered by the UT License Agreement to include products with certain other active ingredients for the treatment of pulmonary arterial hypertension. Each such optioned product would be subject to UT's payment to the Company of up to $40.0 million in additional option exercise and development milestone payments, as well as a low double-digit royalty on net sales of any such product.

In August 2021, the Company and UT entered into a CSA, pursuant to which the Company is responsible for manufacturing and supplying to United Therapeutics, and United Therapeutics is responsible for purchasing from the Company on a cost-plus basis, Tyvaso DPI and BluHale inhalation profiling devices, as required for commercial distribution and sale by UT. 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. Pursuant to the CSA, UT is obligated to reimburse certain pre-production costs incurred by the Company to support the manufacturing and supply of Tyvaso DPI.

The activities and deliverables under the CSA and the current development plan resulted in three distinct performance obligations which include: (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 Next-Gen R&D Services; and (3) a material right associated with future commercial manufacturing and supply of product ("Manufacturing Services"). Following the FDA's approval of Tyvaso DPI, UT began issuing the Company 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.

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 the modification. The modification did not result in a change to the activities and deliverables under the CSA.

Description	Anticipated Cash Flow	Anticipated Revenue Allocation(1)	Recognition Method	Progress Measure	Revenue Recognition	
	(in millions)					
Total anticipated cash flow(2)	$ 463.5					
Distinct Performance Obligation						
R&D Services and License(3)		$ —	Over time	Ratably	Aug 2021 - Oct 2021	(4)
Next-Gen R&D Services(5)		$ 4.8	Over time	Input	% of completion of costs	(6)
Manufacturing Services(7)		$ 458.7	Point in time		Transfer of control	(8)

(1) Allocation is based on management's assessment of the stand-alone selling price of each performance obligation.

(2) The total anticipated cash flow includes a transaction price of $64.3 million for the contractual obligations under the CSA for the Manufacturing Services and the Next-Gen R&D Services performance obligations and $399.2 million for future supply of Tyvaso DPI over the remaining term of the CSA.

(3) The license for the Company's IP was considered to be interdependent with the development activities to support approval of Tyvaso DPI. A sales-based royalty is promised in exchange for the IP license; therefore, the royalties associated with the license are excluded from the determination of the transaction price and the Company will recognize revenue as the sale of Tyvaso DPI to a patient occurs.

(4) Represents the period when the revenue for the R&D Services performance obligation was recognized.

(5) The standalone selling price ("SSP") for the Next-Gen R&D Services performance obligation was based on industry ratios as well as the Company's historical R&D projects. The transaction price for the Next-Gen R&D Services was based on fixed consideration which was allocated between performance obligations as discussed in note (2) above.

(6) The Next-Gen R&D Services performance obligation will be satisfied over time using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer.

(7) Pre-production activities under the CSA, such as facility expansion services and certain other administrative services, were considered bundled services that are part of the Company's Manufacturing Services performance obligation, given the nature of the Company's contractual responsibilities and ASC 606 requirements.

(8) The Manufacturing Services 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 includes a material right related to the Company's estimated production of product in the amount of $144.5 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 April 2022, the Company and UT agreed to fund $2.3 million in capital improvements to support commercialization and continuous improvement activities and $0.7 million in the development of alternative manufacturing processes. The Company determined that the capital improvements 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.

Description	Anticipated Cash Flow	Revenue Allocation	Recognition Method	Progress Measure	Revenue Recognition
	(in millions)				
Total anticipated cash flow(1)	$ 483.2				
Distinct Performance Obligation					
R&D Services and License		$ —	Over time	Ratably	Aug 2021 - Oct 2021
Next-Gen R&D Services		$ 5.9	Over time	Input	% of completion of costs
Manufacturing Services and Product Sales(2)		$ 477.2	Point in time		Transfer of control

Notes presented in the previous modification table above also apply to this modification table unless noted otherwise.

(1) The total anticipated cash flow includes a transaction price of $71.5 million for the contractual obligations under the CSA for the Manufacturing Services and the Next-Gen R&D Services performance obligations and $411.7 million for future supply of Tyvaso DPI over the remaining term of the CSA.

(2) The Manufacturing Services 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 includes a material right related to the Company's estimated production of product in the amount of $150.2 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.

As of June 30, 2022, deferred revenue consisted of $29.8 million, of which $1.5 million was classified as current and $28.3 million was classified as long-term on the condensed consolidated balance sheet.

Vertice Pharma Co-Promotion Agreement — In December 2020, the Company entered into a co-promotion agreement with Vertice Pharma pursuant to which the Company's sales force promoted Thyquidity to adult endocrinologists, pediatric endocrinologists and other healthcare providers who treat hypothyroidism. Following the commercial launch of Thyquidity in February 2021, Vertice Pharma became obligated to pay fixed quarterly payments to the Company, as well as variable consideration based on gross profits resulting from all sales of Thyquidity.

In September 2021, the Company and Vertice Pharma mutually agreed that the Company would cease promotional activities under the co-promotion agreement effective September 30, 2021, other than certain transitional activities that continued until October 15, 2021.

As of December 31, 2021, the Company had fully reserved $0.8 million of revenue from the co-promotion of Thyquidity, which was recognized as allowance for credit losses and was included in accounts receivable, net in the condensed consolidated balance sheet.

In June 2022, the Company and Vertice Pharma reached a final settlement of all obligations related to the termination of the co-promotion agreement of $0.3 million, which was recognized as revenue from collaboration and services in the Company's condensed consolidated statement of operations and the balance was written off against the reserve.

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 pulmonary fibrosis. 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 will be accounted for under ASC 808, Collaborative Agreements; however, no consideration will be exchanged between the parties. The Company will expense the costs incurred as research and development in the condensed consolidated statements of operations.

Biomm Supply and Distribution Agreement — In May 2017, the Company and 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. There were no shipments of product to Biomm in 2021 or the first six months of 2022.

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 June 30, 2022, the deferred revenue balance was $1.6 million, of which $0.2 million is classified as current and $1.4 million is classified as long term in the condensed consolidated balance sheets.

11. 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 cash equivalents, long- and short-term investments, MidCap credit facility, Mann Group promissory notes, 2024 convertible notes, Senior convertible notes, Milestone Rights liabilities and Financing liability are disclosed below.

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. As of June 30, 2022 and December 31, 2021, the Company held $35.5 million and $124.2 million, respectively, of cash and cash equivalents.

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):

	June 30, 2022		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
Senior convertible notes[1]	$ 224.7	$ 223.5	$ 223.5
MidCap credit facility[2]	39.0	41.3	41.3
Mann Group convertible note[3]	8.8	15.8	15.8
Milestone rights[4]	5.9	13.2	13.2

(1) Fair value determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 12%, volatility of 77.2% 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 $213.4 million and $234.5 million, respectively.

(2) Fair value determined by applying a discounted cash flow analysis with a hypothetical yield of 10%. A change in yield of + or – 2% would result in a fair value of $39.9 million and $42.9 million, respectively.

(3) The fair value assessed as of June 30, 2022 was determined by applying a discounted cash flow analysis with a hypothetical yield of 12% and volatility of 75.3% 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 $15.4 million and $16.3 million, respectively.

(4) Fair value determined by applying a Monte Carlo simulation.

	December 31, 2021		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
Senior convertible notes(1)	$ 223.9	$ 237.5	$ 237.5
MidCap credit facility(2)	38.8	40.8	40.8
Mann Group convertible note(3)	18.4	37.8	37.8
Milestone rights(4)	5.9	18.1	18.1

(1) Fair value determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 12%, volatility of 90% 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 $226.6 million and $249.4 million, respectively.

