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, 2021

Or

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

For the transition period from _____ to _____.

Commission file number: 000-50865

MannKind Corporation
(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
30930 Russell Ranch Road, Suite 300 Westlake Village, California	**91362**
(Address of principal executive offices)	**(Zip Code)**

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

N/A

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of July 30, 2021, there were 249,660,178 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, 2021

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,522	$ 67,005
Restricted cash	—	158
Short-term investments	99,970	—
Accounts receivable, net	6,305	4,218
Inventory	7,482	4,973
Prepaid expenses and other current assets	3,624	3,122
Total current assets	179,903	79,476
Property and equipment, net	28,139	25,867
Long-term investments	38,950	—
Other assets	5,799	3,265
Total assets	$ 252,791	$ 108,608
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,486	$ 5,582
Accrued expenses and other current liabilities	22,406	19,707
PPP loan — current	4,873	4,061
Deferred revenue — current	20,126	33,275
Recognized loss on purchase commitments — current	5,538	11,080
Total current liabilities	60,429	73,705
Senior convertible notes	223,217	—
MidCap credit facility	38,614	49,335
Mann Group promissory notes	18,425	63,027
Accrued interest — Mann Group promissory notes	169	4,150
PPP loan — long term	—	812
2024 convertible notes	—	5,000
Recognized loss on purchase commitments — long term	83,179	84,208
Operating lease liability	564	1,202
Deferred revenue — long term	1,589	1,662
Milestone rights liability	4,839	5,926
Deposits from customer	5,317	—
Total liabilities	436,342	289,027
Commitments and contingencies (Note 12)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value - 400,000,000 shares authorized, 249,617,550 and 242,117,089 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2,496	2,421
Additional paid-in capital	2,911,535	2,866,303
Accumulated deficit	(3,097,582)	(3,049,143)
Total stockholders' deficit	(183,551)	(180,419)
Total liabilities and stockholders' deficit	$ 252,791	$ 108,608

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,	
	2021	2020	2021	2020
Revenues:				
Net revenue — commercial product sales	$ 9,976	$ 6,985	$ 18,075	$ 14,985
Revenue — collaborations and services	13,304	8,129	22,641	16,364
Total revenues	23,280	15,114	40,716	31,349
Expenses:				
Cost of goods sold	4,411	3,677	8,726	7,841
Cost of revenue — collaborations and services	5,515	1,983	8,810	5,345
Research and development	2,329	1,464	4,771	3,219
Selling, general and administrative	20,056	13,670	37,469	28,020
Asset impairment	—	368	—	1,889
Loss (gain) on foreign currency translation	903	1,867	(2,935)	71
Loss on purchase commitments	339	—	339	—
Total expenses	33,553	23,029	57,180	46,385
Loss from operations	(10,273)	(7,915)	(16,464)	(15,036)
Other (expense) income:				
Interest income	25	14	28	147
Interest expense on notes	(2,812)	(1,084)	(8,234)	(2,155)
Interest expense on Mann Group promissory notes	(368)	(1,281)	(1,398)	(2,540)
Loss on extinguishment of debt	(22,130)	—	(22,130)	—
Other income (expense)	35	14	(241)	10
Total other expense	(25,250)	(2,337)	(31,975)	(4,538)
Loss before provision for income taxes	(35,523)	(10,252)	(48,439)	(19,574)
Provision for income taxes	—	—	—	—
Net loss	$ (35,523)	$ (10,252)	$ (48,439)	$ (19,574)
Net loss per share - basic and diluted	$ (0.14)	$ (0.05)	$ (0.20)	$ (0.09)
Shares used to compute basic and diluted net loss per share	249,295	213,880	247,970	212,943

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,	
	2021	2020	2021	2020
Net loss	$ (35,523)	$ (10,252)	$ (48,439)	$ (19,574)
Other comprehensive loss:				
Cumulative translation loss	—	—	—	(19)
Comprehensive loss	$ (35,523)	$ (10,252)	$ (48,439)	$ (19,593)

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, 2020	211,788	$ 2,118	$ 2,799,278	$ (19)	$ (2,991,903)	$ (190,526)
Issuance of common stock under Employee Stock Purchase Plan	334	3	315	—	—	318
Stock-based compensation expense	—	—	1,128	—	—	1,128
Issuance of common stock associated with debt interest payment	99	1	143	—	—	144
Net issuance of common stock associated with stock options and restricted stock units	504	5	(322)	—	—	(317)
Issuance of common stock in at-the-market offering	413	4	518	—	—	522
Issuance cost associated with at-the-market offering	—	—	(16)	—	—	(16)
Write-off of cumulative translation loss	—	—	—	19	—	19
Net loss	—	—	—	—	(9,322)	(9,322)
BALANCE, MARCH 31, 2020	213,138	$ 2,131	$ 2,801,044	$ —	$ (3,001,225)	$ (198,050)
Stock-based compensation expense	—	—	2,185	—	—	2,185
Issuance of common stock from the exercise of warrants	7,250	73	11,527	—	—	11,600
Issuance of common stock pursuant to conversion of the June 2020 note	1,235	12	2,618	—	—	2,630
Net issuance of common stock associated with stock options and restricted stock units	297	3	114	—	—	117
Issuance of common stock in at-the-market offering	7,459	75	12,291	—	—	12,366
Issuance cost associated with at-the-market offering	—	—	(320)	—	—	(320)
Issuance of common stock from market price stock purchase	10	—	14	—	—	14
Adjustment of common stock in association with restricted stock units	(461)	(5)	5	—	—	—
Net loss	—	—	—	—	(10,252)	(10,252)
BALANCE, JUNE 30, 2020	228,928	$ 2,289	$ 2,829,478	$ —	$ (3,011,477)	$ (179,710)

	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 common stock in at-the-market offering	578	6	1,880	—	—	1,886
Issuance cost associated with at-the-market offering	—	—	(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)

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (48,439)	$ (19,574)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt	22,130	—
Stock-based compensation expense	5,861	3,313
Interest on milestone payment	3,663	—
(Gain) loss on foreign currency translation	(2,935)	71
Depreciation, amortization and accretion	1,671	1,105
Interest expense on Mann Group promissory notes	1,398	2,536
Amortization of right-of-use assets	668	576
Asset impairment	—	1,889
Write-off of inventory	—	496
Other, net	—	19
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,087)	147
Inventory	(2,509)	(164)
Prepaid expenses and other current assets	(502)	1,352
Other assets	(202)	82
Accounts payable	1,904	1,032
Accrued expenses and other current liabilities	3,215	(1,343)
Deferred revenue	(13,222)	(3,803)
Operating lease liabilities	(1,554)	(1,401)
Recognized loss on purchase commitments	(3,636)	(1,236)
Deposits from customer	5,317	—
Accrued interest on Mann Group promissory notes	(4,919)	—
Net cash used in operating activities	(34,178)	(14,903)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of debt securities	(138,920)	—
Purchase of available-for-sale securities	(3,000)	—
Purchase of property and equipment	(2,030)	(300)
Proceeds from sale of treasury bills	—	20,000
Net cash (used in) provided by investing activities	(143,950)	19,700
CASH FLOWS FROM FINANCING ACTIVITIES:		
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	12,564
Issuance costs associated with at-the-market offering	(38)	(331)
Payment of employment taxes related to vested restricted stock units and exercise of stock options	(148)	(201)
Proceeds from market price stock purchase	106	14
Issuance of common stock from the exercise of warrants	—	11,600
Proceeds from PPP loan	—	4,873
Net cash provided by financing activities	173,487	28,519
NET INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(4,641)	33,316
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	67,163	30,222
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 62,522	$ 63,538
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	$ 6,717	$ 1,820
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Premium on Mann Group convertible note	22,107	—
Payment on Mann Group convertible note through issuance of common stock	9,573	—
Payment of 2024 convertible notes through issuance of common stock	5,000	—
Non-cash construction in progress and property and equipment	1,183	—
Payment of Mann Group convertible note interest through issuance of common stock	427	—
Issuance of common stock under Employee Stock Purchase Plan	390	318
Payment of interest on 2024 convertible notes through issuance of common stock	143	144
Payment of principal on Senior convertible notes through issuance of common stock	—	2,630
Receivable from at-the-market offering	—	470

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, 2020 filed with the SEC on February 25, 2021 (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, 2021 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 and the COVID-19 pandemic has increased the level of judgment used by management in developing these estimates and assumptions. The COVID-19 pandemic continues to rapidly evolve and the ultimate impact of the COVID-19 pandemic is highly 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 and gross-to-net adjustments, 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 is a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases. The Company's lead product is Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, which was approved by the U.S. Food and Drug Administration ("FDA") in June 2014. Since September 2018, the Company has been collaborating with United Therapeutics to develop an inhaled formulation of treprostinil, known as Tyvaso DPI. In April 2021, United Therapeutics submitted a new drug application ("NDA") to the FDA seeking approval of Tyvaso DPI.

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 Afrezza, and development of other product candidates in the Company's pipeline. As of June 30, 2021, the Company had capital resources of $62.5 million in cash and cash equivalents, $100.0 million in short-term investments, $39.0 million in long-term investments, an accumulated deficit of $3.1 billion and total principal amount of outstanding borrowings of $293.3 million.

In August 2019, the Company 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 $110.0 million, leaving a balance of $50.0 million outstanding as of December 31, 2020. In April 2021, $10.0 million of the outstanding principal amount was repaid leaving a balance of $40.0 million at June 30, 2021. See Note 6 – *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 cash received from this debt issuance has resolved the Company's significant risks and uncertainties regarding sources of liquidity, which previously raised substantial doubt about the Company's ability to continue as a going concern.

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. Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported condensed consolidated balance sheets or statements of operations. An adjustment has been made to the condensed consolidated statements of cash flows for the six months ended June 30, 2020 to combine payment of employment taxes related to vested restricted stock units and exercise of stock options in the cash flows from financing activities. These changes in classification do not affect previously reported cash flows from operating or investing activities.

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.

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*, 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 Topic 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 Topic 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 and specialty pharmacies and (ii) collaboration arrangements.

Revenue Recognition – Net Revenue – Commercial Product Sales – The Company sells Afrezza to a limited number of wholesale distributors and specialty pharmacies 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 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. 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 Topic 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, 2021 and, therefore, the transaction price was not reduced further during the six months ended June 30, 2021. 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 our 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 the product from the Company. Customers charge the Company for the difference between what they pay for the product 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 Medicare, 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 product that has 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 prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with the product 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. 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 7 – *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.

