UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2020

Or

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

For the transition period from ________ to ________.

Commission file number: 000-50865

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

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

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

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 October 26, 2020, there were 232,600,608 shares of the registrant's common stock, $0.01 par value per share, outstanding.

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended September 30, 2020

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MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except per share data)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,398	$ 29,906
Restricted cash	316	316
Short-term investments	—	19,978
Accounts receivable, net	4,135	3,513
Inventory	4,881	4,155
Prepaid expenses and other current assets	4,616	2,889
Total current assets	66,346	60,757
Property and equipment, net	25,736	26,778
Other assets	3,599	6,190
Total assets	$ 95,681	$ 93,725
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,797	$ 4,789
Accrued expenses and other current liabilities	15,814	15,904
Short-term notes payable	45,379	5,028
Deferred revenue — current	28,867	32,503
Recognized loss on purchase commitments — current	10,267	7,394
Total current liabilities	106,124	65,618
Promissory notes	70,025	70,020
Accrued interest — promissory notes	5,854	2,002
Long-term Midcap credit facility	—	38,851
Senior convertible notes	5,000	5,000
Paycheck Protection Program loan — long term	1,421	—
Recognized loss on purchase commitments — long term	84,529	84,639
Operating lease liability	1,523	2,514
Deferred revenue — long term	1,699	8,344
Milestone rights liability	5,926	7,263
Total liabilities	282,101	284,251
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value - 400,000,000 and 280,000,000 shares authorized, 230,922,513 and 211,787,573 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	2,309	2,118
Additional paid-in capital	2,834,003	2,799,278
Accumulated other comprehensive loss	—	(19)
Accumulated deficit	(3,022,732)	(2,991,903)
Total stockholders' deficit	(186,420)	(190,526)
Total liabilities and stockholders' deficit	$ 95,681	$ 93,725

See notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net revenue — commercial product sales	$ 7,275	$ 6,402	$ 22,260	$ 17,543
Revenue — collaborations and services	8,077	8,193	24,441	29,502
Total revenues	15,352	14,595	46,701	47,045
Expenses:				
Cost of goods sold	3,591	7,099	11,432	15,446
Cost of revenue — collaborations and services	1,581	1,836	6,926	5,512
Research and development	1,484	1,580	4,703	4,879
Selling, general and administrative	13,899	16,666	41,919	58,948
Asset impairment	—	—	1,889	—
Loss (gain) on foreign currency translation	3,927	(3,807)	3,998	(4,495)
Total expenses	24,482	23,374	70,867	80,290
Loss from operations	(9,130)	(8,779)	(24,166)	(33,245)
Other (expense) income:				
Interest income	18	220	165	794
Interest expense on notes	(1,057)	(4,126)	(3,212)	(5,283)
Interest expense on promissory notes	(1,318)	(1,162)	(3,858)	(3,351)
Gain on extinguishment of debt	—	3,529	—	3,529
Other income (expense)	14	(52)	24	(84)
Total other expense	(2,343)	(1,591)	(6,881)	(4,395)
Loss before provision for income taxes	(11,473)	(10,370)	(31,047)	(37,640)
Benefit for income taxes	218	—	218	—
Net loss	$ (11,255)	$ (10,370)	$ (30,829)	$ (37,640)
Net loss per share - basic and diluted	$ (0.05)	$ (0.05)	$ (0.14)	$ (0.20)
Shares used to compute basic and diluted net loss per share	229,668	199,906	218,559	191,786

See notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Net loss	$ (11,255)	$ (10,370)	$ (30,829)	$ (37,640)
Other comprehensive loss:				
Cumulative translation loss	—	(1)	(19)	(1)
Comprehensive loss	$ (11,255)	$ (10,371)	$ (30,848)	$ (37,641)

See notes to condensed consolidated financial statements.

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

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
BALANCE, JANUARY 1, 2019	187,030	$ 1,870	$ 2,763,067	$ (19)	$ (2,940,000)	$ (175,082)
Net issuance of common stock associated with stock options and restricted stock units	66	1	1	—	—	2
Issuance of common stock under Employee Stock Purchase Plan	296	3	314	—	—	317
Stock-based compensation expense	—	—	999	—	—	999
Issuance of common stock pursuant to conversion of Senior Convertible Notes	386	4	534	—	—	538
Restricted stock unit award	—	—	105	—	—	105
Net loss	—	—	—	—	(14,883)	(14,883)
BALANCE, MARCH 31, 2019	187,778	$ 1,878	$ 2,765,020	$ (19)	$ (2,954,883)	$ (188,004)
Net issuance of common stock associated with stock options and restricted stock units	101	1	14	—	—	15
Stock-based compensation expense	—	—	2,568	—	—	2,568
Issuance of common stock in at the market offering	1,568	15	1,835	—	—	1,850
Issuance costs associated with at the market offering	—	—	(41)	—	—	(41)
Net loss	—	—	—	—	(12,387)	(12,387)
BALANCE, JUNE 30, 2019	189,447	$ 1,894	$ 2,769,396	$ (19)	$ (2,967,270)	$ (195,999)
Net issuance of common stock associated with stock options and restricted stock units	576	6	25	—	—	31
Issuance of common stock under Employee Stock Purchase Plan	356	4	335	—	—	339
Stock-based compensation expense	—	—	1,640	—	—	1,640
Issuance of common stock pursuant to conversion of Senior Convertible Notes	4,525	45	4,992	—	—	5,037
Issuance of common stock pursuant to conversion of Facility Financing Obligation	4,193	42	4,533	—	—	4,575
Issuance of common stock pursuant to conversion of Promissory Notes	7,143	71	7,929	—	—	8,000
Issuance of common stock in at-the-market offering	168	2	186	—	—	188
Issuance of warrants pursuant to Credit facility	—	—	1,854	—	—	1,854
Cumulative translation loss	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(10,370)	(10,370)
BALANCE, SEPTEMBER 30, 2019	206,408	$ 2,064	$ 2,790,890	$ (20)	$ (2,977,640)	$ (184,706)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated 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)
Stock-based compensation expense	—	—	1,294	—	—	1,294
Issuance of common stock associated with debt interest payment	89	1	143	—	—	144
Net issuance of common stock associated with stock options and restricted stock units	82	1	100	—	—	101
Issuance of common stock in at the market offering	1,531	15	2,664	—	—	2,679
Issuance cost associated with at the market offering	—	—	(39)	—	—	(39)
Issuance of common stock under Employee Stock Purchase Plan	293	3	363	—	—	366
Net loss	—	—	—	—	(11,255)	(11,255)
BALANCE, SEPTEMBER 30, 2020	230,923	$ 2,309	$ 2,834,003	$ —	$ (3,022,732)	$ (186,420)

See notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (30,829)	$ (37,640)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest expense on promissory notes	3,852	3,517
Stock-based compensation expense	4,607	5,312
Asset impairment	1,889	—
Depreciation, amortization and accretion	1,639	407
Amortization of right-of-use assets	879	903
Write-off of inventory	496	—
Loss (gain) on foreign currency translation	3,998	(4,495)
Payment-in-kind interest on promissory notes	—	(32,822)
Gain on extinguishment of debt	—	(3,529)
Other, net	19	103
Changes in operating assets and liabilities:		
Accounts receivable, net	(622)	(76)
Inventory	(1,222)	(95)
Prepaid expenses and other current assets	(1,306)	(1,028)
Other assets	191	(356)
Accounts payable	1,008	6,282
Accrued expenses and other current liabilities	641	(134)
Deferred revenue	(10,281)	(12,721)
Operating lease liabilities	(2,087)	(1,064)
Recognized loss on purchase commitments	(1,235)	(4,395)
Accrued interest on promissory notes	—	(1,545)
Net cash used in operating activities	(28,363)	(83,376)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of treasury bills	20,000	24,995
Purchase of property and equipment	(304)	(2,456)
Purchase of treasury bills	—	(44,880)
Purchase of limited liability company ownership interest	—	(300)
Net cash provided by (used in) investing activities	19,696	(22,641)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from at the market offering	15,139	2,042
Issuance costs associated with at the market offering	(368)	(47)
Issuance of common stock from the exercise of warrants	11,600	—
Proceeds from Paycheck Protection Program loan	4,873	—
Payment of employment taxes related to vested restricted stock units and exercise of stock options	(99)	50
Proceeds from market price stock purchase plan	14	—
Proceeds from promissory notes	—	70,051
Proceeds from MidCap Credit Facility	—	40,000
Proceeds from senior convertible notes	—	9,910
Principal payments on promissory notes	—	(38,264)
Principal payments on senior convertible notes	—	(11,081)
Principal payments on facility financing obligation	—	(6,920)
Issuance cost associated with MidCap Credit Facility	—	(886)
Issuance cost associated with promissory notes	—	(33)
Net cash provided by (used in) financing activities	31,159	64,822
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	22,492	(41,195)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	30,222	71,684
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 52,714	$ 30,489
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	$ 2,861	$ —
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Payment of principal on senior convertible notes through common stock issuance	2,630	4,500
Receivable from at the market offering	574	—
Common stock issuance to settle employee stock purchase plan liability	684	656
Payment of interest on senior convertible notes through common stock issuance	288	1,075
Payment on promissory notes through issuance of common stock	—	8,000
Addition of right-of-use assets upon adoption of new lease guidance	—	5,192
Payment of facility obligation through common stock issuance	—	4,575
Non-cash construction in progress and property and equipment	—	203

See notes to condensed consolidated financial statements.