(2) Fair value determined by applying a discounted cash flow analysis with a hypothetical yield of 10%. A change in yield of + or – 2% would result in a fair value of $39.1 million and $42.7 million, respectively.

(3) The April 2021 amendment to the Mann Group convertible note resulted in a substantial premium of $22.1 million based on the fair value post modification which was recognized as additional paid-in capital in the condensed consolidated balance sheet as of December 31, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company. The fair value assessed as of December 31, 2021 was determined by applying a discounted cash flow analysis with a hypothetical yield of 12% and volatility of 85% 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 $36.9 million and $38.8 million, respectively.

(4) Fair value determined by applying a Monte Carlo simulation.

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 Monte-Carlo Simulation Method to simulate the Afrezza net sales under a neutral framework to estimate the payment. 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.

Contingent milestone liability — The acquisition of V-Go on May 31, 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 selling, general and administrative expenses. As of June 30, 2022, the fair value of the contingent milestone liability was consistent with the fair value on the Acquisition Date.

Financing Liability — The Sale-Leaseback Transaction in November 2021 resulted in a financing liability which is included in our condensed consolidated balance sheets as a current financing liability of $9.5 million and a long-term financing liability of $94.4 million. The fair value of $110.7 million was determined using level 3 inputs. As of June 30, 2022, the fair value was determined using a discounted cash flow analysis with a hypothetical yield of 9.0%. As of December 31, 2021, the Company evaluated the fair value of its financing liability and determined that the fair value approximated the carrying value.

12. Common and Preferred Stock

The Company is authorized to issue 400,000,000 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 June 30, 2022 and December 31, 2021, 257,276,847 and 251,477,562 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. For the six months ended June 30, 2022, there were no sales under the CF Sales Agreement. For the six months ended June 30, 2021, the Company sold an aggregate of 578,063 shares of the Company's common stock at a weighted average purchase price of $3.26 per share for an aggregate gross proceeds of approximately $1.9 million pursuant to the CF Sales Agreement.

In the second quarter of 2022, Mann Group converted $10.0 million of principal and capitalized interest into 4,000,000 shares of common stock. In addition, the Company paid quarterly interest by issuing the Mann Group 31,541 shares of common stock.

For the six months ended June 30, 2022, the Company received $0.7 million from the market price stock purchase plan ("MPSPP") for 252,176 shares. The Company received $0.1 million from the MPSPP for 25,000 shares during the three and six months ended June 30, 2021.

For shares of common stock issued pursuant to the ESPP, see Note 14 – *Stock-Based Compensation Expense.*

13. Earnings per Common Share ("EPS")

Basic EPS excludes dilution for potentially dilutive securities and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted EPS reflects the potential dilution under the treasury method that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. 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 antidilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
EPS — basic and diluted:				
Net loss (numerator)	$ (29,023)	$ (35,523)	$ (55,021)	$ (48,439)
Weighted average common shares (denominator)	253,644	249,295	252,775	247,970
Net loss per share	$ (0.11)	$ (0.14)	$ (0.22)	$ (0.20)

Common shares issuable represents incremental shares of common stock which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the Senior convertible notes and the Mann Group convertible notes.

Potentially dilutive securities outstanding that are considered antidilutive are summarized as follows (in shares):

	Six Months Ended June 30,	
	2022	2021
Senior convertible notes	44,120,463	44,120,463
Mann Group convertible notes	3,370,000	7,370,000
Common stock options and PNQs	9,766,028	11,092,080
RSUs and Market RSUs (1)	15,848,183	7,986,898
Employee stock purchase plan	235,794	250,000
Warrants associated with MidCap credit facility	—	1,283,467
Total shares	73,340,468	72,102,908

(1) Market RSUs issued in 2020, 2021 and 2022 are included at the maximum share delivery of 300%, 0% and 200%, respectively, in accordance with a valuation assessment obtained as of June 30, 2022.

14. Stock-Based Compensation Expense

During the six months ended June 30, 2022, the Company granted the following awards (in shares):

	Three Months Ended March 31, 2022	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
Employee awards:			
RSUs	88,415 (1)	2,169,317 (2)	2,257,732
Market RSUs	—	1,359,500 (3)	1,359,500
Non-employee director RSUs	—	360,360 (4)	360,360
Total awards	88,415	3,889,177	3,977,592

(1) RSUs had a weighted average grant date fair value of $2.72 per share, of which 12,800 RSUs had a cliff vesting period of three years and 75,615 RSUs had a vesting period of four years.

(2) RSUs had a weighted average grant date fair value of $2.95 per share, of which 66,600 had a cliff vesting period of three years and 2,102,717 RSUs had a vesting period of four years.

(3) Market RSUs had a grant date fair value of $6.10 per share and will vest on May 10, 2025 provided the closing price of the Company's common stock on such vesting date is not less than the closing price on May 10, 2022. The number of shares delivered on the vesting date is determined by the percentile ranking of MannKind total shareholder return (TSR) over the period from May 10, 2022 until May 10, 2025 relative to the TSR of the Russell 3000 Pharmaceutical & Biotechnology Index over the same three-year period, as follows: less than 25th percentile=0% of target, 25th percentile=50% of target, 50th percentile=100% of target, 75th percentile=200% of target, 90th percentile or higher=300% maximum. Payout values will be interpolated between the percentile rankings above.

(4) RSUs had a weighted average grant date fair value of $2.95 per share and vested immediately upon grant, but the underlying shares of common stock will not be delivered until there is a separation of service, such as resignation, retirement or death.

As of June 30, 2022, there was $1.6 million of unrecognized stock-based compensation expense related to options and PNQs, which is expected to be recognized over a weighted average period of approximately 2.82 years, and $14.5 million and $15.3 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 2.92 and 1.81 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, research and development and selling, general and administrative expense for the three and six months ended June 30, 2022 and 2021 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
RSUs and options	$ 4,239	$ 3,819	$ 6,883	$ 5,625
Employee stock purchase plan	183	107	345	236
Total stock compensation expense	$ 4,422	$ 3,926	$ 7,228	$ 5,861

Employee Stock Purchase Plan

The Company provides all employees, including executive officers, the ability to purchase common stock at a discount under the Company's 2004 employee stock purchase plan (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 identical to those of all other employees.

The Company issued 233,401 and 292,981 shares of common stock pursuant to the ESPP for the six months ended June 30, 2022 and 2021, respectively. There were approximately 0.9 million shares of common stock available for issuance under the ESPP as of June 30, 2022.

15. 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. The Company has not recorded any liability for these indemnities in the condensed consolidated balance sheets. However, 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. As of June 30, 2022, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company and no accrual has been recorded. 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 — 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, $65.0 million of which remains payable to the Milestone Purchasers upon achievement of such milestones (see Note 9 – *Borrowings*). The fair value of the Milestone Rights is recorded in the condensed consolidated balance sheet, including $2.0 million in accrued expenses and other current liabilities and $3.9 million in milestone liabilities.

Sale-Leaseback Transaction— In November 2021, the Company sold the Property to 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 June 30, 2022, the related financing liability was $103.9 million, which was recognized in our condensed consolidated balance sheet as $94.4 million of financing liability — long-term and $9.5 million of financing liability — short-term. As of December 31, 2021, the related financing liability was $100.5 million, which was recognized in our condensed consolidated balance sheet as $93.5 million of financing liability — long-term and $7.0 million of financing liability — short-term.