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 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. The Company does not develop assets jointly with collaboration partners, and does not share in significant risks of their development or commercialization activities. Accordingly, the Company concluded that its collaborative agreements must generally be accounted for pursuant to Topic 606, Revenue from Contracts with Customers.

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. Rather, the Company evaluates grants of additional licensing rights upon option exercises to determine whether such should be accounted for as separate contracts. The Company concluded there is no material right in these options.

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.

PPP loan — On April 10, 2020, the Company received the proceeds from a loan in the amount of approximately $4.9 million (the "PPP loan") from JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The Company accounted for the PPP loan as a financial liability in accordance with ASC Topic 470, *Debt*. Accordingly, the PPP loan was recognized as current and long-term debt in the Company's consolidated balance sheets and is included as PPP loan — current and PPP loan — long term. In addition, a *de minimis* amount of accrued interest is included in accrued expenses and other current liabilities. On July 28, 2021, the Company received notification from the U.S. Small Business Administration ("SBA") that the full principal amount of the PPP loan was forgiven. See Note 6 – *Borrowings* for additional information.

Cost of Goods Sold — Cost of goods sold includes material, labor costs and manufacturing overhead. Cost of goods sold also includes a significant 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. The cost of goods sold excludes the cost of insulin purchased under our 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.

Cash and Cash Equivalents and Restricted Cash —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, 2021 and December 31, 2020, cash equivalents were comprised of money market accounts with maturities less than 90 days from the date of purchase.

The Company records restricted cash when cash and cash equivalents are restricted as to withdrawal or usage. The Company presents amounts of restricted cash that will be available for use within 12 months of the reporting date as restricted cash in current assets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported on the condensed consolidated balance sheets that sum to amounts reported on the condensed consolidated statements of cash flows (in thousands):

	June 30, 2021	December 31, 2020	June 30, 2020
Cash and cash equivalents	$ 62,522	$ 67,005	$ 63,222
Restricted cash	—	158	316
Total cash, cash equivalents, and restricted cash	$ 62,522	$ 67,163	$ 63,538

Held-to-Maturity Investments — The Company's investments generally consist of commercial paper, corporate notes or bonds and U.S. Treasury securities. For the three and six months ended June 30, 2021, the Company held short-term and long-term investments of debt securities, including commercial paper and bonds. The Company intends to hold its investments until maturity and are therefore stated at amortized cost. Those 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 our condensed consolidated balance sheets. The amortization of the Company's investments is recognized as interest expense in the condensed consolidated statements of operations and was approximately $0.1 million for the three and six months ended June 30, 2021. There was no such amortization for the three or six months ended June 30, 2020. *No allowance for credit losses on held-to-maturity securities was required as of June 30, 2021.*

Available-for-Sale Investment — In June 2021, the Company invested $3.0 million in Thirona Bio, Inc. ("Thirona") and received a $3.0 million convertible promissory note (the "Thirona convertible note"). 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 2022. Interest shall accrue at a rate of 6% per annum. The Thirona convertible note is a general unsecured obligation of Thirona. The Thirona convertible note is classified as an available-for-sale security and is 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. As of June 30, 2021, the Company evaluated the fair value of its investment in Thirona and determined that the fair value approximates the carrying value of $3.0 million. 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 7 – *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 accounts. 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 Doubtful Accounts — Accounts receivable are recorded at the invoiced amount and are not interest bearing. Accounts receivable are presented net of an allowance for doubtful accounts 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 doubtful accounts. 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 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.

In August 2019, the Company recorded a $1.5 million commitment asset and a $0.4 million other asset for deferred debt issuance costs related to the future funding commitments of the MidCap Credit Facility. A quarterly assessment was performed to determine if

the Company was on target to achieve certain required milestone conditions in order for the Company to access further borrowings under the MidCap credit facility. The Company determined that such milestone conditions related to Afrezza trailing net revenue were unlikely to be achieved. As a result, an asset impairment of $1.9 million was recognized during the six months ended June 30, 2020 and is reflected in the Company's condensed consolidated statements of operations. See Note 6 – *Borrowings* for further information on the MidCap credit facility.

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 was $88.7 million and $95.3 million as of June 30, 2021 and December 31, 2020, respectively. No new contracts were identified in 2020 or in the first six months of 2021 that required a new loss on purchase commitment accrual.

Milestone Rights Liability — On July 1, 2013, in conjunction with the execution of a financing facility with Deerfield Private Design Fund II L.P. and Deerfield Private Design International I L.P., the Company issued to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (the "Milestone Purchasers") certain rights to receive payments of up to $90.0 million, of which $65.0 million remains payable as of June 30, 2021 upon the occurrence of specified strategic and sales milestones, including the achievement of specified net sales figures (the "Milestone Rights"). The Company analyzed the Milestone Rights and determined that they did not meet the definition of a freestanding derivative. Since the Company has not elected to apply the fair value option to the Milestone Rights, the Company recorded them at their estimated initial fair value and accounted for the Milestone Rights as a liability.

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 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 6 – *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.

Recently Adopted Accounting Standards — In August 2020, the FASB issued ASU 2020-06, *Issuer's Accounting for Convertible Instruments and Contracts on an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The Company early adopted this standard as of January 1, 2021. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

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. Accounts Receivable

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

	June 30, 2021	December 31, 2020
Accounts receivable – commercial		
Accounts receivable, gross	$ 8,467	$ 8,090
Wholesaler distribution fees and prompt pay discounts	(1,335)	(1,205)
Reserve for returns	(2,928)	(2,667)
Total accounts receivable – commercial, net	4,204	4,218
Accounts receivable – collaborations and services	2,101	—
Total accounts receivable, net	$ 6,305	$ 4,218

As of June 30, 2021 and December 31, 2020, the allowance for doubtful accounts was *de minimis*. The Company had three wholesale distributors representing approximately 88% of commercial accounts receivable as of June 30, 2021 and approximately 82% and 82% of gross sales for the three and six months ended June 30, 2021, respectively.

3. Inventories

Inventories consist of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw materials	$ 2,479	$ 1,393
Work-in-process	3,095	2,484
Finished goods	1,908	1,096
Total inventory	$ 7,482	$ 4,973

Work-in-process and finished goods as of June 30, 2021 and December 31, 2020 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, 2021 and December 31, 2020, which consisted of FDKP received in November 2019 that will be used to manufacture Afrezza under an enhanced manufacturing process for FDKP. The Company expects to receive FDA approval of the new source of FDKP in 2023, after which the pre-launch raw materials inventory will be reclassified as raw materials inventory for use in the manufacturing of Afrezza and Tyvaso DPI.

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. Inventory that was forecasted to become obsolete due to expiration is recorded in costs of goods sold in the condensed consolidated statements of operations. For the six months ended June 30, 2020, there was an inventory write-off of $0.5 million as a result of this assessment. There was no inventory write-off for the three and six months ended June 30, 2021.

4. Property and Equipment

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

	Estimated Useful Life (Years)	June 30, 2021	December 31, 2020
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	37,717	37,543
Machinery and equipment	3-15	55,081	55,054
Furniture, fixtures and office equipment	5-10	3,004	3,004
Computer equipment and software	3	8,319	8,319
Construction in progress	—	3,072	503
		125,457	122,687
Less accumulated depreciation		(97,318)	(96,820)
Total property and equipment, net		$ 28,139	$ 25,867

Depreciation expense related to property and equipment for the three and six months ended June 30, 2021 and 2020 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Depreciation Expense	$ 481	$ 448	$ 941	$ 891

5. Accrued Expenses and Other Current Liabilities

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

	June 30, 2021	December 31, 2020
Salary and related expenses	$ 10,318	$ 11,250
Discounts and allowances for commercial product sales	4,035	3,688
Accrued interest	2,132	519
Deferred lease liability	1,351	1,422
Milestone rights liability — current	1,088	1,337
Danbury facility buildout	1,055	—
Professional fees	521	533
Sales and marketing services	347	99
Other	1,559	859
Total accrued expenses and other current liabilities	$ 22,406	$ 19,707

Included in salary and related expenses is approximately $1.0 million of deferred social security taxes as permitted under the CARES Act. The Company was permitted to defer the employer share of social security taxes otherwise owed on dates beginning March 27, 2020 and ending December 31, 2020. The amount of the deferral was based on wages paid from April through December 2020. The Company received notification of forgiveness by the SBA for the full principal balance of the PPP loan as discussed in Note 6 – *Borrowings*. Therefore, the deferred social security taxes will be repaid in August 2021.

6. Borrowings

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

	June 30, 2021	December 31, 2020
Senior convertible notes	$ 223,217	$ —
MidCap credit facility	38,614	49,335
Mann Group promissory notes(1)	18,425	63,027
PPP loan	4,873	4,873
2024 convertible notes	—	5,000
Total debt — net carrying amount	$ 285,129	$ 122,235

(1) The amendment to the Mann Group convertible note resulted in a substantial premium of $22.1 million based on the fair value post modification, which contributed to the loss on extinguishment in the condensed consolidated statement of operations for the three and six months ended June 30, 2021 and was recognized as additional paid-in capital in the condensed consolidated balance sheet as of June 30, 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 following table provides a summary of the Company's debt and key terms as of June 30, 2021:

	Amount Due		Terms		
	June 30, 2021	December 31, 2020	Annual Interest Rate	Maturity Date	Conversion Price
Senior convertible notes	$230.0 million	$ —	2.50%	March 2026	$5.21 per share
MidCap credit facility(1)	$40.0 million	$50.0 million	one-month LIBOR (1% floor) plus 6.25% (1)	August 2025 (1)	N/A
Mann Group convertible note	$18.4 million (plus $0.2 million accrued interest paid-in-kind)	$28.0 million (plus $0.6 million accrued interest paid-in-kind)	2.50% (2)	December 2025 (2)	$2.50 per share
Mann Group non-convertible note(3)	$ —	$35.1 million (plus $3.6 million accrued interest paid-in-kind)	7.00%	November 2024	N/A
PPP loan(4)	$4.9 million	$4.9 million	0.98%	April 2022	N/A
2024 convertible notes(5)	$ —	$5.0 million	5.75%	November 2024	$3.00 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.
(3) In April 2021, the Company prepaid $35.1 million principal balance as well as accrued unpaid interest.
(4) In July 2021, the Company received full forgiveness from the SBA for the $4.9 million principal balance of the PPP loan.
(5) In February 2021, the $5.0 million principal balance was converted into 1,666,667 shares of the Company's common stock.