1. Description of Business and Significant Accounting Policies

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiary (“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, 2019 filed with the SEC on February 25, 2020 (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 nine months ended September 30, 2020 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 accompanying 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 — The Company is a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for diabetes and orphan lung diseases, such as pulmonary arterial hypertension. The Company’s only approved product, Afrezza (insulin human) Inhalation Powder, is an ultra rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the “FDA”) in June 2014 to improve glycemic control in adults with diabetes. Afrezza became available by prescription in United States retail pharmacies in February 2015. Currently, the Company promotes Afrezza to endocrinologists and certain high-prescribing primary care physicians in the United States through its specialty sales force.

The Company’s partner in Brazil, Biomm S.A. (“Biomm”), commenced commercialization of Afrezza in January 2020. The Company’s partners in India and Australia are preparing for regulatory submissions and have not yet commenced commercialization in their respective territories.

Basis of Presentation — The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

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 costs for product candidates in the Company’s pipeline. As of September 30, 2020, the Company had an accumulated deficit of $3.0 billion and $122.6 million of total principal amount of outstanding borrowings, with limited capital resources of $52.4 million in cash and cash equivalents. These financial conditions raise substantial doubt about the Company’s ability to continue as a going concern.

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”) to restructure its existing debts and to provide additional operating capital (the “recapitalization”) (Refer to Note 6 – *Borrowings* for further details). The MidCap Credit Facility provides a secured term loan facility with an aggregate principal amount of up to $65.0 million, of which $40.0 million was outstanding as of September 30, 2020 and December 31, 2019. The availability of the remaining $25.0 million will be available to the Company until June 30, 2021, subject to the satisfaction of certain milestone conditions associated with Afrezza net revenue and certain milestone conditions related to the Company’s collaboration with United Therapeutics (see Note 7 – *Collaboration and Licensing Arrangements* for more information on the collaboration agreement with United Therapeutics).

Principal payments on the MidCap Credit Facility begin in September 2021. In addition, the MidCap Credit Facility contains certain covenants, one of which includes a requirement to maintain a minimum of $15.0 million of unrestricted cash and cash equivalents at all times. This amount will increase to $20.0 million if the Company draws additional funding under the MidCap Credit Facility.

In August 2020, the Company entered into an 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. After the November 30, 2020 reporting period, the amendment will expire and a breach of the minimum Afrezza net revenue covenant is probable. The Company intends to amend the MidCap Credit Facility to address this probable covenant violation; however, such amendment, if completed, would occur after the date of this report. Accordingly, the $40.0 million outstanding principal under the MidCap Credit Facility was classified as current debt in the September 30, 2020 balance sheet, even though the 36 equal monthly principal payments remain payable over the period of September 1, 2021 through August 1, 2024. This debt will continue to be classified as current unless the MidCap Credit Facility is further amended or the debt is repaid.

The Company's capital resources may not be sufficient to continue to meet its current and anticipated obligations over the next twelve months if the Company cannot increase its operating cash inflows by growing revenue or obtaining access to the remaining $25.0 million in borrowings that may become available under its MidCap Credit Facility. In the event these capital resources are not sufficient, the Company may need to raise additional capital by selling equity or debt securities, entering into strategic business collaboration agreements with other companies, seeking other funding facilities, or licensing arrangements, selling assets or by other means. However, the Company cannot provide assurances that additional capital will be available on acceptable terms or at all.

If the Company is unable to meet its current and anticipated obligations over the next twelve months through its existing capital resources, or obtain new sources of capital when needed, the Company may have to reduce the scope of its commercial operations, reduce or eliminate one or more of its development programs, or make significant changes to its operating plan. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Principles of Consolidation — The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. Intercompany balances and transactions have been eliminated. 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. Changes were made to the condensed consolidated statements of stockholder's deficit as of September 30, 2019, June 30, 2019 and March 31, 2019 to combine the exercise of stock options and the issuance of common stock from the release of restricted stock units ("RSUs"). Changes were also made to Note 10 — Stock-Based Compensation Expense to separately disclose the stock-based compensation expense related to the employee stock purchase plan from the expense for RSUs and options for the three and nine months ended September 30, 2019.

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 adopted Accounting Standards Codification ("ASC") Topic 606 - *Revenue from Contracts with Customers* ("the new revenue guidance"), on January 1, 2018. Under Topic 606, 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 Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under 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 payors 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 for variable consideration, including discounts and allowances.

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, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payors, 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 September 30, 2020 and, therefore, the transaction price was not reduced further during the three and nine months ended September 30, 2020. 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.

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 judgement 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.

Payor Rebates — The Company contracts with certain private payor 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.

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 payors. 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 or research agreements under which the Company licenses certain rights to its product candidates to third parties or conducting research 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 and Licensing 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 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 and provides research and development services, 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 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.

Paycheck Protection Program 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 ("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 Accounting Standards Codification ("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 short-term notes payable and PPP Loan — long term. In addition, a *di minimis* amount of accrued interest is included in accrued expenses and other current liabilities. 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 annual revaluation of inventory to standard costs, 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 (see Note 11 – *Commitments and Contingencies*). 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 September 30, 2020 and December 31, 2019, 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. Restricted cash amounts that will not be available for use in the Company's operations within 12 months of the reporting date are presented as restricted cash in long-term assets.

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 52,398	$ 29,906
Restricted cash	316	316
Total cash, cash equivalents, and restricted cash	$ 52,714	$ 30,222

Short-term Investments —The Company's short-term investments consist of U.S. Treasury securities stated at amortized cost that the Company intends to hold until maturity. Those with maturities less than 12 months are included in short-term investments and any investments with maturities in excess of twelve months are included in long-term investments in our condensed consolidated balance sheets. As of September 30, 2020, the Company did not hold any short-term or long-term investments nor did it record any material gains or losses on investment securities during the three and nine months ended September 30, 2020.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and short-term investments. Cash and cash equivalents are held in high credit quality institutions. Cash equivalents consist of interest-bearing money market accounts and U.S. Treasury securities, which 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 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 second quarter of 2020 and is reflected in the Company's condensed consolidated statement 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 statement of operations. The liability balance of the recognized loss on insulin purchase commitments was $94.8 million and $92.0 million as of September 30, 2020 and December 31, 2019, respectively. No new contracts were identified in the first nine months of 2020 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 $70.0 million remains payable as of September 30, 2020 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*). As of September 30, 2020 and December 31, 2019, the remaining liability balance was $7.3 million.

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.

Income tax positions are considered for uncertainty. The Company 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 liabilities for uncertain income tax positions have been recorded. If a tax position does not meet the minimum statutory threshold to avoid payment of penalties, the Company recognizes an expense for the amount of the penalty in the period the tax position is claimed in the tax return of the Company. The Company recognizes interest accrued related to unrecognized tax benefits in income tax expense, if any. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense.

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 option awards ("PNQ"), 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. The Company evaluates stock awards with performance conditions as to 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 accompanying condensed consolidated statements of operations, result from obligations under contracts with vendors, consultants and clinical site agreements in connection with conducting clinical trials.

Net Income (Loss) Per Share of Common Stock — Basic net income or loss per share excludes dilution for potentially dilutive securities and is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period. Diluted net income or loss per share reflects the potential dilution under the treasury method that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be anti-dilutive.