Financing liability information is as follows:

	June 30, 2022	December 31, 2021
Weighted average remaining lease term (in years)	19.3	19.8
Weighted average discount rate	9.0%	9.0%

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Interest expense on financing liability	$ 2,443	$ —	$ 4,814	$ —

Financing liability payments as of June 30, 2022 were as follows (in thousands):

	June 30, 2022	December 31, 2021
2022[1]	$ 4,795	$ 6,373
2023	9,774	9,778
2024	10,018	10,023
2025	10,269	10,274
2026	10,533	10,539
Thereafter	199,302	199,091
Total	244,691	246,078
Interest expense	(137,785)	(142,485)
Debt issuance costs	(2,989)	(3,091)
Total financing liability	$ 103,917	$ 100,502

(1) 2022 includes amortization of the rent abatement.

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 May 2021, the Company and Amphastar amended the Insulin Supply Agreement to extend the term and restructure the annual purchase commitments. In connection with the amendment, the Company agreed to pay $2.0 million of amendment fees, which were recognized in cost of goods sold for the six months ended June 30, 2021. The remaining purchase commitments as of June 30, 2022 were as follows:

	June 30, 2022	
2022	€	2.7 million
2023	€	8.8 million
2024	€	14.6 million
2025	€	15.5 million
2026	€	19.4 million
2027	€	9.2 million

Pursuant to the amendment, the term of the Insulin Supply Agreement expires on December 31, 2027, 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.

Vehicle Leases – During the second quarter of 2018, the Company entered into a master lease agreement with Enterprise Fleet Management Inc. During 2021, 85 vehicles were retired and replaced, resulting in a fleet size of 89 vehicles. The Company received proceeds for the gain on the retired vehicles residual value in the amount of $0.5 million, which is included as a reduction to our lease expense. The revised monthly payment inclusive of maintenance fees, insurance and taxes is approximately $0.1 million and the additional right of use asset and lease obligation is approximately $1.4 million in the condensed consolidated balance sheets. The lease expense is included in selling, general and administrative 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. The office lease commenced in August 2017. The Company agreed to pay initial monthly lease payments of $40,951, subject to 3% annual increases, plus the estimated cost of maintaining the property and common areas by the landlord, with a five-month concession from October 2017 through February 2018. The lease also provides for allowances for tenant alterations and maintenance. The lease expense is included in selling, general and administrative expenses in the condensed consolidated statements of operations.

In November 2017, the Company executed an office lease with Russell Ranch Road II LLC to expand the office space for the Company's corporate offices in Westlake Village, California which was renewed in April 2022. Pursuant to the renewal, the Company will pay initial monthly payments of $79,543, beginning in February 2023, subject to 3% annual increases, plus the estimated cost of maintaining the property and common areas by the landlord. The Company will receive a six-month concession at the start of the lease extension period on July 31, 2023. The Company has no further right to extend the lease term beyond the Extension Period.

The Company assumed certain leased real property (the "Marlborough Lease") pursuant to the APA entered into in May 2022. The Marlborough Lease pertains to certain premises in a building located in Marlborough, Massachusetts. The Company will pay initial monthly payments of $28,895, beginning 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 are manufactured using Company-owned equipment located at the manufacturing facility. The Company determined that this arrangement results in an embedded lease which grants 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 is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease costs	$ 341	$ 340	$ 629	$ 685
Variable lease costs	73	114	159	231
Cash paid	446	454	887	916

	June 30, 2022	December 31, 2021
Weighted average remaining lease term (in years)	5.1	2.6
Weighted average discount rate	7.3%	7.3%

Future minimum office and vehicle lease payments as of June 30, 2022 and December 31, 2021, are as follows (in thousands):

	June 30, 2022	December 31, 2021
2022	$ 960	$ 1,444
2023	1,368	497
2024	1,892	409
2025	1,861	311
2026	1,140	—
Thereafter	1,715	—
Total	$ 8,936	$ 2,661

16. Income Taxes

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 six months ended June 30, 2022 the Company did not recognize any interest or penalties. The Company’s tax years since 2017 remain subject to examination by tax authorities.

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, 2021 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

MannKind focuses on the development and commercialization of therapeutic products for patients with endocrine and orphan lung diseases. We are 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. We also collaborate with third parties to formulate their drugs on our Technosphere drug delivery platform. In May 2022, our partner, United Therapeutics, received approval from the FDA for Tyvaso DPI (treprostinil) inhalation powder, which is indicated for the treatment of pulmonary arterial hypertension and for the treatment of pulmonary hypertension associated with interstitial lung disease. UT 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.

Our business is subject to significant risks, including but not limited to our ability to commercialize our products successfully as well as our ability to manufacture sufficient quantities of our products and Tyvaso DPI. Other significant risks also include 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.

We continue to manage the risk to our business posed by the global COVID-19 pandemic. We do not yet know the full extent of potential delays or impacts on our business, our collaboration arrangements, commercialization efforts, healthcare systems or to the global economy as a whole. The COVID-19 pandemic has the potential to have additional adverse impacts on our operations. We will continue to monitor the COVID-19 situation closely.

As of June 30, 2022, we had an accumulated deficit of $3.2 billion and a stockholders' deficit of $247.1 million. Our net loss was $29.0 million and $55.0 million for the three and six months ended June 30, 2022. To date, we have funded our operations through the sale of convertible debt securities and equity, from the receipt of upfront and milestone payments from certain collaborations, from borrowings, from sales of Afrezza and V-Go, and royalties from UT from the sale of Tyvaso DPI and proceeds of the Sale-Leaseback Transaction.

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

We continue to experience the impact of the COVID-19 pandemic on our sales activities, Biomm's ability to market Afrezza in Brazil and Cipla's ability to enroll a clinical study in India. In addition, we have increased the safety stock of raw materials due to concerns that COVID-19 may impact the supply chain for manufacturing Afrezza, V-Go and Tyvaso DPI.

Our manufacturing of Tyvaso DPI may not meet the required demand of our partner, UT. If we fail as an effective manufacturing organization, we may be unable to support commercialization of Tyvaso DPI.

Three and six months ended June 30, 2022 and 2021

Revenues

The following tables provide a comparison of the revenue categories for the three and six months ended June 30, 2022 and 2021 (dollars in thousands):

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 21,384	$ 16,575	$ 4,809	29%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(8,662)	(6,599)	$ 2,063	31%
Net revenue — commercial product sales	12,722	9,976	$ 2,746	28%
Gross-to-net revenue adjustment percentage	-40.5%	-39.8%		
Revenue — collaborations and services	5,868	13,304	$ (7,436)	(56%)
Royalties	304	—	$ 304	*
Total revenues	$ 18,894	$ 23,280	$ (4,386)	(19%)

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 37,420	$ 30,185	$ 7,235	24%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(14,872)	(12,110)	$ 2,762	23%
Net revenue — commercial product sales	22,548	18,075	$ 4,473	25%
Gross-to-net revenue adjustment percentage	-39.7%	-40.1%		
Revenue — collaborations and services	8,034	22,641	$ (14,607)	(65%)
Royalties	304	—	$ 304	*
Total revenues	$ 30,886	$ 40,716	$ (9,830)	(24%)

* Not meaningful

Afrezza — Gross revenue from sales of Afrezza increased by $0.7 million, or 4%, for the three months ended June 30, 2022 compared to the same period in the prior year. The increase was mainly attributable to increased price and demand, partially offset by wholesaler inventory ordering patterns resulting in lower inventory levels for the second quarter of 2022. The gross-to-net adjustment was 38.4% of gross revenue, or $6.7 million, for the three months ended June 30, 2022, compared to 39.8% of gross revenue, or $6.6 million, for the same period in the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in wholesaler distribution fees (as a percentage of gross sales) due to an increased mix of specialty and retail pharmacy sales and a decrease in anticipated product returns, partially offset by higher co-pay assistance. As a result, net revenue from sales of Afrezza increased by $0.7 million, or 7%, for the three months ended June 30, 2022 compared to the same period in the prior year.