The maturities of our borrowings as of June 30, 2021 are as follows (in thousands):

	Amounts
2021	$ 4,061
2022	812
2023	6,667
2024	38,425
Thereafter	243,333
Total principal payments	293,298
Discount	(1,386)
Debt issuance cost	(6,783)
Total debt — net carrying amount	$ 285,129

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 the 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 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 Notes, at least $75.0 million aggregate principal amount of 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 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, 2021, the unamortized debt issuance cost was $6.8 million.

MidCap credit facility — In August 2019, the Company entered into the MidCap credit facility and borrowed the first advance of $40.0 million ("Tranche 1") in August 2019 and the second advance of $10.0 million ("Tranche 2") in December 2020. In April 2021, $10.0 million was prepaid. Under the terms of the MidCap credit facility, a third advance of $60.0 million ("Tranche 3") will be available to the Company between January 1, 2022 and June 30, 2022, subject to the satisfaction of certain milestone conditions associated with Tyvaso DPI through the Company's collaboration with United Therapeutics (see Note 7 – *Collaboration, Licensing and Other Arrangements*).

In December 2019, the Company entered into the first amendment to the MidCap credit facility, pursuant to which the parties agreed to (i) amend the financial covenant relating to trailing twelve month minimum Afrezza Net Revenue (as defined in the MidCap credit facility) requirements, (ii) add a condition to the third advance that requires the Company achieve certain amounts of Afrezza Net Revenue, and (iii) increase the exit fee from 6.00% to 7.00% of the principal amount of all term loans advanced to the Company under the MidCap credit facility.

In August 2020, the Company entered into the second amendment to the MidCap credit facility, pursuant to which the parties agreed that no breach of the minimum Afrezza net revenue covenant for any trailing twelve-month reporting period between July 31, 2020 and November 30, 2020 will be deemed to occur if the Company delivers satisfactory evidence that it had unrestricted cash of at least $40.0 million. Without this amendment, the Company would have been in violation of the minimum Afrezza net revenue covenant as of September 30, 2020.

In November 2020, the Company entered into the third amendment to the MidCap credit facility, pursuant to which the parties agreed to (i) amend the conditions to draw Tranche 2, which had become unavailable, such that the advance became available and was, in fact, funded to the Company on December 1, 2020, (ii) amend the conditions to Tranche 3 such that the third advance was available upon the satisfaction of certain conditions, including certain milestone conditions associated with Tyvaso DPI, (iii) add a covenant that requires the marketing of Tyvaso DPI if the third advance is funded, (iv) amend the financial covenant relating to trailing twelve month minimum Afrezza Net Revenue (as defined in the MidCap credit facility) requirements, (v) increase the minimum cash covenant to $30.0 million at all times, (vi) extend the interest only period until September 1, 2022, at which time principal on each term loan advance is payable in 24 equal monthly installments, and (vii) amend the prepayment fees.

In connection with the extension of the interest only period for the $40.0 million drawn under Tranche 1, a $0.2 million loss on extinguishment was recognized in the consolidated statements of operations for the year ended December 31, 2020. The funding of $10.0 million under Tranche 2 resulted in the recognition of approximately $0.3 million of debt discount and a *de minimis* amount of debt issuance costs.

In December 2020, the Company entered into the fourth and fifth amendments to the MidCap credit facility. Pursuant to the fourth amendment, MidCap consented to the acquisition by the Company of QrumPharma, Inc. Pursuant to the omnibus joinder and fifth amendment, QrumPharma was joined as a borrower to the MidCap credit facility and to certain related financing documents.

In March 2021 the Company entered into the sixth amendment to the MidCap credit facility to accommodate the issuance of the Senior convertible notes. On April 22, 2021, the Company entered into the seventh amendment of the MidCap credit facility, pursuant to which 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.

Tranche 1, Tranche 2 and, if borrowed, Tranche 3, each 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, Tranche 2 and, if applicable, Tranche 3 is 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. Tranche 3 will be subject to a similar scheme of early termination fees measured from the anniversary of the funding date for such tranche, if ever.

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, 2021, the unamortized debt discount was $0.4 million and the unamortized prepayment penalty was $0.9 million.

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. The Company is also subject to a minimum cash covenant of $10.0 million at all times; however, this covenant will be eliminated in the event that Tyvaso DPI is approved by the FDA. As of June 30, 2021, the Company was in compliance with the financial and minimum cash 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%.

The Company also agreed to issue warrants to purchase shares of the Company's common stock (the "MidCap warrants") upon the drawdown of Tranches 1 and 2 in an aggregate amount equal to 3.25% of the amount drawn, divided by the exercise price per share for that tranche. The exercise price per share is equal to the volume-weighted average closing price of the Company's common stock for the ten business days immediately preceding the second business day before the issue date. As a result of Tranche 1, the Company issued warrants to purchase an aggregate of 1,171,614 shares of the Company's common stock, at an exercise price equal to $1.11 per share. As a result of Tranche 2, the Company issued warrants to purchase an aggregate of 111,853 shares of the Company's common stock, at an exercise price equal to $2.91 per share. The MidCap warrants are immediately exercisable and expire on the earlier to occur of the seventh anniversary of the respective issue date or, in certain circumstances, the closing of a merger, sale or other consolidation transactions in which the consideration is cash, stock of a publicly traded acquirer, or a combination thereof. The Company determined that these warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital.

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 each 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. On April 22, 2021, the Company and Mann Group entered into an amendment of 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 our condensed consolidated statement of operations for the three and six months ended June 30, 2021 and resulted in a corresponding debt premium of $22.1 million which was recognized as additional paid-in capital in our condensed consolidated balance sheet as of June 30, 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.
Pursuant to the terms of the Mann Group convertible note, Mann Group converted $3.0 million of accrued interest and $7.0 million of principal into 1.2 million shares and 2.8 million shares, respectively, of the Company's common stock in the fourth quarter of 2020. During the six months ended June 30, 2021, Mann Group converted $0.4 million of interest and $9.6 million of principal into 4,000,000 shares of common stock.

On April 22, 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.

PPP loan – On April 10, 2020, the Company received the proceeds from the PPP loan from JPMorgan Chase Bank, N.A., as lender, in the amount of approximately $4.9 million pursuant to the PPP of the CARES Act. On July 28, 2021, the Company received notification from the SBA that the full principal amount of the PPP loan was forgiven.

Prior to being forgiven, the PPP loan was evidenced by a promissory note dated April 9, 2020 that matured on April 9, 2022 and bore interest at a rate of 0.98% per annum (which was being deferred). The Company used all proceeds from the PPP loan to retain employees, maintain payroll and make lease, interest and utility payments.

2024 convertible notes — In August 2019, the Company issued 5.75% convertible senior subordinated exchange notes due November 2024 (the "2024 convertible notes") pursuant to an indenture, dated as of August 6, 2019, between the Company and U.S. Bank National Association, as trustee (the "2019 Indenture"). The 2024 convertible notes were the Company's general, unsecured obligations, and were subordinated in right of payment to the indebtedness incurred pursuant to the MidCap credit facility. The 2024 convertible notes ranked equally in right of payment with the Company's other unsecured senior debt. The 2024 convertible notes accrued interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears on February 15 and August 15 of each year, beginning February 15, 2020, with interest accruing from August 6, 2019. Interest on the 2024 convertible notes was payable in cash or, at the option of the Company if certain conditions are met, in shares of the Company's common stock at a price per share equal to the last reported sale price on the trading day immediately prior to the interest payment date.

The 2024 convertible notes were convertible, at the option of the holder, 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 333.3333 shares per $1,000 principal amount of 2024 convertible notes, which is equal to a conversion price of approximately $3.00 per share.

In February 2021, the Company converted the $5.0 million 2024 convertible notes with the issuance of 1,666,667 shares of the Company's common stock.

Amortization of debt discount and debt issuance cost related to all borrowings for the three and six months ended June 30, 2021 and 2020 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Amortization of debt discount	$ 86	$ 90	$ 146	$ 179
Amortization of debt issuance cost	363	27	488	55

Milestone Rights — As of June 30, 2021 and December 31, 2020, the remaining Milestone Rights liability balance was $5.9 million and $7.3 million, respectively, which was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. During the first quarter of 2021, the Company achieved the second Afrezza net sales milestone specified by the Milestone Rights. The milestone carrying value of the Milestone Rights liability related to the $5.0 million payment, which was made in the second quarter of 2021, was approximately $1.3 million, which represented the fair value as determined in 2013 (the most recent measurement date).

The agreement with the Milestone Purchasers that provides for the Milestone Rights 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.

7. Collaboration, Licensing and Other Arrangements

Revenue from collaborations and services for the three and six months ended June 30, 2021 and 2020 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
UT License Agreement	$ 12,163	$ 7,978	$ 21,163	$ 15,956
Vertice Pharma Co-Promotion Agreement	856	—	1,147	—
Receptor CLA	165	63	175	125
Cipla License and Distribution Agreement	37	35	73	72
Other	83	—	83	—
UT Research Agreement	—	53	—	211
Total revenue from collaborations and services	$ 13,304	$ 8,129	$ 22,641	$ 16,364

United Therapeutics License Agreement — In September 2018, the Company and United Therapeutics Corporation ("United Therapeutics" or "UT") entered into an exclusive global license and collaboration agreement (the "UT License Agreement") for the rights to the Company's dry powder formulation of treprostinil ("Tyvaso DPI") and associated inhalation delivery devices. Under the UT License Agreement, UT is responsible for global development, regulatory and commercial activities with respect to Tyvaso DPI. The Company is responsible for manufacturing clinical supplies and commercial supplies of Tyvaso DPI.

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 will also be 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.

At the inception of the agreement, the Company identified one distinct, performance obligation. The Company determined that the key deliverables include the license, supply of product to be used in clinical development, and certain research services upon achievement of specified development targets. Due to the specialized and unique nature of these services and their direct relationship with the license, the Company has determined that these deliverables represent one distinct bundle and thus, one performance obligation. The Company also determined that UT's option to expand the scope of the products to include products with other active ingredients is not a material right, and thus, not a performance obligation at the onset of the agreement. The consideration for the option will be accounted for upon exercise of the option.