The computation of basic and diluted net loss per share for the three and nine months ended September 30, 2020 and 2019 excludes the common stock equivalents of the following potentially dilutive securities because their inclusion would be anti-dilutive while the Company is in a net loss position:

	Nine Months Ended September 30,	
	2020	2019
RSUs and Market RSUs (1)	8,897,020	1,122,283
Employee stock purchase plan	107,003	147,675
Common stock options and PNQs	12,689,522	15,361,337
2024 convertible notes	1,666,667	1,666,667
Mann Group convertible note	14,000,000	14,000,000
Common stock warrants	31,856	31,856
Warrants associated with Midcap Credit Facility	1,171,614	1,171,614
Warrants associated with public offering	—	23,333,333
Total shares	38,563,682	56,834,765

(1) Market RSUs are included at the maximum share delivery percentage (see Note 10 — Stock-Based Compensation Expense).

Recently Adopted Accounting Standards — In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, The Company adopted this standard as of January 1, 2020. This update introduces the current expected credit loss (CECL) model, which requires an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects the entity's current estimate of credit losses expected to be incurred over the life of the financial instrument. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808)* to clarify when transactions between participants in a collaborative arrangement under ASC 808 are within the scope of the new revenue guidance when the collaborative arrangement participant is a customer. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2021. The Company adopted this pronouncement in 2020 with no impact on the 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.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)* to simplify and reduce the cost of accounting for income taxes. The pronouncement calls for removing exceptions to the incremental approach for intraperiod tax allocations, exceptions to the requirement to recognize a deferred tax liability for equity method investment when a foreign subsidiary becomes an equity method investment, exception to the ability to not recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary and exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. We are currently assessing the effect the adoption of this standard will have on the Company's consolidated financial statements.

2. Accounts Receivable

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

	September 30, 2020	December 31, 2019
Accounts receivable, gross	$ 7,424	$ 6,925
Wholesaler distribution fees and prompt pay discounts	(1,231)	(1,767)
Reserve for returns	(2,058)	(1,645)
Accounts receivable, net	$ 4,135	$ 3,513

As of September 30, 2020 and December 31, 2019, the allowance for doubtful accounts was *de minimis*. The Company had three wholesale distributors representing approximately 87% of accounts receivable as of September 30, 2020 and approximately 83% and 87% of gross sales for the three and nine months ended September 30, 2020, respectively.

3. Inventories

Inventories consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ 1,458	$ 1,751
Work-in-process	1,827	1,432
Finished goods	1,596	972
Total inventory	$ 4,881	$ 4,155

Work-in-process and finished goods as of September 30, 2020 and December 31, 2019 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 September 30, 2020 and December 31, 2019, 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 2022, after which the pre-launch raw materials inventory will be reclassified as raw materials inventory for use in the manufacturing of Afrezza.

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 accompanying condensed consolidated statements of operations. For the nine months ended September 30, 2020 there was an inventory write-off of $0.5 million as a result of this assessment. There were no inventory write-offs for the three months ended September 30, 2020 or the three and nine months ended September 30, 2019.

4. Property and Equipment

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

	Estimated Useful Life (Years)	September 30, 2020	December 31, 2019
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	37,543	37,543
Machinery and equipment	3-15	55,165	54,982
Furniture, fixtures and office equipment	5-10	3,005	3,005
Computer equipment and software	3	8,319	8,234
Construction in progress	—	63	114
		122,359	122,142
Less accumulated depreciation		(96,623)	(95,364)
Total property and equipment, net		$ 25,736	$ 26,778

Depreciation expense related to property and equipment for the three and nine months ended September 30, 2020 and 2019 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Depreciation Expense	$ 455	$ 396	$ 1,346	$ 1,135

5. Accrued Expenses and Other Current Liabilities

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

	September 30, 2020	December 31, 2019
Salary and related expenses	$ 7,745	$ 8,835
Discounts and allowances for commercial product sales	3,491	3,162
Deferred lease liability	1,421	1,433
Milestone Rights liability — current	1,337	—
Professional fees	329	620
Sales and marketing services	345	147
Accrued interest	350	409
Other	796	1,298
Total accrued expenses and other current liabilities	$ 15,814	$ 15,904

Included in salary and related expenses is $0.6 million of deferred social security taxes as permitted under the CARES Act. The Company is permitted to defer the employer share of social security taxes otherwise owed on dates beginning March 27, 2020 and ending December 31, 2020. Half of the total deferred payments are payable on December 31, 2021 and the remaining half are payable on December 31, 2022. The amount of the deferral is based on wages paid from April through December 2020. This deferral option is no longer available if the Company receives forgiveness for its PPP Loan as discussed in Note 6 — Borrowings.

6. Borrowings

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

	September 30, 2020	December 31, 2019
Mann Group promissory notes	$ 70,025	$ 70,020
Midcap Credit Facility	39,346	38,851
Senior notes (December 2020 note and 2024 convertible notes)	7,581	10,028
PPP Loan	4,873	—
Total debt — net carrying amount	121,825	118,899
Less current portion of long-term debt	(45,379)	(5,028)
Long-term debt	$ 76,446	$ 113,871

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

	Amount Due		Terms		
	September 30, 2020	December 31, 2019	Annual Interest Rate	Maturity Date	Conversion Price
Mann Group convertible note	$35.0 million (plus $2.9 million accrued interest paid-in-kind)	$35.0 million (plus $1.0 million accrued interest paid-in-kind)	7.00%	November 2024	$2.50 per share
Mann Group non-convertible note	$35.1 million (plus $2.9 million accrued interest paid-in-kind)	$35.1 million (plus $1.0 million accrued interest paid-in-kind)	7.00%	November 2024	N/A
MidCap Credit Facility	$40.0 million	$40.0 million	one-month LIBOR (2% floor) plus 6.75%	August 2024	N/A
2024 convertible notes	$5.0 million	$5.0 million	5.75%	November 2024	$3.00 per share
June 2020 note	—	$2.6 million	—	June 2020	N/A
December 2020 note	$2.6 million	$2.6 million	—	December 2020	N/A
PPP Loan	$4.9 million	—	0.98%	April 2022	N/A

The maturities of our borrowings as of September 30, 2020 are as follows (in thousands):

	Amounts
2020	$ 4,254
2021	6,881
2022	14,146
2023	13,333
2024	83,940
Thereafter	—
Total principal payments	122,554
Unamortized discount	(306)
Unamortized debt issuance costs	(423)
Total debt — net carrying amount	$ 121,825

Current Portion of Long-Term Debt — As of September 30, 2020, the current portion of long-term debt was $45.4 million and consisted of $40.0 million of the MidCap Credit Facility, $3.5 million of the PPP Loan and $2.6 million of the December 2020 note.

MidCap Credit Facility — In August 2019, the Company closed the MidCap Credit Facility, which provides a secured term loan facility with an aggregate principal amount of up to $75.0 million. The Company borrowed the first advance of $40.0 million ("Tranche 1") on August 6, 2019. Under the terms of the MidCap Credit Facility, the second advance of $10.0 million ("Tranche 2") was available to the Company until April 15, 2020, provided that the Company had achieved Afrezza net revenue of at least $30.0 million on a trailing twelve month basis by that date (which was not achieved). The third advance of $25.0 million ("Tranche 3") will be available to the Company until June 30, 2021, subject to the satisfaction of certain milestone conditions associated with Afrezza trailing net revenue and certain milestone conditions related to the Company's collaboration with United Therapeutics (see Note 7 – *Collaboration and Licensing Arrangements*). In August 2019, the Company recognized 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. The Company determined that such milestone conditions related to Afrezza trailing net revenue were unlikely to be achieved. As a result, the Company recognized an asset impairment of $1.9 million during the second quarter of 2020.

In December 2019, the Company entered into an 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 of $25.0 million 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 an 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. After the November 30, 2020 reporting period, the amendment will expire and a breach of the minimum Afrezza net revenue covenant is probable. The Company intends to amend the MidCap Credit Facility to address this probable covenant violation; however, such amendment, if completed, would occur after the date of this report. Accordingly, the $40.0 million outstanding principal under the MidCap Credit Facility was classified as current debt in the September 30, 2020 balance sheet, even though the 36 equal monthly principal payments remain payable over the period of September 1, 2021 through August 1, 2024. This debt will continue to be classified as current unless the MidCap Credit Facility is further amended or the debt is repaid.