Gross revenue from sales of Afrezza increased by $3.1 million, or 10%, for the six months ended June 30, 2022 compared to the same period in the prior year. The increase reflects higher product demand, favorable cartridge mix and price. The gross-to-net adjustment was 38.6% of gross revenue, or $12.9 million, for the six months ended June 30, 2022, compared to 40.1% of gross revenue, or $12.1 million, for the same period in the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in wholesaler distribution fees (as a percentage of gross sales) due to an increased mix of specialty and retail pharmacy sales, a decrease in anticipated product returns and lower commercial rebates. As a result, net revenue from sales of Afrezza increased by $2.4 million, or 13%, for the six months ended June 30, 2022 compared to the same period in the prior year.

V-Go — The acquisition of V-Go on May 31, 2022 resulted in an increase in gross revenue from commercial product sales of $4.1 million and net revenue of $2.1 million for the three and six months ended June 30, 2022. The gross-to-net adjustment of 49.2% of gross revenue, or $2.0 million, is mainly attributable to commercial and government rebates and product distribution fees.

Collaborations and Services — Net revenue from collaborations and services decreased by $7.4 million, or 56%, for the three months ended June 30, 2022 and $14.6 million, or 65%, for the six months ended June 30, 2022 compared to the same periods in the prior

year. The decrease in collaborations and services revenue was primarily attributable to the completion of the R&D Services associated with our collaboration with UT. In August 2021, we entered into a commercial supply agreement with UT (the "CSA"). Revenue associated with the CSA was deferred until we began manufacturing and subsequently selling Tyvaso DPI in June 2022. During the three and six months ended June 30, 2022, we recognized $4.7 million and $5.9 million, respectively, of revenue under the CSA. We also recognized royalty revenue of $0.3 million during the three and six months ended June 30, 2022. See Note 10 – *Collaboration, Licensing and Other Arrangements*.

Commercial product gross profit

The following tables provide a comparison of the commercial product gross profit categories for the three and six months ended June 30, 2022 and 2021 (dollars in thousands):

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 12,722	$ 9,976	$ 2,746	28%
Less: cost of goods sold	4,617	4,411	$ 206	5%
Commercial product gross profit	$ 8,105	$ 5,565	$ 2,540	46%
Gross margin	64%	56%		

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 22,548	$ 18,075	$ 4,473	25%
Less: cost of goods sold	6,901	8,726	$ (1,825)	(21%)
Commercial product gross profit	$ 15,647	$ 9,349	$ 6,298	67%
Gross margin	69%	52%		

Afrezza — Commercial product gross profit for Afrezza increased by $1.7 million, or 31%, for the three months ended June 30, 2022, compared to the same period in the prior year. Gross margin for the three months ended June 30, 2022 was 68% compared to 56% for the same period in the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales as well as a decrease in cost of goods sold. Cost of goods sold decreased by $1.0 million, or 24%, for the three months ended June 30, 2022 compared to the same period in the prior year. The decrease in cost of goods sold was primarily attributable to a $2.0 million fee incurred for the amendment of the Insulin Supply Agreement in the prior year period and a $0.4 million decrease in manufacturing-related spending in the current period, partially offset by a $1.1 million increase in cost of goods sold due to lower manufacturing activities for Afrezza.

Commercial product gross profit for Afrezza increased by $5.4 million, or 58%, for the six months ended June 30, 2022, compared to the same period in the prior year. Gross margin for the six months ended June 30, 2022 was 72% compared to 52% for the same period in the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales as well as a decrease in cost of goods sold. Cost of goods sold decreased by $3.1 million, or 35%, for the six months ended June 30, 2022 compared to the same period in the prior year. The decrease in cost of goods sold was primarily attributable to a $2.6 million decrease in manufacturing-related spending in the current period and a $2.0 million fee incurred for the amendment of the Insulin Supply Agreement in the prior year period, partially offset by a $0.9 million increase in cost of goods sold due to lower manufacturing activities for Afrezza.

V-Go — The acquisition of V-Go on May 31, 2022 resulted in an increase in commercial product gross profit of $0.8 million for the three and six months ended June 30, 2022. Gross margin for V-Go for the three and six months ended June 30, 2022 was 40%.

Expenses

The following tables provide a comparison of the expense categories for the three and six months ended June 30, 2022 and 2021 (dollars in thousands):

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
Expenses:				
Cost of goods sold	$ 4,617	$ 4,411	$ 206	5%
Cost of revenue — collaborations and services	8,298	5,515	$ 2,783	50%
Research and development	4,893	2,329	$ 2,564	110%
Selling	15,868	11,534	$ 4,334	38%
General and administrative	10,175	8,522	$ 1,653	19%
(Gain) loss on foreign currency translation	(4,503)	903	$ 5,406	*
Loss on purchase commitments	—	339	$ (339)	*
Total expenses	$ 39,348	$ 33,553	$ 5,795	17%

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
Expenses:				
Cost of goods sold	$ 6,901	$ 8,726	$ (1,825)	(21%)
Cost of revenue — collaborations and services	17,012	8,810	$ 8,202	93%
Research and development	8,429	4,771	$ 3,658	77%
Selling	28,596	21,153	$ 7,443	35%
General and administrative	18,144	16,316	$ 1,828	11%
Gain on foreign currency translation	(6,486)	(2,935)	$ 3,551	121%
Loss on purchase commitments	—	339	$ (339)	*
Total expenses	$ 72,596	$ 57,180	$ 15,416	27%

* Not meaningful

Cost of revenue — collaborations and services increased by $2.8 million, or 50%, for the three months ended June 30, 2022 and $8.2 million, or 93%, for the six months ended June 30, 2022 compared to the respective periods in the prior year. The increase was attributable to an increase in manufacturing activities leading up to commercial product manufacturing in the second quarter of 2022 and subsequent sale to UT.

Research and development expenses increased by $2.6 million, or 110%, for the three months ended June 30, 2022 and $3.7 million, or 77%, for the six months ended June 30, 2022 compared to the respective periods in the prior year. The increase was primarily attributable to costs incurred for development activities on our product pipeline and the Afrezza pediatrics clinical study (INHALE-1).

Selling expenses increased by $4.3 million, or 38%, for the three months ended June 30, 2022, compared to the same period in the prior year. The increase was primarily attributable to a pilot promotional effort aimed at primary care physicians that began in the fourth quarter of 2021, elimination of the Thyquidity co-promotion (which permitted some expenses associated with the sales force to be recognized as cost of revenue — collaborations and services in the second quarter of 2021), promotional expenses to support Afrezza growth, and V-Go promotional efforts, partially offset by lower personnel related costs due to Afrezza territory restructuring.

Selling expenses increased by $7.4 million, or 35%, for the six months ended June 30, 2022, compared to the same period in the prior year. The increase was primarily attributable to a pilot promotional effort aimed at primary care physicians that began in the fourth quarter of 2021, elimination of the Thyquidity co-promotion (which permitted some expenses associated with the sales force to be recognized as cost of revenue — collaborations and services in the second quarter of 2021), promotional expenses to support Afrezza growth, as well as V-Go promotional efforts.

General and administrative expenses increased by $1.7 million, or 19%, for the three months ended June 30, 2022, compared to the same period in the prior year. This increase was primarily attributable to higher stock-based compensation, increased salaries, increased headcount, and legal fees due to the acquisition of V-Go.