The Company expected to complete the activities specified in the initial development plan and to achieve the milestone events (including a $2.7 million increase in total consideration pursuant to the agreement executed in December 2020) by December 31, 2021 for total consideration of approximately $105.8 million, which included an upfront payment, four milestone payments, various pass-through costs and payments for clinical supplies. Through March 2021, the Company recognized revenue ratably over a 13-quarter period ending December 2021, which represented the estimated period to satisfy the performance obligation.

In May 2021, UT and the Company updated the development plan under the UT License Agreement to provide for additional process-development and stability-testing activities as well as the expansion of the Company's commercial manufacturing capacity. The activities and deliverables under the current development plan resulted in four distinct performance obligations which include: (1) the continued development and approval process for a new drug application ("NDA") ("R&D Services"); (2) certain pre-commercial services in preparation for commercial launch of Tyvaso DPI "(Pre-Commercial Services"); (3) development activities for the next generation of Tyvaso DPI ("Next-gen R&D Services"); and (4) certain design and construction activities in anticipation of expansion of the Company's commercial manufacturing facility ("Facility Expansion Services").

The total consideration for the updated development plan of $50.2 million was allocated to the four distinct performance obligations based on management's assessment of the stand-alone selling price of each performance obligation. Consideration of $0.7 million for additional clinical supplies was added in June 2021 for a total of $50.9 million. The R&D Services performance obligation was allocated a total of $18.3 million, which will be recognized on a ratable basis from May 2021 through October 2021; the estimated date when the performance obligation for the initial development services will be substantially completed.

The Company allocated $4.6 million, $7.2 million, and $20.7 million to the Pre-Commercial Services, Next-gen R&D Services, and Facility Expansion Services performance obligations, respectively. The Company determined that the Pre-Commercial Services and Next-gen R&D Services performance obligations 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. The Facility Expansion Services performance obligation would be recognized as control of manufactured products is transferred to the customer.

The Company will also be acting as agent for the procurement of equipment for the manufacturing expansion for UT (the "UT Equipment"). The $5.3 million received from UT for the UT Equipment was recognized as deposits from customer on our condensed consolidated balance sheet and will be released as the title is transferred to UT.

As of June 30, 2021, deferred revenue consisted of $20.0 million, which was classified as current 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 where the Company's sales force will promote Thyquidity to adult endocrinologists, pediatric endocrinologists and other healthcare providers who treat hypothyroidism. Following the commercial launch of Thyquidity, in consideration of the sales and promotional activities provided by the Company's sales force, Vertice is obligated to pay fixed quarterly payments to the Company, as well as variable consideration based on gross profits resulting from all sales of Thyquidity. Vertice Pharma launched Thyquidity in collaboration with the Company in February 2021.

At inception of the agreement, the Company identified a single performance obligation that the Company will satisfy over time. The Company estimates the total transaction price is approximately $6.3 million, consisting of fixed consideration and the unconstrained amount of estimated variable consideration, which is based on gross profit applied to defined revenue benchmarks. The amount of variable consideration is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur and the payments will be received. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price 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 in the period of adjustment. The total transaction price will be recognized over a two-year period. the period over which the Company is required to satisfy its performance obligation, 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. As of June 30, 2021, a contract asset of approximately $0.1 million was recognized as other assets in the condensed consolidated balance sheet. Subsequent to June 30, 2021, the Company and Vertice Pharma entered into an amendment to the Vertice Pharma Co-Promotion Agreement that modifies the terms of payment where 50% of the previously fixed consideration will be subject to certain promotional conditions, resulting in variable consideration, for the third quarter of 2021.

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 cost of revenue — collaborations and services 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 have now been received. Biomm commenced product sales in January 2020.

In September 2019, the Company delivered its first shipment of Afrezza to Biomm and recorded it as net revenue — commercial product sales for $0.7 million, in advance of the planned launch of the product in Brazil by Biomm. During the second quarter of 2020, the Company sold $0.2 million of product to Biomm. No additional shipments were made to Biomm in 2020 or the first six months of 2021.

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 will be 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, 2021, the deferred revenue balance was $1.7 million, of which $0.1 million is classified as current and $1.6 million is classified as long term in the condensed consolidated balance sheets.

AMSL Distribution Agreement — In May 2019, the Company entered into an exclusive marketing and distribution agreement with the AMSL Diabetes division of Australasian Medical & Scientific Ltd. ("AMSL Diabetes") for the commercialization of Afrezza in Australia. Under the terms of this agreement, AMSL Diabetes is responsible for obtaining regulatory and reimbursement approvals to distribute Afrezza in Australia. Upon regulatory approval, AMSL Diabetes will conduct sales, marketing, and customer support and distribution activities whereas the Company will be responsible for the supply and manufacturing of Afrezza.

8. 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.

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, MidCap credit facility, Mann Group promissory notes, 2024 convertible notes, Senior convertible notes and Milestone Rights liabilities are disclosed below.

Cash Equivalents and Restricted Cash— 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, 2021 and December 31, 2020, the Company held $62.5 million and $67.0 million, respectively, of cash and cash equivalents. The Company held zero and $0.2 million in restricted cash as of June 30, 2021 and December 31, 2020, which are comprised of money market funds. Restricted cash was used to collateralize a letter of credit. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

Investments — Investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. The fair value of investments approximates their carrying value. The measurement of which is based on a market approach using quoted market values (Level 1 in the fair value hierarchy). As of June 30, 2021, the Company held $100.0 million of short-term investments and $39.0 million of long-term investments.

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, 2021		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
Senior convertible notes(1)	$ 223.2	$ 257.0	$ 257.0
MidCap credit facility(2)	38.6	40.5	40.5
Mann Group convertible notes(3)	18.4	44.9	44.9
PPP loan(4)	4.9	4.8	4.8
Milestone rights(5)	5.9	15.0	15.0

(1) Fair value determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 12%, volatility of 96% 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 $245.4 million and $269.8 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 $38.5 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 June 30, 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 June 30, 2021 was determined by applying a discounted cash flow analysis with a hypothetical yield of 12% and volatility of 96% 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 $43.9 million and $45.9 million, respectively.

(4) Fair value determined by applying a discounted cash flow analysis with a hypothetical yield of 12%. A change in yield of + or – 2% would result in a fair value of $4.7 million and $4.8 million, respectively.

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

	December 31, 2020		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:(1)			
MidCap credit facility	$ 49.3	$ 55.4	$ 55.4
Mann Group promissory notes(2)	63.0	78.9	78.9
2024 convertible notes	5.0	7.0	7.0
PPP loan	4.9	4.7	4.7
Milestone rights	7.3	19.8	19.8

(1) Fair value measurements were based on a discounted cash flow model, except for the Milestone rights for which a Monte Carlo simulation was applied.

(2) Mann Group promissory notes consisted of the following carrying values and fair values:
Mann Group convertible notes carrying value of $28.0 million and fair value of $52.2 million.
Mann Group non-convertible notes carrying value of $35.1 million and fair value of $26.7 million.

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 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.

9. 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, 2021 and December 31, 2020, 249,617,550 and 242,117,089 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, 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 Sales Agreement. For the six months ended June 30, 2020, the Company sold an aggregate of 7,871,461 shares of the Company's common stock at a weighted average purchase price of $1.64 per share for an aggregate gross proceeds of approximately $12.9 million pursuant to the CF Sales Agreement.

In the first quarter of 2021, Mann Group converted $0.4 million of interest and $9.6 million of principal into 4,000,000 shares of common stock in accordance with the terms of the Mann Group convertible note. See Note 6 – *Borrowings*.

In February 2021, the Company converted $5.0 million principal amount of 2024 convertible notes into 1,666,667 shares of the Company's common stock in accordance with the terms of the 2024 convertible notes. See Note 6 – *Borrowings*.

For the three and six months ended June 30, 2021, the Company received $0.1 million from the market price stock purchase plan for 25,000 shares. There was a *de minimis* amount of market price stock purchase plan transactions for the three and six months ended June 30, 2020.

10. 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,	
	2021	2020	2021	2020
EPS — basic and diluted:				
Net loss (numerator)	$ (35,523)	$ (10,252)	$ (48,439)	$ (19,574)
Weighted average common shares (denominator)	249,295	213,880	247,970	212,943
Net loss per share	$ (0.14)	$ (0.05)	$ (0.20)	$ (0.09)

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,	
	2021	2020
Senior convertible notes	44,120,463	—
Mann Group convertible notes	7,370,000	14,000,000
Warrants associated with MidCap credit facility	1,283,467	1,171,614
Common stock options and PNQs	11,092,080	13,197,927
RSUs and Market RSUs (1)	7,986,898	2,501,713
Employee stock purchase plan	250,000	276,154
2024 convertible notes	—	1,666,667
Common stock warrants	—	31,851
Total shares	72,102,908	32,845,926

(1) Market RSUs are included at the maximum share delivery percentage.

11. Stock-Based Compensation Expense

During the six months ended June 30, 2021, the Company granted the following awards:

	Three Months Ended March 31, 2021		Three Months Ended June 30, 2021		Six Months Ended June 30, 2021
Employee awards:					
RSUs	370,137	(1)	1,476,059	(2)	1,846,196
Market RSUs	—		918,775	(3)	918,775
Non-employee director RSUs	—		316,232	(4)	316,232
Total awards	370,137		2,711,066		3,081,203

(1) RSUs had a weighted average grant date fair value of $5.53 per share, of which 202,237 RSUs had a vesting period of 1 year and 167,900 RSUs had a vesting period of four years.

(2) RSUs had a weighted average grant date fair value of $4.26 per share and a vesting period of 4 years.

(3) Market RSUs had a grant date fair value of $9.30 per share and will vest on May 17, 2024 provided the closing price of the Company's common stock on such vesting date is not less than the closing price on May 17, 2021. 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 18, 2021 until May 17, 2024 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 $4.31 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, 2021, there was $3.4 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 1.6 years, and $12.6 million and $12.5 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 3.4 and 2.6 years, respectively.

Total stock-based compensation expense recognized in the condensed consolidated statements of operations for the three months ended June 30, 2021 and 2020 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
RSUs and options	$ 3,819	$ 2,122	$ 5,625	$ 3,188
Employee stock purchase plan	107	63	236	125
Total stock compensation expense	$ 3,926	$ 2,185	$ 5,861	$ 3,313

Employee Stock Purchase Plan

The Company provides all employees, including executive officers, the ability to purchase our common stock at a discount under our 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 our 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 292,981 and 333,727 shares of common stock pursuant to the ESPP for the six months ended June 30, 2021 and 2020, respectively. There were approximately 1.3 million shares of common stock available for issuance under the ESPP as of June 30, 2021.