Tranche 1 and, if borrowed, Tranche 3, each accrue interest at an annual rate equal to one-month LIBOR plus 6.75%, subject to a one-month LIBOR floor of 2.00%. Interest on each term loan advance is due and payable monthly in arrears. Principal on the term loan advance under Tranche 1 is payable in 36 equal monthly installments beginning September 1, 2021, until paid in full on August 1, 2024, and principal on any term loan advance under Tranche 3 is payable beginning on the later of (i) September 1, 2021, and (ii) the first day of the first full calendar month immediately following such term loan advance, in an amount equal to the outstanding term loan advance in respect of Tranche 3 divided by the number of full calendar months remaining before August 1, 2024. The Company has the option to prepay the 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 the first anniversary of the closing date, 2.00% of principal prepaid if prepayment occurs after the first anniversary of the closing date but on or prior to the second anniversary of the closing date, and 1.00% of principal prepaid if prepayment occurs after the second anniversary of the closing date and prior to or on the third anniversary of the closing date. In connection with execution of the MidCap Credit Facility, the Company paid MidCap a $0.4 million origination fee.

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 contains customary affirmative covenants and customary negative covenants limiting the Company's ability and the ability of the Company's subsidiary 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, and a minimum cash covenant of $15.0 million at all times, and $20.0 million at all times following the funding of Tranche 3. For any trailing twelve-month reporting period between July 31, 2020 and November 30, 2020, the minimum Afrezza net revenue test will be deemed to occur if the Company delivers satisfactory evidence that it had unrestricted cash of at least $40.0 million. As of September 30, 2020, 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 each term loan advance under the MidCap Credit Facility 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. 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.

Senior Notes — As of September 30, 2020 and December 31, 2019, there was $7.6 million and $10.2 million, respectively, of principal amount of senior notes outstanding.

In August 2019, the Company entered into a privately-negotiated exchange agreement with the holder of the 5.75% Convertible Senior Subordinated Exchange Notes due 2021 (the "2021 notes"), pursuant to which, among other things, the Company (i) repaid $1.5 million in cash to such holder, (ii) issued 4,017,857 shares of the Company's common stock to such holder (at a conversion price of $1.12 per share), (iii) issued 5.75% Convertible Senior Subordinated Exchange Notes due November 2024 (the "2024 convertible notes") to such holder in the principal amount of $5.0 million and (iv) issued a $2.6 million note due June 2020 (the "June 2020 note"), a $2.6 million note due December 2020 (the "December 2020 note", and together with the June 2020 note, the "2020 notes"), all in exchange for the cancellation of the $18.7 million in principal amount of the 2021 notes. The 2020 notes may be prepaid at any time on or prior to their respective maturity dates of June 30, 2020 and December 31, 2020 at the option of the Company. On June 24, 2020, the Company prepaid the June 2020 note with the issuance of 1,235,094 shares of the Company's common stock, pursuant to the Company's election and in accordance with the terms of the June 2020 note. On October 9, 2020, the Company prepaid the December 2020 note with the issuance of 1,377,356 shares of the Company's common stock, pursuant to the Company's election and in accordance with the terms of the December 2020 note. The number of shares issued for the prepayments on June 24, 2020 and October 9, 2020 were determined based on the Company's closing stock price on the settlement date. As a result of the prepayment of the December 2020 note on October 9, 2020, the Company recognized a *de minimis* amount of loss on extinguishment related to unamortized debt discount.

The 2024 convertible notes were issued pursuant to an indenture, dated as of August 6, 2019, between the Company and U.S. Bank National Association, as trustee (the "Indenture"). The 2024 convertible notes are the Company's general, unsecured obligations, and are subordinated in right of payment to the indebtedness incurred pursuant to the MidCap Credit Facility. The 2024 convertible notes rank equally in right of payment with the Company's other unsecured senior debt. The 2024 convertible notes accrue 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 will be 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 will mature on the earlier of (i) November 4, 2024 or (ii) the 91st day after the payment in full of, and termination and discharge of all obligations (other than contingent indemnity obligations) under the MidCap Credit Facility.

The 2024 convertible notes are 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.

If certain bankruptcy and insolvency-related events of default occur, the principal of, and accrued and unpaid interest on, all of the then outstanding 2024 convertible notes shall automatically become due and payable. If an event of default other than certain bankruptcy and insolvency-related events of defaults occurs and is continuing, the Trustee or the holders of at least 25% in aggregate principal amount of the then-outstanding 2024 convertible notes, by written notice to the Trustee, may declare the 2024 convertible notes due and payable at their principal amount plus any accrued and unpaid interest, and thereupon the Trustee may, at its discretion, proceed to protect and enforce the rights of the holders by the appropriate judicial proceedings. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company 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 180 days after such event of default, consist exclusively of the right to receive additional interest on the 2024 convertible notes. The 2024 convertible notes also contain certain cross default provisions related to other debt obligations.

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2024 convertible notes will have the option to require the Company to repurchase all or any portion of that holder's 2024 convertible notes. The fundamental change repurchase price will be 100% of the principal amount of the 2024 convertible notes to be repurchased plus accrued and unpaid interest, if any.

The Company may elect at its option to cause all or any portion of the 2024 convertible notes to be mandatorily converted in whole or in part at any time prior to the close of business on the business day immediately preceding the maturity date, if the last reported sale price of its common stock equals or exceeds 120% of the conversion price then in effect for at least 10 trading days in any 20 trading day period, ending within five business days prior to the date of the mandatory conversion notice.

Mann Group promissory notes — In August 2019, the Company entered into a privately-negotiated exchange agreement with The Mann Group LLC (the "Mann Group"), pursuant to which, among other things, the Company (i) repaid $3.0 million in cash to the Mann Group, (ii) issued 7,142,857 shares of the Company's common stock to the Mann Group (at a conversion price of $1.12 per share), (iii) 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 (iv) issued a non-convertible note to the 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"), all in exchange for the cancellation of the $71.5 million in principal and approximately $9.5 million in accrued interest paid-in-kind under the existing Mann Group loan arrangement.

The Mann Group promissory notes each accrue 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.

The Mann Group convertible note will mature on November 3, 2024. The principal and any accrued and unpaid interest under the Mann Group convertible note may be converted, at the option of the 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 Mann Group 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.

The Mann Group non-convertible note will mature on the earlier of (i) November 3, 2024 or (ii) the 90th day after the repayment in full, and termination and discharge of all obligations (other than contingent indemnity obligations) under the MidCap Credit Facility. Interest on the Mann Group non-convertible note will be payable in kind by adding the amount thereof to the principal amount; provided that MannKind may, at its option, elect to pay any such interest on any interest payment date, if certain conditions are met, in shares of MannKind's common stock at a price per shall equal to the last reported sale price on the trading day immediately prior to the interest payment date.

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. The PPP Loan matures on April 9, 2022 and bears interest at a rate of 0.98% per annum. The PPP Loan is evidenced by a promissory note dated April 9, 2020, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties. All or a portion of the PPP Loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application to the lender by the Company beginning 60 days after loan approval, but not later than ten months after the end of the Company's covered period, and upon documentation of expenditures in accordance with the SBA requirements. Principal and interest payments can be deferred up to ten months after the end of the Company's covered period unless the Company is notified earlier of its loan forgiveness status. In the event the SBA does not authorize loan forgiveness, the deferred principal and interest will be payable to the lender and the Company will then make equal monthly payments as required to fully amortize the remaining principal amount by April 9, 2022.

Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered interest and covered utilities during the 24-week period (or eight-week period at the Company's option) beginning on the date of loan approval. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of $100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. In the event the PPP Loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal. Any unforgiven portion of the PPP Loan will be payable in accordance with the terms of the promissory note as described above.

The Company used all proceeds from the PPP Loan to retain employees, maintain payroll and make lease, interest and utility payments.