General and administrative expenses increased by $1.8 million, or 11%, for the six months ended June 30, 2022, compared to the same period in the prior year. This increase was primarily attributable to higher stock-based compensation and other compensation.

Under the Insulin Supply Agreement with Amphastar, payment obligations are denominated in Euros. We are required to record the foreign currency translation impact of the U.S. dollar to Euro exchange rate associated with the recognized gain or loss on purchase commitments. The foreign currency translation gain was $4.5 million for the three months ended June 30, 2022 compared to a loss of $0.9 million for the same period in the prior year. The foreign currency translation gain was $6.5 million for the six months ended June 30, 2022 compared to $2.9 million for the same period in the prior year.

Other Income (Expense)

The following tables provide a comparison of the other income (expense) categories for the three and six months ended June 30, 2022 and 2021 (dollars in thousands):

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
Interest income	$ 516	$ 25	$ 491	*
Interest expense on financing liability	(2,443)	—	$ 2,443	*
Interest expense on notes	(6,642)	(3,180)	$ 3,462	109%
Loss on extinguishment of debt	—	(22,130)	$ 22,130	*
Other income	—	35	$ 35	*
Total other expense	$ (8,569)	$ (25,250)	$ (16,681)	(66%)

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
Interest income	$ 893	$ 28	$ 865	*
Interest expense on financing liability	(4,814)	—	$ (4,814)	*
Interest expense on notes	(9,390)	(9,632)	$ (242)	(3%)
Loss on extinguishment of debt, net	—	(22,130)	$ (22,130)	*
Other (expense) income	—	(241)	$ 241	*
Total other expense	$ (13,311)	$ (31,975)	$ (18,664)	(58%)

* Not meaningful

Interest income, consisting of interest on investments net of amortization, increased $0.5 million for the three months ended June 30, 2022 and $0.9 million for the six months ended June 30, 2022 compared to the same periods in the prior year primarily due to higher yields on our marketable securities and money market funds.

Interest expense on financing liability was $2.4 million for the three months ended June 30, 2022 and $4.8 million for the six months ended June 30, 2022 and represented interest incurred on the Sale-Leaseback Transaction for our manufacturing facility in Danbury, CT, which closed in the fourth quarter of 2021.

Interest expense on notes increased by $3.5 million, or 109%, for the three months ended June 30, 2022 compared to the same period in the prior year. The increase was primarily due to a $3.9 million increase for the achievement of a milestone under the milestone rights obligation that was achieved during the second quarter of 2022. See Note 9 — *Borrowings*. Interest expense on notes decreased $0.2 million, or 3%, for the six months ended June 30, 2022.

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, the funding of general and administrative expenses, and interest expense on our financing liability and debt.

To date, we have funded our operations through the sale of equity and convertible debt securities, from the receipt of upfront and milestone payments from certain collaborations, from borrowings, from sales of Afrezza and V-Go, royalties from UT from the sale of Tyvaso DPI, and proceeds from the Sale-Leaseback transaction.

We believe we will be able to meet our liquidity needs over the next twelve months based on the balance of cash, cash equivalents and investments on hand. We believe we will meet longer-term expected future cash requirements and obligations, through a combination of cash and investments on hand, operating activities including manufacturing revenue and royalties from the production and sale of Tyvaso DPI.

As of June 30, 2022, we had $278.8 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. 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.
- $40.0 million principal amount under the MidCap credit facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.25%, subject to a one-month LIBOR floor of 1.00%, payable in equal monthly installments beginning in September 2023 through maturity in August 2025.
- $8.8 million principal amount of indebtedness under the Mann Group convertible note bearing interest at a fixed rate of 2.50% per annum compounded quarterly and maturing in December 2025, which is convertible into shares of our common stock at the option of Mann Group at a conversion price of $2.50 per share. Interest was paid-in-kind from August 2019 until the end of 2020, after which we have the option to pay interest in-kind or in shares.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the Senior convertible notes, the MidCap credit facility or the Mann Group convertible note. The Senior convertible notes and Mann Group convertible note are fully convertible prior to maturity as further disclosed in Note 9 – *Borrowings*.

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 repurchase the Mann Group promissory notes, we will be in default under the applicable instrument for such indebtedness and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. 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 July 2013, we issued Milestone Rights 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, $65.0 million of which remains payable upon achievement of such milestones as of June 30, 2022. A $5.0 million milestone payment will be made in the third quarter of 2022. See Note 15 – *Commitments and Contingencies* and Note 9 – *Borrowings* for further information related to the Milestone Rights.

During the six months ended June 30, 2022, we used $50.2 million of cash for our operating activities, which primarily consisted of $38.6 million of selling, general and administrative expenses, $21.5 million of cost of goods sold, $10.9 million of costs for research and development and $5.8 million of cash paid for interest, partially offset by $31.7 million of revenue.

During the six months ended June 30, 2021, we used $34.2 million of cash for our operating activities as a result of our net loss of $48.4 million, partially offset by non-cash charges of $32.5 million of which $22.1 million was a loss on extinguishment of debt related to the first amendment of the Mann Group convertible note. The net change in operating asset and liabilities was primarily a result of the amortization of deferred revenue of $21.2 million and the payment of the Mann Group promissory note interest of $4.9 million, partially offset by the receipt of $5.3 million in customer deposits from UT for expansion equipment as well as other pass- through payments, and an increase in operating payables and accrued expenses.

Cash used in investing activities of $37.5 million for the six months ended June 30, 2022 was primarily due to the purchase of $68.5 million of debt securities, the up-front consideration of $15.1 million for certain assets and assumed liabilities related to V-Go and $5.0 million purchase of available-for-sale securities, and $2.2 million purchase of property and equipment, partially offset by the maturity of $53.3 million of debt securities.

Cash used in investing activities of $144.0 million for the six months ended June 30, 2021 was primarily due to the purchase of $138.9 million of debt securities and $3.0 million of Thirona convertible notes that was recognized as an available-for-sale investment.

Cash used in financing activities of $1.0 million for the six months ended June 30, 2022 was primarily due to the payments on our financing liability of $1.4 million.

Cash provided by financing activities of $173.5 million for the six months ended June 30, 2021 was primarily due to net proceeds from the offering of Senior convertible notes of $222.7 million, partially offset by the repayment of $35.1 million of Mann Group non-convertible notes and related unpaid accrued interest and the repayment of $10.0 million of principal and $1.0 million prepayment penalty for the MidCap credit facility.

Future Liquidity Needs

We are not currently profitable and have rarely generated positive net cash flow from operations. In addition, we expect to continue to incur significant 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 June 30, 2022, we had capital resources of $154.2 million in cash, cash equivalents and short-term investments, $32.6 million in long-term investments, and total principal amount of outstanding borrowings of $278.8 million.

We believe our resources will be sufficient to fund our operations for beyond 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 9 – *Borrowings* and Note 15 – *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 accrues interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month LIBOR (subject to a one-month LIBOR floor of 1.00%) plus 6.25%. Accordingly, our interest expense under the MidCap credit facility is subject to changes in the one-month LIBOR rate. See "Risk Factors — *We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due"* under Part II, Item 1A of this report for additional information regarding the risks we face related to the planned phase-out of LIBOR.

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 amounts borrowed under the Mann Group promissory notes is fixed at 2.50% and the interest rate under the Senior convertible notes is fixed at 2.50%. See Note 9 – *Borrowings* for information about the principal amount of outstanding debt.

If a change in one-month LIBOR interest rates equal to 10% of the one-month LIBOR interest rates on June 30, 2022 were to have occurred, this change would not have had a material effect on our interest payment obligation.