12. 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, 2021, 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.

Following the public announcement in January 2016 of the election by sanofi-aventis U.S. LLC ("Sanofi") to terminate a license and collaboration agreement (the "Sanofi License Agreement") between the Company and Sanofi and the subsequent decline in the Company's stock price, two motions were submitted to the district court at Tel Aviv, Economic Department for the certification of a class action against the Company and certain of its officers and directors. In general, the complaints allege that the Company and certain of its officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court ruled in October 2017 that U.S. law will apply to this case. The plaintiff appealed this ruling, and following an oral hearing before the Supreme Court of Israel, decided to withdraw his appeal. Subsequently, in November 2018, the Company filed a motion to dismiss the certification motion. In September 2019, the plaintiff brought a motion to amend his claim, which the court denied in January 2020. The plaintiff appealed this denial to the Supreme Court of Israel, which issued a decision in July 2021 upholding the lower court decision. Subsequently, the plaintiff withdrew his complaint and the district court dismissed the motion to certify, bringing the litigation to an end.

Contingencies — In July 2013, the Company entered into an agreement with the 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 upon achievement of such milestones (see Note 6 – *Borrowings*). The fair value of the Milestone Rights is recorded in the condensed consolidated balance sheet, including $*1.1* million in accrued expenses and other current liabilities and $*4.8* million in milestone rights liability.

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 three and six months ended June 30, 2021. The remaining purchase commitments as of June 30, 2021 and March 31, 2021 (pre-amendment) were as follows:

	June 30, 2021	March 31, 2021
2021	€ 2.0 million	€ 7.0 million
2022	€ 5.4 million	€ 8.5 million
2023	€ 8.7 million	€ 10.9 million
2024	€ 14.6 million	€ 14.6 million
2025	€ 15.5 million	€ 15.5 million
2026	€ 19.4 million	€ 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.

Warrants – In August 2019, in connection with the MidCap credit facility, the Company issued warrants to purchase an aggregate of 1,171,614 shares of the Company's common stock, at an exercise price equal to $1.11 per share, to the lenders. On November 30, 2020, in connection with the third amendment to the MidCap credit facility, the Company issued warrants to purchase an aggregate of 111,853 shares of the Company's common stock, at an exercise price of $2.91 per share. (see Note 6 – *Borrowings*).

Vehicle Leases – During the second quarter of 2018, the Company entered into a lease agreement with Enterprise Fleet Management Inc. During the six months ended June 30, 2021, 10 vehicles were removed from the fleet, resulting in a fleet size of 78 vehicles. No gain or loss was recorded. The revised monthly payment inclusive of maintenance fees, insurance and taxes is approximately $69,000. 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 headquarters 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 expires in January 2023 and provides the Company with a five-year renewal option. 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 headquarters in Westlake Village, California. The office lease commenced in October 2018. The Company agreed to pay initial monthly lease payments of $35,969, subject to a 3% annual increase, plus the estimated operating cost of maintaining the property by the landlord, which are allocable based an annual assessment made by the landlord. In addition, the Company received reimbursement from the landlord of $56,325 for tenant improvements and was not required to pay a first-year common area maintenance fee. The lease expires in January 2023 and provides the Company with a five-year renewal option.

Lease information is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating lease costs	$ 340	$ 352	$ 685	$ 703
Variable lease costs	114	79	231	180
Cash paid	454	431	916	883

	June 30, 2021	December 31, 2020
Weighted average remaining lease term (in years)	1.5	1.9
Weighted average discount rate	7.3%	7.5%

Future minimum office and vehicle lease payments as of June 30, 2021 and December 31, 2020, are as follows (in thousands):

	June 30, 2021	December 31, 2020
2021	$ 722	$ 1,494
2022	1,213	1,239
2023	88	88
Total	$ 2,023	$ 2,821

13. 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 believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to this guidance. The Company’s tax years since 2016 remain subject to examination by federal, state and foreign 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, 2020 and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for endocrine and orphan lung diseases. Our lead product is Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, which was approved by the FDA in June 2014. Since September 2018, we have been collaborating with United Therapeutics to develop an inhaled formulation of treprostinil known as Tyvaso DPI. In April 2021, United Therapeutics submitted an NDA for Tyvaso DPI to the FDA. United Therapeutics has applied a priority review voucher to the NDA. The FDA has accepted the application for review and is expected to complete their review in October 2021.

Our business is subject to significant risks, including but not limited to our ability to commercialize Afrezza successfully, our ability to manufacture sufficient quantities of Afrezza and Tyvaso DPI and our potential need to raise additional capital to fund our operations. 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. Our sales representatives have resumed in-person sales calls to the extent permitted by state and local public health authorities and by the policies of individual healthcare providers on their call lists. Our offices in California and Connecticut have remained open for essential personnel and, as public health orders allow, have reopened to non-essential personnel. Although our productivity has been impacted by the global pandemic, we have suitably adapted to the changed business environment that now exists.

The impact of the COVID-19 pandemic continues to be uncertain. 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, 2021, we had an accumulated deficit of $3.1 billion and a stockholders' deficit of $183.6 million. We had net loss of $35.5 million and $48.4 million for the three and six months ended June 30, 2021, respectively. 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 under certain loan arrangements and from sales of Afrezza.

CRITICAL ACCOUNTING POLICIES

Our critical accounting policies can be found in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K for the year ended December 31, 2020. 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

Three and six months ended June 30, 2021 and 2020

Revenues

The following tables provide a comparison of the revenue categories for the three and six months ended June 30, 2021 and 2020 (dollars in thousands):

	Three Months Ended June 30,			
	2021	2020	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 16,575	$ 11,900	$ 4,675	39%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(6,599)	(4,915)	$ 1,684	34%
Net revenue — commercial product sales	9,976	6,985	$ 2,991	43%
Revenue — collaborations and services	13,304	8,129	$ 5,175	64%
Total revenues	$ 23,280	$ 15,114	$ 8,166	54%

	Six Months Ended June 30,			
	2021	2020	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 30,185	$ 25,832	$ 4,353	17%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(12,110)	(10,847)	$ 1,263	12%
Net revenue — commercial product sales	18,075	14,985	$ 3,090	21%
Revenue — collaborations and services	22,641	16,364	$ 6,277	38%
Total revenues	$ 40,716	$ 31,349	$ 9,367	30%

Gross revenue from sales of Afrezza increased by $4.7 million, or 39%, for the three months ended June 30, 2021 compared to the same period in the prior year. The increase reflects higher prescription demand, the negative effects of the COVID-19 pandemic on Afrezza sales volumes during the second quarter of 2020 when our sales force had limited access to physicians as a result of the stay-at-home orders implemented around the country, a more favorable mix of Afrezza cartridges, and price. The gross-to-net adjustment was 39.8% of gross revenue, or $6.6 million, for the three months ended June 30, 2021, compared to 41.3% of gross revenue, or $4.9 million, for the same period in the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in accounting estimates for wholesaler distribution fees, prompt pay discounts and government rebates as a result of the termination of our free goods program on December 31, 2020, partially offset by an increase in co-pay discounts. As a result, net revenue from sales of Afrezza increased by $3.0 million, or 43%, for the three months ended June 30, 2021 compared to the prior year period.

Net revenue from collaborations and services increased by $5.2 million, or 64%, for the three months ended June 30, 2021 compared to the same period in the prior year. The increase in collaborations and services revenue was primarily attributed to our collaboration with UT. See Note 7 – *Collaboration, Licensing and Other Arrangements.*

Gross revenue from sales of Afrezza increased by $4.4 million, or 17%, for the six months ended June 30, 2021 compared to the same period in the prior year. The increase reflects higher product demand in the first half of 2021 as a result of increased promotional activity in addition to the negative impact that the COVID-19 pandemic had on the demand of Afrezza prescriptions in 2020. The gross-to-net adjustment was 40.1% of gross revenue, or $12.1 million, for the six months ended June 30, 2021, compared to 42.0% of gross revenue, or $10.8 million, for the same period in the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in accounting estimates for wholesaler distribution fees and government rebates as a result of the termination of our free goods program on December 31, 2020, partially offset by an increase in co-pay discounts. As a result, net revenue from sales of Afrezza increased by $3.1 million, or 21%, for the six months ended June 30, 2021 compared to the prior year period.

Net revenue from collaborations and services increased by $6.3 million, or 38%, for the six months ended June 30, 2021 compared to the same period in the prior year. The increase in collaborations and services revenue was primarily attributed to our collaboration with UT. See Note 7 – *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, 2021 and 2020 (dollars in thousands):

	Three Months Ended June 30,			
	2021	2020	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 9,976	$ 6,985	$ 2,991	43%
Less: cost of goods sold	4,411	3,677	$ 734	20%
Commercial product gross profit	$ 5,565	$ 3,308	$ 2,257	68%
Gross margin	56%	47%		
Non-GAAP gross margin(1)	76%	47%		

	Six Months Ended June 30,			
	2021	2020	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 18,075	$ 14,985	$ 3,090	21%
Less: cost of goods sold	8,726	7,841	$ 885	11%
Commercial product gross profit	$ 9,349	$ 7,144	$ 2,205	31%
Gross margin	52%	48%		
Non-GAAP gross margin(1)	63%	48%		

(1) See the reconciliation of gross margin to non-GAAP gross margin under Non-GAAP Measures below.

Commercial product gross profit for the three months ended June 30, 2021 increased by $2.3 million, or 68%, compared to the same period in the prior year. Gross margin for the three months ended June 30, 2021 was 56% compared to 47% for the same period in the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales partially offset by an increase in cost of goods sold. Cost of goods sold increased by $0.7 million, or 20%, for the three months ended June 30, 2021 compared to the same period in the prior year, primarily due to a $2.0 million fee for the amendment of the Insulin Supply Agreement, partially offset by $1.1 million of increased manufacturing activities, which resulted in a higher amount of costs capitalized to inventory. On a non-GAAP basis, which excludes the $2.0 million insulin supply amendment fee, gross margin was 76% for the second quarter of 2021 compared to 47% for the same period in 2020. See the reconciliation to non-GAAP net loss and EPS under Non-GAAP Measures below.