Amortization of the premium and accretion of debt issuance costs related to all borrowings for the three and nine months ended September 30, 2020 and 2019 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Accretion of debt discount	$ 53	$ 8	$ 232	$ 149
Amortization of debt issuance cost	(27)	(34)	(82)	(84)
Amortization of debt premium	—	(858)	—	(1,049)

Milestone Rights — As of September 30, 2020 and December 31, 2019, the remaining Milestone Rights liability balance was $7.3 million, which was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. During the third quarter of 2019, the Company achieved the first Afrezza net sales milestone specified by the Milestone Rights. The Company currently estimates that it will reach the next milestone in the first quarter of 2021, at which point the Company will be required to make a $5.0 million payment in the following quarter. The carrying value of the Milestone Rights liability related to this $5.0 million payment is approximately $1.3 million, which represents the fair value related to this payment that was determined in 2013 (the most recent measurement date). Accordingly, approximately $1.3 million in value related to the next milestone payment was recorded in accrued expenses and other current liabilities and the remaining long-term portion of $5.9 million is included as Milestone Rights liability in the accompanying condensed consolidated balance sheets as of September 30, 2020.

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. The Company has initially recorded the Milestone Rights at their estimated fair value.

7. Collaboration and Licensing Arrangements

Revenue from collaborations and services for the three and nine months ended September 30, 2020 and 2019 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
UT License Agreement	$ 7,978	$ 7,861	$ 23,934	$ 23,255
UT Research Agreement	—	158	211	5,874
Receptor CLA	63	62	188	187
Cipla License and Distribution Agreement	36	37	108	111
Biomm Distribution Agreement	—	75	—	75
Total revenue from collaborations and services	$ 8,077	$ 8,193	$ 24,441	$ 29,502

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 ("TreT") and associated inhalation delivery devices. Under the UT License Agreement, UT is responsible for global development, regulatory and commercial activities with respect to TreT. The Company is responsible for manufacturing clinical supplies and commercial supplies of TreT.

Under the terms of the UT License Agreement, the Company received an upfront payment of $45.0 million in October 2018 and three $12.5 million milestone payments through the third quarter of 2020. The Company expects to receive an additional milestone payment of $12.5 million upon the achievement of specified development targets. The Company will also be entitled to receive low double-digit royalties on net sales of TreT. 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. During the third quarter of 2020, the Company sold $0.4 million of clinical supplies to UT for use in their clinical study, which was recognized as deferred revenue in the accompanying condensed consolidated balance sheet. The Company recognizes revenue on a ratable basis from October 2018 through December 2021; the estimated date when its performance obligations for development activities under UT License Agreement will be substantially completed.

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 expects to complete the activities specified in the development plan and to achieve the remaining milestone event for total consideration of approximately $102.6 million, which includes an upfront payment, four milestone payments, various pass-through costs and payments for clinical supplies. Future commercial supply remains at UT's option and is valued at a stand-alone selling price and, therefore, is not accounted for under the current arrangement. The Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation. Deferred revenue related to the UT License Agreement is being recognized in net revenue — collaborations over a 13-quarter period ending December 31, 2021, which represents the estimated period to satisfy the performance obligation. As of September 30, 2020, the deferred revenue for the UT License Agreement consisted of $28.7 million, which was classified as current. Deferred revenue is classified as part of current or long-term liability in the accompanying condensed consolidated balance sheets based on the Company's estimate of the portion of the performance obligation that will be completed within the next 12 months, and includes payments received as well as payments receivable. The total consideration for the UT License Agreement, includes $1.2 million related to the manufacturing of clinical supplies, which was included in the current portion of deferred revenue on our condensed consolidated balance sheet as of September 30, 2020. Also associated with the clinical supplies was a contract asset of $0.8 million and an account receivable of $0.4 million which are included in prepaid expenses and other current assets and accounts receivable, net, respectively, on our condensed consolidated balance sheet as of September 30, 2020.

United Therapeutics Research Agreement — In September 2018, the Company and UT also entered into a research agreement ("UT Research Agreement") for the conduct of research and consulting services in connection with multiple potential products, including evaluating the feasibility of preparing a dry powder formulation of a compound for the treatment of pulmonary hypertension outside the scope of the UT License Agreement. In addition, UT, at its option, may obtain a license to develop, manufacture and commercialize products based on specified compounds within the drug classes covered by the UT Research Agreement. Each specified compound advanced into development and commercialization under such a license would be subject to the payment to the Company of additional milestone payments of up to $30.0 million and a low double-digit royalty on net sales of such products. In connection with the UT Research Agreement, the Company received an upfront payment of $10.0 million in September 2018.

At the inception of the UT Research Agreement, the Company identified two distinct performance obligations. The Company determined that the key deliverables of each performance obligation include (i) the development of a product prototype (including a technical feasibility report) and; (ii) engineering consulting services. Due to the separately identifiable nature of these obligations, the Company has determined that these deliverables represent two distinct performance obligations. The Company also determined that UT's option to expand the scope to include specific drug classes covered by the agreement 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 allocated the total $10.0 million transaction price to its two distinct performance obligations based on available observable market inputs. A transaction price of $9.0 million was allocated to the product prototype and a transaction price of $1.0 million was allocated to engineering consulting services. The revenue for the product prototype was recognized using an output method (based on project milestones achieved and surveys of performance completed to date). The Company believed that this method best reflected the measure of progress toward complete satisfaction of the performance obligation. The revenue for the engineering consulting services was recognized using a ratable method until the obligation was satisfied. The Company believed that this method best reflected the measure of progress toward complete satisfaction of the performance obligation. The performance obligations for engineering consulting services and the product prototype were completed in April 2020 and June 2019, respectively.

Receptor Collaboration and License Agreement — In 2016, the Company entered into a collaboration and license agreement (the "CLA") with Receptor Life Sciences, Inc. ("Receptor") pursuant to which Receptor subsequently acquired an exclusive license to develop, manufacture and commercialize products that use the Company's technology to deliver certain compounds via oral inhalation in exchange for upfront license fees, milestone payments upon the completion of certain technology transfer activities and the achievement of specified sales targets as well as royalties upon Receptor's and its sublicensees' sale of products.

A $1.0 million license fee received in 2016 was recorded in deferred revenue from collaborations as of December 31, 2016 and is being recognized in net revenue — collaborations over four years, the estimated period over which the Company is required to satisfy the remaining performance obligations. The remaining performance obligations are to provide certain technology transfer activities. As of September 30, 2020, the deferred revenue balance was $0.1 million, which was classified as a current liability in the accompanying condensed consolidated balance sheets.

The additional payments referred to above represent variable consideration for which the Company has not recognized any revenue because it is uncertain that Receptor will be able to successfully develop, manufacture or sell product related to this license. There was no change to the accounting for this contract as a result of the initial application of the new revenue guidance since (i) the receipt of such payments is highly susceptible to factors outside of the Company's influence, (ii) the uncertainty regarding the receipt of these payments is not expected to be resolved for years, and (iii) the Company has limited experience with similar contracts. See Note 1 – *Description of Business and Significant Accounting Policies* for additional information on the Company's revenue recognition accounting policy.

In 2017, the Company entered into a manufacturing and supply agreement with Receptor pursuant to which the Company agreed to provide certain raw materials and certain additional research and formulation consulting services to Receptor. For the three and nine months ended September 30, 2020 and 2019, the additional research and formulation services provided to Receptor were *de minimis*.

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. There were no sales to Biomm in the third quarter of 2020.

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 September 30, 2020, the deferred revenue balance was $1.8 million, of which $0.1 million is classified as current and $1.7 million is classified as long term in the accompanying condensed consolidated balance sheets. The Company also recognized $0.2 million as income tax expense for a payment made to the India tax authority in 2018. The Company received a tax refund from the India tax authority in October 2020 and recognized an income tax benefit and receivable for $0.2 million in the accompanying condensed consolidated financial statements as of September 30, 2020.

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 accompanying 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, June 2020 note, December 2020 note 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 September 30, 2020 and December 31, 2019, the Company held $52.4 million and $29.9 million, respectively, of cash and cash equivalents. The Company held $0.3 million in restricted cash as of September 30, 2020 and December 31, 2019, which was comprised of money market funds. Restricted cash is 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).

Short-term investments— Short-term investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. The fair value of short-term investments approximate 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 September 30, 2020, the Company did not hold any short-term investments.