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 June 30, 2022, we realized a $4.5 million currency gain, which was included in gain on foreign currency translation 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 June 30, 2022 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $7.3 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 June 30, 2022. 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 June 30, 2022, 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.

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 below 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 Securities and Exchange Commission 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 are commercializing may only achieve a limited degree of commercial success. In addition, the required post-marketing studies of Afrezza will require substantial capital that we may not be able to obtain.
- Manufacturing risks may adversely affect our ability to manufacture our products and could reduce our gross margin and our 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 our products do not become widely accepted by physicians, patients, third-party payers and the healthcare community, we may be unable to generate significant revenue, if any.
- 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.
- 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 business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, 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.
- We may not be successful in our efforts to develop and commercialize our product candidates.
- We have a history of operating losses. We expect to incur losses in the future and we may not generate positive cash flow from operations in the future.
- We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due.
- 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.
- Our products and product candidates may be rendered obsolete by rapid technological change.
- 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 product candidates.
- The safety and efficacy of V-Go is not supported by long-term clinical data, which could limit sales and could lead to unforeseen negative effects.
- 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.
- If our information technology systems or data, or those of third parties upon which we rely, 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.

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

RISKS RELATED TO OUR COMMON STOCK

- We may not be able to generate sufficient cash to service all of our indebtedness and commitments. We may be forced to take other actions to satisfy our obligations or we may experience a financial failure.
- Our stock price is volatile and may affect the market price of our common stock and other securities.
- The future sale of our common stock or the exchange or conversion of our convertible debt into common stock could negatively affect the market price of our common stock and other securities.

GENERAL RISK FACTORS

- 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.
- 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.

RISKS RELATED TO OUR BUSINESS

The products that we are commercializing may only achieve a limited degree of commercial success. In addition, the required post-marketing studies of Afrezza will require substantial capital that we may not be able to obtain.*

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 pharmaceutical and device companies with more experience and resources than us. We ultimately may be unable to gain widespread market acceptance of our products for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, pricing and availability relative to alternative products and failure by patients to use them as directed, which could limit their effectiveness and could have an adverse impact on repeat use. If we are unable to maintain payer coverage of, and adequate reimbursement for, our products, physicians may limit how much or under what circumstances they will prescribe or administer them. As a result, patients may decline to purchase our products, which would have an adverse effect on our ability to generate revenues. We may need to enhance our commercialization capabilities in order to successfully commercialize our products in the United States, and we may not have sufficient resources to do so. 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.

If we are unable to effectively train our sales force and equip them with effective medical and sales materials to help them inform and educate potential customers about the benefits of our products and their proper administration, our efforts to successfully commercialize our products could be put in jeopardy, which would negatively impact our ability to generate product revenues. In addition, Afrezza is a novel insulin therapy with a distinct time-action profile and non-injectable administration, and we are therefore required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing Afrezza to physicians and to ensure that a consistent and appropriate message about Afrezza is being delivered to our potential customers.

We are responsible for the NDA for Afrezza and its maintenance. We may fail to comply with maintenance requirements, including timely submitting required reports. Further, as part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. These studies will require significant capital resources, some of which may not be available to us. We have initiated 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. We have engaged a clinical research organization to assist us with conducting this study and have budgeted the projected costs of the study in our operating plans. 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 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.

Any factor that negatively impact sales of our products, or that result in sales of our products increasing at a lower rate than expected, would also negatively impact our prospects for generating significant revenues.

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

We use our Danbury, Connecticut facility to formulate both the Afrezza and Tyvaso DPI inhalation powders, fill plastic cartridges with the powders, and package the cartridges into secondary packaging. We also assemble the inhalers from their individual molded parts. These semi-finished goods are then 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 and yields and quality control and assurance. We may experience shortages of qualified personnel, which could impact our ability to meet production schedules. There is also 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, most recently in July 2021 when the FDA conducted a pre-approval inspection related to Tyvaso DPI and a GMP inspection related to Afrezza. The FDA made one observation during its most recent inspection, which we corrected and addressed with the FDA following the site visit. 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.

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. As demand increases, we will 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.

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 practices ("cGMP") for drug products, and the molding of the inhaler and cartridges components in accordance with quality system regulations ("QSRs").

For V-Go, we generally use a small number of suppliers for our product, some parts and components of which 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 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 our products do not become widely accepted by physicians, patients, third-party payers and the healthcare community, we may be unable to generate significant revenue, if any.*

Our products, including products that we may develop in the future, may not gain market acceptance among physicians, patients, third-party payers and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of our products depends on many factors, including the following:

- Approved labeling claims;
- Effectiveness of efforts by us or any future marketing partner to support and educate physicians about the benefits and advantages of our products, and the perceived advantages and 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, our products may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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 still 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 will depend 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.

The requirements governing drug pricing vary widely from country to country. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. 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. We may face competition for Afrezza or any of our other product candidates that receives marketing approval from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

If we or any 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 marketing partner's ability to successfully commercialize such products and would impact our profitability, results of operations, financial condition, and prospects.

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 certain foreign markets the pricing of prescription pharmaceuticals is subject to direct governmental control. 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.

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

As of June 30, 2022, we had cash, cash equivalents and short-term investments of $154.2 million and long-term investments of $32.6 million, and we had $278.8 million principal amount of outstanding debt. 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 revenue from Afrezza exceeds or does not exceed the minimum revenue covenants under the MidCap credit facility, if applicable;
- the degree to which we are able to generate revenue from our Technosphere drug delivery platform, including through our collaborations;
- the costs of developing and commercializing Afrezza and V-Go on our own in the United States, including the costs of expanding our commercialization capabilities;
- the demand by any or all of the holders of our debt instruments 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 notes with conversion options 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 research and development activities;
- the costs of procuring raw materials and operating our manufacturing facility;
- our obligation to make lease payments and milestone payments;
- 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 and our product candidates and 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 we may in the future pursue the sale of additional equity and/or debt securities, 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. In addition, the ongoing

COVID-19 pandemic continues to have the potential for disruption of global financial markets. Similarly, the current Russia-Ukraine conflict has created extreme volatility in the global capital markets as well as other global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility or disruption, 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.

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 may not realize the benefit of our recent acquisition of V-Go or any future acquisition or strategic transaction; we be unable to successfully integrate new products or businesses we may acquire.*

We periodically evaluate and pursue acquisition of therapeutic products. We completed the acquisition of V-Go on May 31, 2022 and it is possible that we will encounter challenges with integrating the product into our business. Moreover, 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;
- 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 business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, 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. In particular, the ongoing COVID-19 pandemic could materially affect our operations, including at our manufacturing facilities in Connecticut and Southern China and with respect to our sales force and their ability to interact with health care professionals, as well as the business or operations of our suppliers, distributors or other third parties with whom we conduct business.

The ongoing COVID-19 pandemic has resulted in a number of restrictions to reduce the spread of the disease, many of which have been eased or lifted in recent months. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of infection and corresponding restrictions will be imposed in the future, notwithstanding vaccination and other public health efforts. The effects of the restrictions related to the COVID-19 pandemic and our related policies addressing the pandemic, including the evolving nature of such policies, may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines. We may also face challenges or distractions as we navigate the balance between a productive workplace and the need to accommodate a certain amount of remote work by some employees at least some of the time. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

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 COVID-19 or other 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 particular, our contract manufacturers in China could be impacted by that country's zero-tolerance coronavirus policy, which has led to strict lockdowns that continue to be in place in many regions of China. Although we believe we have sufficient quantities of raw materials for planned manufacturing operations in 2022, a prolonged supply interruption of certain components could adversely affect our ability to conduct commercialization activities and planned clinical trials. In addition, we believe that the COVID-19 pandemic will continue to negatively impact the distribution of Afrezza by our partner in Brazil.