Commercial product gross profit for the six months ended June 30, 2021 increased by $2.2 million, or 31%, compared to the same period in the prior year. Gross margin for the six months ended June 30, 2021 was 52% compared to 48% for the same period in the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales, partially offset by an increase in cost of goods sold. Cost of goods sold increased by $0.9 million, or 11%, for the six months ended June 30, 2021 compared to the same period in the prior year, primarily due to a $2.0 million fee for the amendment of the Insulin Supply Agreement, partially offset by $0.8 million of costs associated with lower cost per unit and the termination of the free goods program in December 31, 2020, in addition to $0.5 million of inventory write-offs in 2020. On a non-GAAP basis, which excludes the $2.0 million insulin supply amendment fee, gross margin was 63% for the six months ended June 30, 2021 compared to 48% for the same period in 2020. See the reconciliation to non-GAAP net loss and EPS under Non-GAAP Measures below.

Expenses

The following tables provide a comparison of the expense categories for the three and six months ended June 30, 2021 and 2020 (dollars in thousands):

	Three Months Ended June 30,			
	2021	2020	$ Change	% Change
Expenses:				
Cost of goods sold	$ 4,411	$ 3,677	$ 734	20%
Cost of revenue — collaborations and services	5,515	1,983	$ 3,532	178%
Research and development	2,329	1,464	$ 865	59%
Selling	11,534	7,271	$ 4,263	59%
General and administrative	8,522	6,399	$ 2,123	33%
Asset impairment	—	368	$ (368)	*
Loss on foreign currency translation	903	1,867	$ (964)	(52%)
Loss on purchase commitments	339	—	$ 339	*
Total expenses	$ 33,553	$ 23,029	$ 10,524	46%

* Not meaningful

	Six Months Ended June 30,			
	2021	2020	$ Change	% Change
Expenses:				
Cost of goods sold	$ 8,726	$ 7,841	$ 885	11%
Cost of revenue — collaborations and services	8,810	5,345	$ 3,465	65%
Research and development	4,771	3,219	$ 1,552	48%
Selling	21,153	15,417	$ 5,736	37%
General and administrative	16,316	12,603	$ 3,713	29%
Asset impairment	—	1,889	$ (1,889)	*
(Gain) loss on foreign currency translation	(2,935)	71	$ (3,006)	*
Loss on purchase commitments	339	—	$ 339	*
Total expenses	$ 57,180	$ 46,385	$ 10,795	23%

* Not meaningful

Cost of revenue — collaborations and services increased by $3.5 million, or 178%, for the three months ended June 30, 2021 and $3.5 million, or 65%, for the six months ended June 30, 2021 compared to the respective periods in the prior year. The increases were attributable to an increase in costs for the UT License agreement and pre-commercial activities and the allocation of selling expenses related to the Vertice Pharma Co-Promotion Agreement.

Research and development expenses increased by $0.9 million, or 59%, for the three months ended June 30, 2021 and $1.6 million, or 48%, for the six months ended June 30, 2021 compared to the respective periods in the prior year. The increases were attributable to personnel costs primarily related to increased headcount for research and development, regulatory and medical affairs in addition to costs incurred for clinical studies and pipeline research.

Selling expenses increased by $4.3 million, or 59%, for the three months ended June 30, 2021 compared to the same period in the prior year as we expanded our investment behind Afrezza and lowered expenses in the prior year period when we voluntarily reduced compensation and field force activities in response to the onset of the COVID-19 pandemic. As we continued to re-engage our selling activities behind Afrezza, we increased promotional and marketing expenses by $1.8 million and patient support services by $0.6 million during the three months ended June 30, 2021. Personnel expenses increased $3.1 million due to the favorable impact of lower spending during the COVID-19 pandemic as well as increased headcount and stock compensation to support Afrezza growth. The increases in selling expenses were partially offset by a reduction related to the co-promotional cost for Thyquidity which was recognized as cost of revenue — collaboration and services.

Selling expenses increased by $5.7 million, or 37%, for the six months ended June 30, 2021 compared to the same period in the prior year as we expanded our investment behind Afrezza and lowered expenses in the prior year period when we voluntarily reduced compensation and field force activities in response to the onset of the COVID-19 pandemic. As we continued to re-engage our selling activities behind Afrezza, we increased promotional and marketing expenses by $2.4 million and patient support services by $0.9 million during the six months ended June 30, 2021. Personnel expenses increased $3.8 million due to the favorable impact of lower spending during the COVID-19 pandemic as well as increased headcount and stock compensation to support Afrezza growth. The increases in selling expenses were partially offset by a reduction related to the co-promotional cost for Thyquidity which was recognized as cost of revenue — collaboration and services.

General and administrative expenses increased by $2.1 million, or 33%, for the three months ended June 30, 2021 compared to the same period in the prior year. This increase was primarily attributable to personnel-related costs, including higher stock-based compensation and bonus, as well as lower salaries in the prior year period related to the onset of the COVID-19 pandemic. Additional increases in general and administrative expenses consisted of UT pre-commercial preparations and professional fees.

General and administrative expenses increased by $3.7 million, or 29%, for the six months ended June 30, 2021 compared to the same period in the prior year. This increase was primarily attributable to personnel-related costs, including higher stock-based compensation and bonus, as well as lower salaries in the prior year period related to the onset of the COVID-19 pandemic. Additional increases in general and administrative expenses consisted of UT pre-commercial preparations, professional fees and business development expenses.

An impairment of $0.4 million and $1.9 million was recognized for the three and six months ended June 30, 2020 for a commitment asset related to the future funding commitments of the MidCap credit facility. There were no asset impairments for the three and six months ended June 30, 2021.

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 loss decreased $1.0 million for the three months ended June 30, 2021 compared to the same period in the prior year. The foreign currency translation gain was $2.9 million for the six months ended June 30, 2021 compared to a $0.1 million loss 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, 2021 and 2020 (dollars in thousands):

	Three Months Ended June 30,			
	2021	2020	$ Change	% Change
Interest income	$ 25	$ 14	$ 11	79%
Interest expense on notes	(2,812)	(1,084)	$ 1,728	159%
Interest expense on Mann Group promissory notes	(368)	(1,281)	$ (913)	(71%)
Loss on extinguishment of debt	(22,130)	—	$ 22,130	*
Other income	35	14	$ 21	150%
Total other expense	$ (25,250)	$ (2,337)	$ 22,913	980%

	Six Months Ended June 30,			
	2021	2020	$ Change	% Change
Interest income	$ 28	$ 147	$ (119)	(81%)
Interest expense on notes	(8,234)	(2,155)	$ 6,079	282%
Interest expense on Mann Group promissory notes	(1,398)	(2,540)	$ (1,142)	(45%)
Loss on extinguishment of debt	(22,130)	—	$ 22,130	*
Other (expense) income	(241)	10	$ 251	*
Total other expense	$ (31,975)	$ (4,538)	$ 27,437	605%

* Not meaningful

Interest expense increased by $1.7 million, or 159%, for the three months ended June 30, 2021 compared to the same period in the prior year. The increase was primarily due to the interest expense from the Senior convertible notes. Interest expense increased by $6.1 million, or 282%, for the six months ended June 30, 2021 compared to the same period in the prior year. The increase was primarily due to a $3.7 million milestone obligation that was achieved during the first quarter of 2021 and interest expense on the Senior convertible notes issued in the first quarter of 2021.

Interest expense on Mann Group promissory notes decreased by $0.9 million, or 71%, for the three months ended June 30, 2021 and $1.1 million, or 45%, for the six months ended June 30, 2021 compared to the same periods in the prior year. The decrease was primarily due to the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible note and the reduction of the interest rate from 7.00% to 2.50% pursuant to the first amendment. See Note 6 — *Borrowings*.

Loss on extinguishment of debt for the three and six months ended June 30, 2021 was $22.1 million as a result of the amendment to the Mann Group convertible note. See Note 6 — *Borrowings*.

Other income or expense consists primarily of the gain or loss associated with a foreign currency hedging transaction for the three and six months ended June 30, 2021 which is entered into to mitigate our exposure to foreign currency exchange risks associated with our insulin purchase obligation under the Insulin Supply Agreement. There was no hedging transaction for the same periods in the prior year.

Net Loss and Earnings Per Share (“EPS”)

The net loss for the three months ended June 30, 2021 was $35.5 million, or $0.14 per share, compared to a $10.3 million net loss in the prior year period, or $0.05 per share. The increased net loss of $25.3 million was primarily due to a non-cash loss on extinguishment of the Mann Group convertible note of $22.1 million as well as an increase in SG&A expenses and cost of revenue from collaboration and services, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services.

The net loss for the six months ended June 30, 2021 was $48.4 million, or $0.20 per share, compared to a $19.6 million net loss in the six months ended June 30, 2020, or $0.09 per share. The increased net loss of $28.9 million was primarily due to the non-cash loss on extinguishment of the Mann Group convertible note of $22.1 million as well as an increase in SG&A expenses, cost of revenue from collaboration and services, and loss on purchase commitments, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services.

Non-GAAP net loss, adjusted to exclude the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note was $13.4 million, or $0.05 per share, for the three months ended June 30, 2021 compared to $10.3 million, or $0.05 per share, for the prior

year period and $26.3 million, or $0.11 per share, for the six months ended June 30, 2021 compared to $19.6 million, or $0.09 per share, for the same period in the prior year. See the reconciliation to non-GAAP net loss and EPS under Non-GAAP Measures below.

Non-GAAP Measures

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

The following tables reconcile our financial measure for net loss and EPS as reported in our condensed consolidated statement of operations to a non-GAAP presentation as adjusted for the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note, which did not result in a change in our financial position.

	Three Months Ended June 30,			
(In thousands, except per share data)	**2021**	**2020**	**$ Change**	**% Change**
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (35,523)	$ (10,252)	$ 25,271	246%
Net loss per share - basic and diluted	$ (0.14)	$ (0.05)	$ 0.09	180%
Less non-cash loss on extinguishment of debt(1)	22,130	—	$ 22,130	*
Non-GAAP net loss	$ (13,393)	$ (10,252)	$ 3,141	31%
Non-GAAP net loss per share - basic and diluted	$ (0.05)	$ (0.05)	$ —	—%
Shares used to compute non-GAAP basic and diluted net loss per share	249,295	213,880	35,415	17%

	Six Months Ended June 30,			
	2021	**2020**	**$ Change**	**% Change**
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (48,439)	$ (19,574)	$ 28,865	147%
Net loss per share - basic and diluted	$ (0.20)	$ (0.09)	$ 0.11	122%
Less non-cash loss on extinguishment of debt(1)	22,130	—	$ 22,130	*
Non-GAAP net loss	$ (26,309)	$ (19,574)	$ 6,735	34%
Non-GAAP net loss per share - basic and diluted	$ (0.11)	$ (0.09)	$ 0.02	22%
Shares used to compute non-GAAP basic and diluted net loss per share	247,970	212,943	35,027	(16%)

* Not meaningful
(1) There is no provision for income taxes associated with the non-cash loss on extinguishment of debt as a result of our full valuation allowance.