The fair value measurement of debt instruments is based on a discounted cash flow model and is sensitive to the change in yield (Level 3 in the fair value hierarchy):

	Yield	Hypothetical Change in Yield: % Change	Hypothetical Change in Yield: Hypothetical Yield	FV of Notes	Hypothetical Change in Notes Payable: FV	Hypothetical Change in Notes Payable: $ Change	Hypothetical Change in Notes Payable: % Change
					(in millions)		
Mann Group promissory notes:							
(with conversion feature)	25.5%	1%	26.5%	$ 63.7	$ 62.4	$ (1.3)	-2.0%
	25.5%	-1%	24.5%	$ 63.7	$ 65.0	$ 1.3	2.0%
	25.5%	2%	27.5%	$ 63.7	$ 61.2	$ (2.5)	-3.9%
	25.5%	-2%	23.5%	$ 63.7	$ 66.4	$ 2.7	4.2%
Senior notes:							
(with conversion feature)	25.5%	1%	26.5%	$ 7.1	$ 7.0	$ (0.1)	-1.4%
	25.5%	-1%	24.5%	$ 7.1	$ 7.2	$ 0.1	1.4%
	25.5%	2%	27.5%	$ 7.1	$ 7.0	$ (0.1)	-1.4%
	25.5%	-2%	23.5%	$ 7.1	$ 7.3	$ 0.2	2.8%
MidCap Credit Facility							
	11.0%	1%	12.0%	$ 41.2	$ 40.4	$ (0.8)	-1.9%
	11.0%	-1%	10.0%	$ 41.2	$ 42.0	$ 0.8	1.9%
	11.0%	2%	13.0%	$ 41.2	$ 39.6	$ (1.6)	-3.9%
	11.0%	-2%	9.0%	$ 41.2	$ 42.9	$ 1.7	4.1%
PPP Loan							
	11.0%	1%	12.0%	$ 4.6	$ 4.6	$ —	0.0%
	11.0%	-1%	10.0%	$ 4.6	$ 4.6	$ —	0.0%
	11.0%	2%	13.0%	$ 4.6	$ 4.6	$ —	0.0%
	11.0%	-2%	9.0%	$ 4.6	$ 4.7	$ 0.1	2.2%

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

	September 30, 2020		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
MidCap Credit Facility	$ 39.3	$ 41.2	$ 41.2
2024 convertible notes	5.0	4.6	4.6
December 2020 note	2.6	2.5	2.5
Mann Group promissory notes	70.0	63.7	63.7
PPP Loan	4.9	4.6	4.6
Milestone rights	7.3	16.0	16.0
Total financial liabilities	$ 129.1	$ 132.6	$ 132.6

	December 31, 2019		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
MidCap Credit Facility	$ 38.9	$ 40.0	$ 40.0
2024 convertible notes	5.0	3.7	3.7
June 2020 note	2.5	2.3	2.3
December 2020 note	2.5	2.0	2.0
Mann Group promissory notes	70.0	46.2	46.2
Milestone rights	7.3	16.4	16.4
Total financial liabilities	$ 126.2	$ 110.6	$ 110.6

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

On May 21, 2020, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment of its Amended and Restated Certificate of Incorporation to increase the authorized number of shares of the Company's common stock from 280,000,000 to 400,000,000 shares. As of September 30, 2020 and December 31, 2019, 230,922,513 and 211,787,573 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 CF Sales Agreement. Under the CF 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 nine months ended September 30, 2020, the Company sold an aggregate of 9,401,827 shares of the Company's common stock at a weighted average purchase price of $1.66 per share for an aggregate gross proceeds of approximately $15.6 million pursuant to the CF Sales Agreement.

In December 2018, the Company entered into an underwriting agreement with Leerink Partners LLC relating to the issuance and sale in a public offering of 26,666,667 shares of the Company's common stock and warrants to purchase up to an aggregate of 26,666,667 shares of the Company's common stock (the "December warrants") at a combined purchase price of $1.50 per share and accompanying warrant. The shares of common stock and the December warrants were immediately separable. The December warrants were immediately exercisable at issuance at a price of $1.60 per share and had an expiry date of December 26, 2019. On December 26, 2019, 11,583,333 December warrants expired unexercised and 7,250,000 remained available for purchase at a price of $1.60 per share, which were subsequently exercised in June 2020.

On June 24, 2020, the Company prepaid the June 2020 note with the issuance of 1,235,094 shares of the Company's common stock, in accordance with the terms of the June 2020 note. On October 9, 2020, the Company prepaid the December 2020 note with the issuance of 1,377,356 shares of the Company's common stock, in accordance with the terms of the December 2020 note. The number of shares issued for the prepayments on June 24, 2020 and October 9, 2020 were determined based on the Company's closing stock price on the settlement date. See Note 6 – *Borrowings*.

10. Stock-Based Compensation Expense

On May 16, 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan") as the successor to and continuation of the 2013 Equity Incentive Plan (the "2013 Plan"). The 2018 Plan initially consisted of 12,000,000 new shares plus the number of unallocated shares remaining available for grant for new awards under the 2013 Plan. In May 2020, the 2018 Plan was amended to increase the number of shares of common stock that may be issued under the 2018 Plan by 12,500,000 shares.

Effective upon the approval of the 2018 Plan by the Company's stockholders in May 2018, no additional awards have been or may be granted under the 2013 Plan. Any Prior Plans' Returning Shares will increase the number of shares issuable under the 2018 Plan. The "Prior Plans' Returning Shares" are shares subject to outstanding stock awards granted under the 2013 Plan or the 2004 Equity Incentive Plan (collectively, "Prior Plans") that, from and after the effective date of the 2018 Plan, (i) expire or terminate for any reason prior to exercise or settlement, (ii) are forfeited, cancelled or otherwise returned to the Company because of the failure to meet a contingency or condition required for the vesting of such shares, or (iii) other than with respect to outstanding stock options and stock appreciation rights granted under the Prior Plans with an exercise or strike price of at least 100% of the fair market value of the underlying common stock on the date of grant, are reacquired or withheld (or not issued) by the Company to satisfy a tax withholding obligation in connection with a stock award.

The 2018 Plan provides for the granting of stock awards including stock options and restricted stock units to employees, directors and consultants. The Company's board of directors or its compensation committee determines eligibility, vesting schedules and criteria, and exercise prices for stock awards granted under the 2018 Plan. Options and restricted stock unit awards under the 2018 Plan or the Prior Plans expire not more than ten years from the date of the grant and are exercisable upon vesting. Stock options that vest over time generally vest over four years. Current time-based vesting stock option grants vest and become exercisable at the rate of 25% after one year and ratably on a monthly basis over a period of 36 months thereafter. The Company also issues PNQ awards with performance conditions. For PNQs, the Company evaluates the probability that the performance conditions will be met and estimates the service period for recognition of the associated expense. Restricted stock units with time-based vesting generally vest at a rate of 25% per year over four years with consideration satisfied by service to the Company. The Company also issues restricted stock units with market conditions. The grant date fair value and the effect of the market conditions was estimated using a Monte Carlo valuation. The resulting stock-based compensation expense will be recognized over the service period regardless of whether the market conditions are achieved, as long as the service condition is rendered.

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2020 and 2019 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
RSUs and options	$ 1,225	$ 1,534	$ 4,413	$ 4,931
Employee stock purchase plan	69	106	194	381
Total stock compensation expense	$ 1,294	$ 1,640	$ 4,607	$ 5,312

During 2020, the Company granted the following awards:

	Three Months Ended March 31, 2020		Three Months Ended June 30, 2020		Three Months Ended September 30, 2020		Nine Months Ended September 30, 2020
Employee awards:							
Market RSUs	—		—		1,571,000	(7)	1,571,000
RSUs	230,000	(1)	2,109,228	(2)	1,776,250	(8)	4,115,478
Options	78,500	(3)	117,900	(4)	—		196,400
Non-employee director awards:							
RSUs	42,067	(5)	772,685	(6)	—		814,752
Total awards:							
Market RSUs	—		—		1,571,000		1,571,000
RSUs	272,067		2,881,913		1,776,250		4,930,230
Options	78,500		117,900		—		196,400

(1) RSUs had a weighted average grant date fair value of $1.25 per share and a primary vesting period of four years.
(2) RSUs had a weighted average grant date fair value of $1.34 per share and a primary vesting period of four years.
(3) Options had a weighted average exercise price of $1.25 per share and vest over a four year period. The weighted average grant date fair value was $0.93 per share, as determined using a Black-Scholes option pricing model, with the following key assumptions: risk-free interest rate of 0.79%; expected life of approximately 5.67 years; volatility of 93.83%, and dividend yield of zero.
(4) Options had a weighted average exercise price of $1.34 per share and vest over a four year period. The weighted average grant date fair value was $0.99 per share, as determined using a Black-Scholes option pricing model, with the following key assumptions: risk-free interest rate of 0.39%; expected life of approximately 5.67 years; volatility of 93.83%, and dividend yield of zero.
(5) RSUs had a weighted average grant date fair value of $1.17 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.
(6) RSUs had a weighted average grant date fair value of $1.34 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.
(7) Market RSUs had a grant date fair value of $3.77 per share and will vest on May 22, 2023 provided that the closing price of the Company’s common stock on such vesting date is not less than the closing price on August 27, 2020. 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 August 27, 2020 until May 22, 2023 related to the TSR of the Russell 3000 Pharmaceutical & Biotechnology Index over the same period, as follows: less than 25th percentile=0% of target, 25th percentile=50% of target, 50th percentile=100% of target, 75th percentile=200% percent of target, 90th percentile or higher=300% maximum. Payout values will be interpolated between the percentile rankings above.
(8) RSUs had a weighted average grant date fair value of $1.70 per share and a primary vesting period of four years.