Sales and demand for our products have been adversely affected at times during the COVID-19 pandemic, and we expect this risk to continue for at least the near term. Although our sales representatives are conducting in-person sales calls to the extent permitted by state and local public health authorities and by the policies of individual healthcare providers that they interact with, they have not fully returned to conducting in-person office visits with healthcare providers, which impacts their productivity. Disruptions in the prescription volume of our products could also 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 diabetes 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 Afrezza to be prescribed and reimbursed.

In addition, our ongoing or planned clinical trials of our products or those conducted by Cipla or our other regional partners may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. 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 who, as healthcare providers, may have heightened exposure to COVID-19 would adversely impact our clinical trial operations.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic continues to have 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 resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, commercialization efforts, healthcare systems or to the global economy as a whole. These effects could have a material impact on our operations. We will continue to monitor the COVID-19 situation closely.

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.

We may not be successful in our efforts to develop and commercialize our product candidates.*

We have generally sought to develop inhaled therapeutic 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.

Even if our research programs identify product candidates that initially show promise, these candidates may fail to progress through clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to develop and commercialize our product candidates, or if we are significantly delayed in doing so, our ability to generate product revenues will be limited.

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

We are not currently profitable and have rarely generated positive net cash flow from operations. As of June 30, 2022, we had an accumulated deficit of $3.2 billion. The accumulated deficit has resulted principally from costs incurred in our research and development 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 to incur increasing operating losses in the future in order to continue the commercialization of Afrezza and advance product candidates in our pipeline. In addition, under our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin through 2027. As of June 30, 2022, there was approximately $73.4 million remaining in aggregate purchase commitments under this agreement. We may not have the necessary capital resources to service this contractual commitment.

Our losses have had, and are expected to 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 we cannot be sure when, if ever, we will generate positive cash flow from operations or become profitable.

We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due.*

The notes to our condensed consolidated financial statements in this Quarterly Report on Form 10-Q provide details about our various debt obligations. As of June 30, 2022, we had $278.8 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 will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. 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.
- $40.0 million principal amount under the MidCap credit facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.25%, subject to a one-month LIBOR floor of 1.00%, payable in equal monthly installments beginning in September 2023 through maturity in August 2025.
- $8.8 million principal amount of indebtedness under the Mann Group convertible note bearing interest at a fixed rate of 2.50% per annum compounded quarterly and maturing in December 2025, which is convertible into shares of our common stock at the option of Mann Group at a conversion price of $2.50 per share. Interest is paid-in-kind from August 2019 until the end of 2020, after which we have the option to pay interest in-kind or in shares.

Under the MidCap credit facility, our interest rate on borrowed amounts is dependent on one-month LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market. LIBOR is widely used as a reference for setting the interest rate on loans globally. In March 2021, the Chief Executive of the United Kingdom Financial Conduct Authority, which regulates LIBOR, announced that the one-month LIBOR will either cease to be provided by any administrator or no longer be representative, effective immediately after June 30, 2023. The United States Federal Reserve has also advised banks to cease entering into new contracts that use LIBOR as a reference rate. Before one-month LIBOR is phased out, we may need to renegotiate the MidCap credit facility to replace one-month LIBOR with a new standard, which has not yet been agreed upon. The Alternative Reference Rate Committee, a committee convened by the Federal Reserve that includes major market participants, has identified the Secured Overnight Financing Rate ("SOFR"), a new index calculated by short-term repurchase agreements, backed by Treasury securities, as its preferred alternative rate for LIBOR. We are not able to predict how markets will respond to SOFR or other alternative reference rates as the transition away from the LIBOR benchmarks. Accordingly, the outcome of these reforms is uncertain and any changes in the methods by which LIBOR is determined or regulatory activity related to LIBOR's phase-out could cause LIBOR to perform differently than in the past or cease to exist. The consequences of these developments cannot entirely be predicted, but could result in higher interest rates on our loans under the MidCap credit facility. Furthermore, we cannot predict or quantify the time, effort and cost required to transition to the use of new benchmark rates, including with respect to negotiating and implementing any necessary changes to existing contractual agreements, and implementing changes to our systems and processes. Additionally, if interest rates continue to increase, as they have been throughout 2022, we would be obligated to make higher interest payments to our lenders under the MidCap credit facility. We cannot provide assurance that future interest rate changes will not have a material negative impact on our business, financial position, or operating results.

The MidCap credit facility requires us, and any debt arrangements we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness or modify existing debt agreements;

- amend or modify certain material agreements;
- engage in additional lines of business;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- change certain key management personnel or organizational documents; and
- engage in transactions with our affiliates.

We may be required to comply with additional covenants in the future under certain circumstances. The restrictive covenants in the MidCap credit facility could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

If our unrestricted cash and short-term investments balance falls below $90.0 million, we will be subject to a covenant relating to trailing twelve-month minimum Afrezza net revenue, tested on a monthly basis, which is set forth in the MidCap credit facility Agreement, as amended. If we fail to meet this covenant, any outstanding borrowings, together with accrued interest, under the MidCap credit facility could be declared immediately due and payable.

A breach of any of these covenants could result in an event of default under the MidCap credit facility. If we default under our obligations under the MidCap credit facility, the lender could proceed against the collateral granted to them to secure our indebtedness or declare all obligations under the MidCap credit facility to be due and payable. In certain circumstances, procedures by the lender could result in a loss by us of all of our equipment and inventory, which are included in the collateral granted to the lender. In addition, upon any distribution of assets pursuant to any liquidation, insolvency, dissolution, reorganization or similar proceeding, the holders of secured indebtedness will be entitled to receive payment in full from the proceeds of the collateral securing our secured indebtedness before the holders of other indebtedness or our common stock will be entitled to receive any distribution with respect thereto.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on, or repay, our outstanding term loan under the MidCap credit facility or borrowings under the Mann Group promissory notes when required, we will be in default under the instrument for such debt securities or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

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.*

We anticipate that revenues from our existing or future licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us will depend on our ability to achieve the performance obligations specified in such arrangements. 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;
- 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 (such as the Russia-Ukraine conflict), man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic.

In addition, if we do not obtain sufficient additional funds through sales of securities, strategic collaborations or the license or sale of certain of our assets on a timely basis, we may be required to reduce expenses by delaying, reducing or curtailing our development of product candidates. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical 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 will be harmed and the market price of our common stock and other securities may decline.

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.

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 product candidates.*

Forecasts about the effects of the use of drugs, including Afrezza, over terms longer than the clinical studies or in much larger populations may not be consistent with the earlier clinical results. If long-term use of a drug results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our or any future marketing partner's ability to market and sell the drug, 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.

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, including, for example, the COVID-19 pandemic.

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 the drug 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.

The safety and efficacy of V-Go is not supported by long-term clinical data, which could limit sales and could lead to unforeseen negative effects.*

V-Go has received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or 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 payors 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.

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 Afrezza or our product candidates.

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 Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flow, financial conditions or results of operations. 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.

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

As of December 31, 2021, we had federal and state net operating loss carryforwards of $2.2 billion and $1.3 billion, respectively, which we assess annually. A portion of our federal and state net operating loss carryforwards have begun to expire. Net operating loss carryforwards that expire unused will be unavailable to offset future income tax liabilities. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of our 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 carry forwards of approximately $216.0 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, 2021, to determine whether additional limitations may be placed on our net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met the Section 382 ownership change threshold were identified through December 31, 2021. There is a risk that changes in ownership may occur in tax years after December 31, 2021. If a change in ownership were to occur, our net operating loss carryforwards and other tax attributes could be further limited or restricted. If an ownership change were to occur and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. 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 or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), wars, conflicts (including the current Russia-Ukraine conflict), wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, volcanic eruptions, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. 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.