The following tables reconcile our gross margin financial measure as reported in Management's Discussion and Analysis of Financial Condition and Results of Operations to a non-GAAP presentation as adjusted for the nonrecurring amendment fee related to an amendment to our Insulin Supply Agreement.

	Three Months Ended June 30,			
(In thousands)	**2021**	**2020**	**$ Change**	**% Change**
Net revenue — Afrezza	$ 9,976	$ 6,985	$ 2,991	43%
Less cost of goods sold	(4,411)	(3,677)	$ (734)	20%
GAAP gross profit — Afrezza	5,565	3,308	$ 2,257	68%
Exclude Amphastar amendment fee	2,000	—	$ 2,000	*
Non-GAAP gross profit — Afrezza	$ 7,565	$ 3,308	$ 4,257	129%
Non-GAAP gross margin	76%	47%		

	Six Months Ended June 30,			
	2021	2020	$ Change	% Change
Net revenue — Afrezza	$ 18,075	$ 14,985	$ 3,090	21%
Less cost of goods sold	(8,726)	(7,841)	$ 885	11%
GAAP gross profit — Afrezza	9,349	7,144	$ 2,205	31%
Exclude Amphastar amendment fee	2,000	—	$ 2,000	*
Non-GAAP gross profit — Afrezza	$ 11,349	$ 7,144	$ 4,205	59%
Non-GAAP gross margin	63%	48%		

* Not meaningful

LIQUIDITY AND CAPITAL RESOURCES

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 under certain loan arrangements and from sales of Afrezza.

As of June 30, 2021, we had $293.3 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.
- $18.4 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 either pay interest in-kind in cash or in shares.
- $4.9 million principal amount under a PPP loan, all of which was forgiven by the SBA subsequent to June 30, 2021.

In February 2021, we elected to convert the $5.0 million principal amount of 2024 convertible notes into 1,666,667 shares of our common stock in accordance with the terms of the 2024 convertible notes. 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 6 – *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 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. See Note 12 – *Commitments and Contingencies* and Note 6 – *Borrowings* for further information related to the Milestone Rights.

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.

During the six months ended June 30, 2020, we used $14.9 million of cash for our operating activities as a result of our net loss of $19.6 million, in addition to a net cash outflow from changes in balances of operating assets and liabilities of $5.3 million, partially offset by non-cash charges of $10.0 million. The change in operating asset and liabilities was primarily a result of deferred revenue amortization of $16.4 million, partially offset by a milestone payment from UT of $12.5 million.

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 provided by investing activities of $19.7 million for the six months ended June 30, 2020 was primarily due to the proceeds from the sale of treasury bills.

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.

Cash provided by financing activities of $28.5 million for the six months ended June 30, 2020 was primarily due to the receipt of $12.6 million in gross proceeds from at-the-market offerings for an aggregate of 7,871,461 shares of our common stock under the CF Sales Agreement, the exercise of outstanding warrants to purchase shares of our common stock of $11.6 million, and proceeds from the PPP Loan of $4.9 million.

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 Afrezza, and development costs for other product candidates in our pipeline. As of June 30, 2021, we had capital resources of $62.5 million in cash and cash equivalents, $100.0 million in short-term investments and $39.0 million in long-term investments, and we had an accumulated deficit of $3.1 billion and total principal amount of outstanding borrowings of $293.3 million.

In March 2021, we issued $230.0 million of Senior convertible notes. In April 2021, we made a $10.0 million principal prepayment against outstanding term loans under the MidCap credit facility and 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) as further disclosed in Note 6 – *Borrowings*. As amended, the MidCap credit facility provides a secured term loan facility with an aggregate principal amount of up to $100.0 million, of which $60.0 million remains available for borrowing if the conditions for Tranche 3 are met.

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

Off-Balance Sheet Arrangements

As of June 30, 2021 and December 31, 2020, we did not have any off-balance sheet arrangements.

Contractual Obligations

See Note 6 – *Borrowings* and Note 12 – *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. 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%, the interest rate under the PPP loan was fixed at 0.98%, and the interest rate under the Senior convertible notes is fixed at 2.50%. See Note 6 – *Borrowings* for information about the principal amount of outstanding debt.

Foreign Currency Exchange Risk

In April 2021, we entered into 90-day foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks associated with our insulin purchase obligation under the Insulin Supply Agreement. The hedging transaction hedges against short-term currency fluctuations for the remaining current year purchase obligation under the Insulin Supply Agreement of €2.0 million. We realized a *de minimis* currency gain during the three months ended June 30, 2021. This amount is recorded in other income and expense.

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, 2021, we realized a $0.9 million currency loss, which was included in loss (gain) on foreign currency translation in the 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, 2021 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $8.9 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, 2021. 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, 2021, 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

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, two motions were submitted to the district court at Tel Aviv, Economic Department for the certification of a class action against MannKind and certain of our officers and directors. In general, the complaints allege that MannKind and certain of our officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court ruled in October 2017 that U.S. law will apply to this case. The plaintiff appealed this ruling, and following an oral hearing before the Supreme Court of Israel, decided to withdraw his appeal. Subsequently, in November 2018, we filed a motion to dismiss the certification motion. In September 2019, the plaintiff brought a motion to amend his claim, which the court denied in January 2020. The plaintiff has appealed this denial to the Supreme Court of Israel, which issued a decision in July 2021 upholding the lower court decision. Subsequently, the plaintiff withdrew his complaint and the district court dismissed the motion to certify, bringing the litigation to an end.

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

- Our only approved product, Afrezza, may only achieve a limited degree of commercial success. The continued commercialization and development of Afrezza will require substantial capital that we may not be able to obtain.
- If we fail as an effective manufacturing organization, we may be unable to support commercialization of Afrezza or Tyvaso DPI.
- 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.
- If we do not obtain regulatory approval of Afrezza in foreign jurisdictions, we will not be able to market Afrezza 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 Afrezza outside of the United States.
- 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.
- Afrezza or our product candidates may be rendered obsolete by rapid technological change.

- Continued testing of Afrezza or our product candidates may not yield successful results, and even if it does, we may still be unable to commercialize our product candidates.
- 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 Afrezza or any other product that we develop does 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 Afrezza or any of our product candidates for which we receive regulatory approval, Afrezza or such product candidates might not be prescribed, used or purchased, which would adversely affect our revenues.
- 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.
- We are increasingly dependent on information technology systems, and infrastructure, which are vulnerable to service interruptions and attacks.

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

RISKS RELATED TO OUR COMMON STOCK

- We may not be able to generate sufficient cash to service all of our indebtedness. We may be forced to take other actions to satisfy our obligations under our indebtedness 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, or exercise of our outstanding warrants for, 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.

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

Our only approved product, Afrezza, may only achieve a limited degree of commercial success. The continued commercialization and development of Afrezza will require substantial capital that we may not be able to obtain.*

We have expended significant time, money and effort in the commercialization and development of Afrezza, which has been on the market since February 2015. To date, Afrezza sales have been modest by comparison to other mealtime insulins. If we remain on the existing growth curve, we may never generate significant revenues from Afrezza in the United States.

Successful commercialization of Afrezza 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 drug products, including by pharmaceutical companies with more experience and resources than us. We ultimately may be unable to gain widespread market acceptance of Afrezza for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, pricing and availability relative to alternative products and lack of coverage or adequate reimbursement by payers. We may need to enhance our commercialization capabilities in order to successfully commercialize Afrezza 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. 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. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of Afrezza and its proper administration, our efforts to successfully commercialize Afrezza could be put in jeopardy, which would negatively impact our ability to generate product revenues.

If we are unable to maintain payer coverage of, and adequate reimbursement for, Afrezza, physicians may limit how much or under what circumstances they will prescribe or administer Afrezza. As a result, patients may decline to purchase Afrezza, which would have an adverse effect on our ability to generate revenues.

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 expect to initiate 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, in the second half of 2021. 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 FDA has also required that we conduct a five-year, randomized, controlled trial in patients with type 2 diabetes, the primary objective of which is 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 endpoints and goals for this study. To date, we have not commenced a long-term safety study or budgeted any amount for it, but such a study would be anticipated to require substantial capital resources that we may not be able to obtain.

We are responsible for the NDA for Afrezza and its maintenance. We may fail to comply with maintenance requirements, including timely submitting required reports. Furthermore, we are responsible for the conduct of the remaining required post-approval trials of Afrezza. Our financial and other resource constraints may result in delays or adversely impact the reliability and completion of these trials.

If we fail to achieve better commercial success with Afrezza in the United States, our prospects for generating significant revenues from this product will be materially and adversely affected.

If we fail as an effective manufacturing organization, we may be unable to support commercialization of Afrezza or Tyvaso DPI.*

We use our Danbury, Connecticut facility to formulate both the Afrezza and Tyvaso DPI inhalation powders, fill plastic cartridges with the powders, package the cartridges in blister packs, and place the blister packs into foil pouches. A contract packager assembles the foil-pouched blister packs along with inhalers and package inserts into the final kits for commercial sale.

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, which is the stage of production that we have now reached with Tyvaso DPI. These problems include difficulties with production costs and yields and quality control and assurance. We may also experience shortages of qualified personnel, particularly at this time when we are seeking to fill a large number of open positions in our Danbury facility. 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 late July 2021 when the FDA conducted a pre-approval inspection related to Tyvaso DPI and a GMP inspection related to Afrezza. The onsite portion of these inspections concluded in early August. We expect the FDA to deliver a formal establishment inspection report in September. If the FDA makes any major observations related to such inspections or in its review of information submitted as part of the NDA, the approval and launch of Tyvaso DPI may be delayed.

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.

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

As of June 30, 2021, we had cash and cash equivalents of $62.5 million, short-term investments of $100.0 million and long-term investments of $39.0 million, and we had $293.3 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 Afrezza 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 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 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, 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 COVID-19 pandemic continues to have the potential for disruption of global financial markets. This 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 or upon the exercise of our currently outstanding warrants 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. Moreover, if we do not obtain such additional funds, there may be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to total loss of investment to our stockholders and other security holders. If we are or become insolvent, holders of our common stock or other securities may lose the entire value of their investment.