As of September 30, 2020, there was $5.6 million of unrecognized stock-based compensation expense related to options and PNQs, which is expected to be recognized over a weighted average period of approximately 2.2 years, and $5.8 million and $5.7 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 3.7 and 2.6 years, respectively.

11. 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 accompanying 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 September 30, 2020, 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 has appealed this denial to the Supreme Court of Israel. The Company will continue to vigorously defend against the claims advanced.

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, $70.0 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 $1.3 million in accrued expenses and other current liabilities and $5.9 million in milestone rights and other liabilities.

Commitments — In July 2014, the Company entered into an Insulin Supply Agreement (the "Insulin Supply Agreement") with Amphastar Pharmaceuticals, Inc. ("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 August 2019, the Company and Amphastar amended the Insulin Supply Agreement to extend the term to 2026 and to restructure the annual purchase commitments. As of September 30, 2020, the annual purchase requirements under the amended contract are as follows:

	Minimum Commitment	
2020	€	5.5 million
2021	€	6.6 million
2022	€	8.5 million
2023	€	10.9 million
2024	€	14.6 million
2025	€	15.5 million
2026	€	19.4 million

Unless terminated earlier, the term of the Insulin Supply Agreement expires on December 31, 2026 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. Additional MidCap warrants will be issued if the Company accesses additional tranches under the MidCap Credit Facility (see Note 6 – *Borrowings*).

Vehicle Leases – During the second quarter of 2018, the Company entered into a lease agreement with Enterprise Fleet Management Inc. for the lease of 119 vehicles. The lease requires monthly payments of approximately $83,000 per month including the cost of maintaining the vehicles, taxes and insurance. The lease commenced when the Company took possession of the majority of the vehicles in the second quarter of 2018 and expires 48 months after the delivery date. During 2019, 29 vehicles were removed from the fleet, resulting in a fleet size of 90 vehicles. An additional vehicle was removed from the fleet in 2020. The revised monthly payment inclusive of maintenance fees, insurance and taxes is $65,000. The lease expense is included in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations.

Upon adoption of ASC 842, the agreement was classified as an operating lease which resulted in recording right-of-use assets and lease liabilities of approximately $1.6 million and $1.9 million, respectively, as of January 1, 2019. These amounts included approximately $1.6 million of non-current other assets and approximately $0.6 million and $1.3 million of other current liabilities and operating lease liabilities, respectively.

Office Lease — 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 accompanying condensed consolidated statement 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.

Upon adoption of ASC 842, this lease was classified as an operating lease, which resulted in recording right-of-use assets and lease liabilities of approximately $3.2 million and $3.5 million, respectively, as of January 1, 2019. These amounts included approximately $0.9 million and $2.6 million of other current liabilities and operating lease liabilities, respectively.

For the three and nine months ended September 30, 2020, operating lease costs under all operating leases, including office space and equipment, was approximately $0.4 million and $1.1 million, respectively. Cash paid for all operating leases for the three and nine months ended September 30, 2020 was $0.5 million and $1.3 million, respectively. Variable lease costs were approximately $0.1 million and $0.3 million for the three and nine months ended September 30, 2020, respectively.

For the three and nine months ended September 30, 2019, operating lease costs under all operating leases, including office space and equipment, was approximately $0.4 million and $1.1 million, respectively. Cash paid for all operating leases for the three and nine months ended September 30, 2019 was $0.5 million and $1.3 million, respectively. Variable lease costs were approximately $0.1 million and $0.3 million for the three and nine months ended September 30, 2019, respectively.

	September 30, 2020	December 31, 2019
Weighted average remaining lease term (in years)	2.2	3.0
Weighted average discount rate	7.5%	7.5%

Future minimum office and vehicle lease payments as of September 30, 2020 and December 31, 2019, are as follows (in thousands):

	September 30, 2020	December 31, 2019
2020	$ 371	$ 1,470
2021	1,494	1,499
2022	1,239	1,241
2023	88	88
Total	$ 3,192	$ 4,298

12. 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 and 2015 remain subject to examination by federal and state tax authorities, respectively.

The Company has recorded an income tax benefit of $0.2 million for the three and nine months ended September 30, 2020 for an effective tax rate of 1.90% and 0.70% respectively, compared to zero effective tax rate and tax benefit for the same periods in the prior year. The income tax rates for the three and nine months ended September 30, 2020 diverge from the federal statutory rate due to the full valuation allowance offsetting the Company's net deferred tax assets and a discrete benefit of $0.2 million related to refunded foreign withholding taxes paid in 2018.

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, 2019 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 only approved product, Afrezza (insulin human) Inhalation Powder, is an ultra rapid-acting inhaled insulin that was approved by the FDA in June 2014 to improve glycemic control in adult patients with diabetes. Afrezza became available by prescription in United States retail pharmacies in February 2015.

Our business is subject to significant risks, including but not limited to our need to raise additional capital to fund our operations, our ability to commercialize Afrezza successfully, our ability to manufacture sufficient quantities of Afrezza and competition from other products and technologies. Other significant risks also include the risks inherent in 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 reopened to non-essential personnel, although many employees continue to work from home for a portion of each workweek. Although our productivity has been impacted by the global pandemic, we have suitably adapted to the changed business environment that now exists.

The COVID-19 pandemic continues to evolve rapidly and its ultimate impact remains highly 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. We expect the COVID-19 pandemic to continue to negatively impact our near-term revenues from Afrezza and believe it has the potential to have additional adverse impacts on our operations. We will continue to monitor the COVID-19 situation closely.

As of September 30, 2020, we had an accumulated deficit of $3.0 billion and a stockholders' deficit of $186.4 million. We had net loss of $11.3 million and $30.8 million for the three and nine months ended September 30, 2020, respectively. 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 commercial product sales. As discussed below in "Liquidity and Capital Resources," if we are unable to obtain additional funding, there will continue to be substantial doubt about our ability to continue as a going concern.

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, 2019. 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 nine months ended September 30, 2020 and 2019

Revenues

The following tables provide a comparison of the revenue categories for the three and nine months ended September 30, 2020 and 2019 (dollars in thousands):

	Three Months Ended September 30,			
	2020	2019	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 12,393	$ 11,150	$ 1,243	11%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(5,118)	(4,748)	$ 370	8%
Net revenue — commercial product sales	7,275	6,402	$ 873	14%
Revenue — collaborations and services	8,077	8,193	$ (116)	(1%)
Total revenues	$ 15,352	$ 14,595	$ 757	5%

	Nine Months Ended September 30,			
	2020	2019	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 38,225	$ 29,697	$ 8,528	29%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(15,965)	(12,154)	$ 3,811	31%
Net revenue — commercial product sales	22,260	17,543	$ 4,717	27%
Revenue — collaborations and services	24,441	29,502	$ (5,061)	(17%)
Total revenues	$ 46,701	$ 47,045	$ (344)	(1%)

Gross revenue from the sales of Afrezza increased by $1.2 million, or 11%, for the three months ended September 30, 2020 compared to the same period in the prior year. The increase was primarily driven by higher product demand with a more favorable mix of Afrezza cartridges and a price increase, partially offset by a reduction in sales to Biomm (Brazil). The gross-to-net adjustment was $5.1 million (or 41% of gross revenue) for the three months ended September 30, 2020, compared to $4.7 million (or 43% of gross revenue) for the same period in the prior year. The increase of $0.4 million was primarily driven by an increase in commercial product sales and a decrease in accounting estimates for product returns, partially offset by an increase in the utilization of our patient co-pay assistance program. As a result, net revenue from the sales of Afrezza increased by $0.9 million, or 14%, for the three months ended September 30, 2020 compared to the prior year period. During the third quarter of 2020, our sales force had varying degrees of access to physicians due to restrictions enacted in response to the COVID-19 pandemic. This limitation on access continued to have an unfavorable impact on our commercial sales during the three months ended September 30, 2020 and is expected to continue to negatively impact our near-term revenues from Afrezza.