If our information technology systems or data, or those of third parties upon which we rely, 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 acting on our behalf, employ and are increasingly dependent upon information technology systems, infrastructure, applications, websites and other resources. Our business requires collecting, manipulating, analyzing, storing and otherwise processing large amounts of data, including proprietary data, sensitive data, personal data and other confidential information. In addition, 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 acting on our behalf, including computer hardware, software, networks, Internet servers and related infrastructure.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through 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), 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, telecommunications failures, earthquakes, fires, floods, 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. Similarly, 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. The COVID-19 pandemic and our workforce that works remotely at least part of the time pose increased risks to our information technology systems and data, as our employees work from home, utilizing network connections outside our premises. 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.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) 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. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We have not always been able in the past and may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. For example, like many companies, we use SolarWinds to help manage our information technology systems. A cyberattack 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. We use 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. Thus, despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) 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; 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.

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 FDA, SEC and other 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.

The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period that ended December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, and a separate marketing authorization will be required to market our product candidates in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency, or MHRA, in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom ("UK") and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the UK diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export

regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

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 manufacture, marketing and sale of drug product are subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning the safety or efficacy of a product appear following approval. We cannot be sure that FDA and United States Congressional initiatives or actions by foreign regulatory bodies pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

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.

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 GCP requirements 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.

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.

We are required to comply with FDA regulations concerning the advertising and promotion of Afrezza. Failure to comply with these regulations can result in the receipt of warning letters and further liability if off-label promotion is involved. For example, in October 2018, we received a warning letter from the FDA's Office of Prescription Drug Promotion ("OPDP") related to a particular post on our Afrezza Facebook page. The warning letter stated that the post in question failed to adequately disclose the risks associated with the use of Afrezza. As a result, we temporarily inactivated all Afrezza social media accounts (including Facebook, Instagram and Twitter) then, after consultation with OPDP, placed a corrective post on Facebook and Instagram.

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 an 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. 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 have 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. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act (collectively, the "PPACA") substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly affect the healthcare industry. Among the provisions of PPACA of importance to us are the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price ("AMP") for most branded and generic drugs, respectively;
- A licensure framework for follow-on biological products;
- Expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- A Medicare Part D coverage gap discount program, in which manufacturers must agree to now offer 75% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- Requirements to report annually to CMS certain financial arrangements with physicians, certain other healthcare professionals, and teaching hospitals, and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, as described in more detail below;
- A requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and

- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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. 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. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. In addition, Congress is considering additional health reform measures. 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. 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. For example, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic. Such reforms may limit our ability to generate revenues from sales of our products and achieve profitability. 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 PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, 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 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 now available in Brazil and as we 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 obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations,

guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the CCPA imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA 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. In addition, it is anticipated that the CPRA, effective January 1, 2023, will expand the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the GDPR, the United Kingdom's GDPR ("UK GDPR"), and Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018) impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. The more reliant our business is on the ability to effectuate cross-border data transfers, the more impact we may experience in light of any changes in the legal landscape.

In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply.

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 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 upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party vendor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we 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); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, 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, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP, for single source and innovator multiple source drugs, beginning 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.

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 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.

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, based on our investment securities as of the most recent balance sheet date set forth in this report, the value of our investment securities relative to our total assets (exclusive of government securities and cash items) exceeds safe harbor limits prescribed in the '40 Act. We can provide no assurance that the SEC would not 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. To ensure we do not fall within the '40 Act, we may need to take various actions which we might otherwise not pursue. These actions may include modifying our mixture of assets and income or a liquidation of certain of our assets.

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 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 Afrezza or our product candidates 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 Afrezza or our 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

We may not be able to generate sufficient cash to service all of our indebtedness and commitments. We may be forced to take other actions to satisfy our obligations or we may experience a financial failure.*

Our ability to make scheduled payments on our lease and debt obligations will depend on our financial and operating performance, which is subject to the commercial success of our products, the extent to which we are able to successfully develop and commercialize our Technosphere drug delivery platform and any other product candidates that we develop, prevailing economic and competitive conditions, and to 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 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 indebtedness and 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.

Our stock price is volatile and may affect the market price of our common stock and other securities.*

The trading price of our common stock has been and is likely to continue to be volatile. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue. The COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility.

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, Tyvaso DPI 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 conflict;
- legislative developments;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- 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. In 2016, we received a notice of non-compliance from the Listing Qualifications Department of the Nasdaq Stock Market with respect to the $1.00 minimum closing bid price requirement. Although we regained compliance with the minimum closing bid price requirement after effecting a reverse stock split in March 2017, there can be no assurance that we will be able to meet the minimum closing bid price requirement or other listing requirements in the future.

The future sale of our common stock or the exchange or conversion of our convertible debt into common stock could negatively affect the market price of our common stock and other securities.*

As of July 29, 2022, we had 257,338,259 shares of common stock outstanding. All of these shares are available for public sale, subject in some cases to volume and other limitations. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock and other securities may decline. Likewise, the issuance of additional shares of our common stock upon the exchange or conversion of the Mann Group promissory notes, or the Senior convertible notes, could adversely affect the market price of our common stock and other securities. In addition, 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, 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.

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, or 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. In addition, pursuant to the MidCap credit facility, we are subject to contractual restrictions on the payment of dividends. 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.

GENERAL RISK FACTORS

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.

If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that 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. Any such sales of our common stock in the public market may affect the price of our common stock or the market price of our other securities.

In the future, we may sell additional shares of our common stock to raise capital. 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 employee stock purchase program. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. 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 Global 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.

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 further 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, 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. 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. While we cannot predict the broader consequences, the conflict 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.

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 instance, the SEC has recently proposed climate change and ESG reporting requirements, which, if approved, would significantly increase our costs. We currently do not report our environmental emissions, and lack of reporting or future reporting could result in certain investors from declining to invest in our common stock.

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

In the second quarter of 2022, the Mann Group converted $10.0 million of principal and capitalized interest under the Mann Group convertible note into 4,000,000 shares of common stock. In addition, we elected to pay quarterly interest under the Mann Group convertible note by issuing the Mann Group 31,541 shares of common stock. See Note 9 – *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	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 and 3.5.
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	Convertible Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 6, 2019 (incorporated by reference to Exhibit 4.6 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.6	Amendment No. 1 to Convertible Promissory Note, dated April 22, 2021, by and between MannKind Corporation and The Mann Group LLC (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 26, 2021).
4.7	Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 6, 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.8	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).
4.9	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	Third Amendment to Office Lease, dated April 8, 2022, between MannKind Corporation and Russell Ranch Road II LLC. (incorporated by reference to Exhibit 10.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 5, 2022)
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.

Exhibit Number	Description of Document
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.

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: August 9, 2022

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/ STEVEN B. BINDER
Steven B. Binder
Chief Financial Officer
(Principal Financial and Accounting 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 June 30, 2022 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: August 9, 2022

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, Steven B. Binder, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022 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/ Steven B. Binder

Steven B. Binder
Chief Financial Officer

Date: August 9, 2022

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 June 30, 2022, 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 9th day of August, 2022.

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

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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 June 30, 2022, 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), Steven B. Binder, 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 9th day of August, 2022.

/s/ Steven B. Binder
Steven B. Binder
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.