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.”

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.

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 could cause significant disruption 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 headquarters in California and at our manufacturing facility in Connecticut 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, including executive orders in California and Connecticut, and several other state and local orders across the country, which, among other things, directed individuals to shelter at their places of residence, directed schools, businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. In some places, these orders have been lifted whereas other locations, including Los Angeles County where our headquarters is located, continue to be subject to restrictions. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of restrictions will be imposed in the future, notwithstanding vaccination efforts. The effects of state and local stay-at-home orders and our own work-from-home policies may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. 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. Although we believe we have sufficient quantities of raw materials for planned manufacturing operations in 2021, 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 severity of the COVID-19 pandemic in Brazil has the potential to negatively impact the distribution of Afrezza by our partner in that country.

Sales and demand for Afrezza have been adversely affected by the global COVID-19 pandemic, and we expect that the COVID-19 pandemic will continue to negatively impact near-term revenues from Afrezza. Our sales representatives have not fully returned to conducting in-person office visits with healthcare providers, which impacts their productivity. Disruptions in the prescription volume of Afrezza 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 period 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 planned clinical trials of Afrezza and those of our partner for Tyvaso DPI 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.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. 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.

We are still in the midst of the COVID-19 pandemic. 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 Afrezza in foreign jurisdictions, we will not be able to market Afrezza 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 Afrezza 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. In order to market Afrezza 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 pharmaceutical 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 Afrezza, and we have not yet identified all of the requirements that we will need to satisfy to submit Afrezza 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 Afrezza in the United States.

Our current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary regulatory approvals, is to seek and establish 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 Afrezza. 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 Afrezza 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 sought to develop our product candidates through our internal research programs. Other than Tyvaso DPI, which UT submitted for regulatory approval in April 2021, all of our 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, our need to support the regulatory submission and launch preparations of Tyvaso DPI and our ongoing attention on the development and commercialization of Afrezza, 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 to 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, 2021, we had an accumulated deficit of $3.1 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, 2021, there was €74.8 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 Afrezza, 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, 2021, we had $293.3 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.
- $18.4 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 either pay interest in-kind in cash or in shares.
- $4.9 million principal amount under a PPP loan, all of which was forgiven by the SBA subsequent to June 30, 2021.

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 and is currently scheduled to be phased out in 2023. 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 consequences of these developments cannot entirely be predicted, but could result in higher interest rates on our loans 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.

Under the MidCap credit facility, we must comply with a minimum cash covenant of $10.0 million at all times and may be required to comply with additional covenants in the future under certain circumstances. Further, 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.

The restrictive covenants in the MidCap credit facility could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

We expect that the COVID-19 pandemic will continue to negatively impact near-term revenues from Afrezza, which could also affect our compliance with 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 or the minimum cash 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 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.

Afrezza or our product candidates may be rendered obsolete by rapid technological change.

The rapid rate of scientific discoveries and technological changes could result in Afrezza 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 Afrezza 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 and to improve Afrezza 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 Afrezza or our product candidates may not yield successful results, and even if it does, we may still be unable to 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.

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 the FDA's cGMP for drug products, and the production of the Afrezza inhaler and related cartridges in accordance with QSRs. 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 the production of Afrezza. 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 Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payers and the healthcare community, we may be unable to generate significant revenue, if any.

Afrezza, and other 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 Afrezza and other products that we may develop in the future 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 Afrezza or our other 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, Afrezza and any other product that we develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If third-party payers do not cover Afrezza or any of our product candidates for which we receive regulatory approval, Afrezza or such product candidates 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 Afrezza and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payers' drug formularies, which are the lists of medications 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 companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Even if favorable coverage and reimbursement status is attained for Afrezza or our product candidates for which we or our collaborators receive regulatory approval, 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 future marketing partner is unable to obtain and maintain coverage of, and adequate payment levels reimbursement for, Afrezza or any of our other product candidates that receive marketing approval from third-party payers, 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 and any future marketing partner’s ability to successfully commercialize Afrezza and our ability to successfully commercialize any of our other product candidates that receives regulatory approval and 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.

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 Afrezza 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 $10.0 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, particularly in the areas of manufacturing and sales and marketing. 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, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the "Tax Act"), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future 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, 2020, we had federal and state net operating loss carryforwards of $2.4 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 the Tax Act as modified by the CARES Act, 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. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), 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, 2020, 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, 2020. There is a risk that changes in ownership may occur in tax years after December 31, 2020. 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. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. 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 Danbury, Connecticut will be the sole location for the manufacturing of Afrezza and Tyvaso DPI. This facility and the manufacturing equipment we use 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, some of whom are located in other countries. 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), 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 Afrezza.

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. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. 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 the facilities located in Danbury, Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection, which is not completed. The responsible party will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. 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.

We are increasingly dependent on information technology systems and infrastructure, which are vulnerable to service interruptions and attacks.*

We are increasingly dependent upon information technology systems, infrastructure and data security. Our business requires manipulating, analyzing and storing large amounts of data. In addition, we rely on an enterprise software system to operate and manage our business. Our business therefore depends on the continuous, effective, reliable and secure operation of our computer hardware, software, networks, Internet servers and related infrastructure. The multitude and complexity of our computer systems and the potential value of our data make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data including intellectual property, trade secrets or personal information belonging to us or our customers or other business partners may be exposed to unauthorized persons or to the public. Our systems are also potentially subject to cyber-attacks, which can be highly sophisticated and may be difficult to detect. Such attacks are often carried out by motivated, well-resourced, skilled and persistent actors including nation states, organized crime groups and “hacktivists.” Cyber-attacks could include the deployment of harmful malware and key loggers, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our information technology systems, infrastructure and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security status. Additionally, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), terrorism, war and telecommunication and electrical failures may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information. While we continue to invest in the protection of our critical or sensitive data and information technology, there can be no assurance that our efforts will prevent or detect service interruptions or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us.

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 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, as well as the manufacturing and marketing of Afrezza and our product candidates, 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 and manufacturing and marketing of Afrezza and our product candidates 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 Afrezza 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 requirements, known as 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 potential 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 Afrezza and any approved drug 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, a third party has 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. 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 of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "PPACA") became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects 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 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. For example, the Tax Act included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA

marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. 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 Biden administration will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and, following passage of the BBA, will stay in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the "ATRA"), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, 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. 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services ("HHS"), finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of this rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the United States District Court of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the United States District Court for the Northern District of California and that performance for any final regulation stemming from the Most Favored Nation Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. 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 is taken in response to the COVID-19 pandemic. Such reforms may limit our ability to generate revenues from sales of Afrezza or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future marketing partner for Afrezza, and companies that are prospective collaborators for our product candidates, our ability to commercialize Afrezza and our product candidates under development 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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. 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 marketing partner fails to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security 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. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The 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 Health Insurance Portability and Accountability Act ("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 ("HITECH"), and their respective implementing regulations, which imposes 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. In addition, in May 2018, the European Union, or EU, adopted European General Data Protection Regulation, or GDPR, which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR;
- The California Consumer Privacy Act ("CCPA"), which created individual privacy rights for California consumers (as that word is broadly defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information;
- 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), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their

immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- 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 of 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, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from U.S. federal or state healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely 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 privacy, security and fraud laws may prove costly.

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 average manufacturer price ("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 Afrezza or any other products we may develop.

If other pharmaceutical companies announce that they observed frequent adverse events in their studies involving insulin therapies, we may be subject to class warnings in the label for Afrezza. In addition, the public perception of Afrezza might be adversely affected, 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, even if the concern relates to another company's products or product candidates.

There are also 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 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.

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. For example, various patents providing protection for the powder component of Afrezza have terms extending into 2026, 2028, 2029 or 2030. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 or 2032. Our method of treatment claims extends into 2026, 2029, 2030 or 2031. As and when these different patents expire, Afrezza 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 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 infringes any third-party patents, if a plaintiff was to allege that Afrezza infringed 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. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

Our ability to make scheduled payments on or to refinance our debt obligations will depend on our financial and operating performance, which is subject to the commercial success of Afrezza, 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 debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. 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 debt service 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 Afrezza outside of the United States and to find collaboration partners for the commercialization of Afrezza in foreign jurisdictions;
- future estimates of Afrezza sales, Tyvaso DPI royalties, prescriptions or other operating metrics;
- our ability to successfully commercialize other products (in addition to Afrezza) based on our Technosphere drug delivery platform;
- the progress of preclinical and clinical studies of our product candidates and of post-approval studies of Afrezza required by the FDA;
- the results of preclinical and clinical studies of our product candidates;
- general economic, political or stock market conditions, especially for emerging growth and pharmaceutical market sectors;
- 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 Afrezza, Tyvaso DPI or other 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 Afrezza, Tyvaso DPI, our other product candidates, 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 and our investigational products 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, or exercise of our outstanding warrants for, common stock could negatively affect the market price of our common stock and other securities.*

As of July 30, 2021, we had 249,660,178 shares of common stock outstanding. Substantially 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 upon issuance of our outstanding warrants, 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.

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

None.

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	Form of 5.75% Convertible Senior Subordinated Exchange Notes Due 2024 (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 August 7, 2019).
4.6	Indenture, dated as of August 6, 2019, by and between MannKind Corporation and U.S. Bank National Association (incorporated by reference to Exhibit 4.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.7	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).
4.8	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).
4.9	Promissory Note, dated April 9, 2020, by and between MannKind Corporation and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 15, 2020).
4.10	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).
4.11	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	Amendment No. 7 to Credit and Security Agreement, dated April 22, 2021, by and among MannKind Corporation, MannKind LLC, QrumPharma, Inc., and MidCap Financial Trust (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 26, 2021).
10.2	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).
10.3*	Sixth Amendment to Supply Agreement, dated May 24, 2021, by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 25, 2021).

Exhibit Number	Description of Document
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
32.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Inline Interactive Data Files pursuant to Rule 405 of Regulation S-T.
104	The cover page has been formatted in Inline XBRL.

* Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 11, 2021

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, 2021 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 11, 2021

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, 2021 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 11, 2021

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, 2021, 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 11th day of August, 2021.

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

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

Exhibit 32.2

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

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

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended June 30, 2021, 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 11th day of August, 2021.

/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.