Net revenue from collaborations and services decreased by $0.1 million, or 1%, for the three months ended September 30, 2020 compared to the same period in the prior year. During the third quarter of 2020, the Company sold clinical supplies to UT for use in their clinical study. See Note 7 – *Collaboration and Licensing Agreements* in the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited).

Gross revenue from the sales of Afrezza increased by $8.5 million, or 29%, for the nine months ended September 30, 2020 compared to the same period in the prior year. The increase was primarily driven by higher product demand with a more favorable mix of Afrezza cartridges and a price increase, partially offset by a reduction in sales to Biomm (Brazil). The gross-to-net adjustment was $16.0 million (or 42% of gross revenue) for the nine months ended September 30, 2020, compared to $12.2 million (or 41% of gross revenue) for the same period in the prior year. The increase of $3.8 million was primarily driven by an increase in commercial product sales and a decrease in accounting estimates for product returns, partially offset by an increase in the utilization of our patient co-pay assistance program and accounting estimates for rebates. As a result, net revenue from the sales of Afrezza increased by $4.7 million, or 27%, for the nine months ended September 30, 2020 compared to the prior year period. The stay-at-home orders implemented around the country in response to the COVID-19 pandemic negatively impacted the sales of Afrezza by limiting the access of our sales force to physicians. The COVID-19 pandemic is expected to continue to negatively impact our near-term revenues from Afrezza.

Net revenue from collaborations and services decreased by $5.1 million, or 17%, for the nine months ended September 30, 2020 compared to the same period in the prior year. This was primarily driven by a $5.7 million decrease in revenue recognized from the UT Research Agreement, which was substantially completed in the second quarter of 2019. During the third quarter of 2020, the Company sold clinical supplies to UT. See Note 7 – *Collaboration and Licensing Agreements* in the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited).

Commercial product gross profit

The following tables provide a comparison of the commercial product gross profit categories for the three and nine months ended September 30, 2020 and 2019 (dollars in thousands):

	Three Months Ended September 30,			
	2020	2019	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 7,275	$ 6,402	$ 873	14%
Less: cost of goods sold	3,591	7,099	$ (3,508)	(49%)
Commercial product gross profit (loss)	$ 3,684	$ (697)	$ 4,381	*
Gross margin	51%	-11%		

	Nine Months Ended September 30,			
	2020	2019	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 22,260	$ 17,543	$ 4,717	27%
Less: cost of goods sold	11,432	15,446	$ (4,014)	(26%)
Commercial product gross profit	$ 10,828	$ 2,097	$ 8,731	416%
Gross margin	49%	12%		

* Not meaningful.

Commercial product gross profit for the three months ended September 30, 2020 increased by $4.4 million compared to the same period in the prior year. Gross margin for the three months ended September 30, 2020 increased to 51% from a negative 11% for the same period in the prior year. The increase in gross profit and gross margin was attributable to a reduction in cost of goods sold combined with higher commercial product sales. Cost of goods sold decreased by $3.5 million, or 49%, for the three months ended September 30, 2020 compared to the same period in the prior year, primarily attributable to a $2.8 million amendment fee associated with our Insulin supply agreement in 2019, $0.5 million in reduced manufacturing-related spending and $0.5 million of costs associated with product sales in Brazil (Biomm) in 2019, partially offset by $0.4 million of decreased manufacturing activities which resulted in a reduced amount of costs capitalized to inventory.

Commercial product gross profit for the nine months ended September 30, 2020 increased by $8.7 million compared to the same period in the prior year. Gross margin for the nine months ended September 30, 2020 increased to 49% from 12% for the same period in the prior year. The increase in gross profit and gross margin was attributable to a reduction in cost of goods sold combined with higher commercial product sales. Cost of goods sold decreased by $4.0 million, or 26%, for the nine months ended September 30, 2020 compared to the same period in the prior year. The reduction in cost of goods sold was primarily attributable to a $2.8 million amendment fee associated with our Insulin supply agreement in 2019, $0.8 million of increased manufacturing activities which resulted in a greater amount of costs capitalized to inventory and $1.1 million in reduced manufacturing-related spending, partially offset by $0.5 million of inventory write-offs and $0.4 million in costs associated with higher commercial product sales.

Expenses

The following tables provide a comparison of the expense categories for the three and nine months ended September 30, 2020 and 2019 (dollars in thousands):

	Three Months Ended September 30,			
	2020	2019	$ Change	% Change
Expenses:				
Cost of goods sold	$ 3,591	$ 7,099	$ (3,508)	(49%)
Cost of revenue — collaborations and services	1,581	1,836	$ (255)	(14%)
Research and development	1,484	1,580	$ (96)	(6%)
Selling	8,270	9,550	$ (1,280)	(13%)
General and administrative	5,629	7,116	$ (1,487)	(21%)
Loss (gain) on foreign currency translation	3,927	(3,807)	$ 7,734	203%
Total expenses	$ 24,482	$ 23,374	$ 1,108	5%

	Nine Months Ended September 30,			
	2020	2019	$ Change	% Change
Expenses:				
Cost of goods sold	$ 11,432	$ 15,446	$ (4,014)	(26%)
Cost of revenue — collaborations and services	6,926	5,512	$ 1,414	26%
Research and development	4,703	4,879	$ (176)	(4%)
Selling	23,687	37,580	$ (13,893)	(37%)
General and administrative	18,232	21,368	$ (3,136)	(15%)
Asset impairment	1,889	—	$ 1,889	100%
Loss (gain) on foreign currency translation	3,998	(4,495)	$ 8,493	189%
Total expenses	$ 70,867	$ 80,290	$ (9,423)	(12%)

Cost of revenue — collaborations and services decreased by $0.3 million, or 14%, for the three months ended September 30, 2020 compared to the same period in the prior year. The decrease was attributable to resource costs related to conducting activities for our collaboration partner, UT, in addition to the cost of clinical supplies.

Cost of revenue — collaborations and services increased by $1.4 million, or 26%, for the nine months ended September 30, 2020 compared to the same period in the prior year. The increase was attributable to resource costs related to conducting activities for our collaboration partners, UT and Cipla, in addition to the cost of clinical supplies.

Research and development expenses decreased by $0.1 million, or 6%, for the three months ended September 30, 2020 compared to the same period in the prior year. The decrease was attributable to lower clinical trial spending, partially offset by an increase in preventative maintenance efforts in 2020.

Research and development expenses decreased by $0.2 million, or 4%, for the nine months ended September 30, 2020 compared to the same period in the prior year. The decrease was attributable to lower clinical trial spending, partially offset by an increase in preventative maintenance efforts in 2020.

Selling expenses decreased by $1.3 million, or 13%, for the three months ended September 30, 2020 compared to the same period in the prior year. The decrease was primarily attributable to a $1.2 million reduction in promotional and marketing activities.

Selling expenses decreased by $13.9 million, or 37%, for the nine months ended September 30, 2020 compared to the same period in the prior year. The decrease was primarily attributable to a $9.3 million decrease in costs for television advertising for Afrezza and a $4.1 million decrease from a reduction in promotional and marketing activities.

General and administrative expenses decreased by $1.5 million, or 21%, for the three months ended September 30, 2020 compared to the same period in the prior year. This decrease was primarily attributable to a $0.8 million decrease in professional costs.

General and administrative expenses decreased by $3.1 million, or 15%, for the nine months ended September 30, 2020 compared to the same period in the prior year. This decrease was primarily attributable to a $1.3 million decrease in consulting costs, a $1.2 million decrease in personnel and employee related costs and a $0.3 million reduction in property taxes.

During the nine months ended September 30, 2020, an impairment of $1.9 million was recognized for a commitment asset and debt issuance costs related to the future funding commitments of the MidCap Credit Facility (see Note 1 – *Description of Business and Significant Accounting Policies* and Note 6 – *Borrowings* in the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited).There were no asset impairments for the three months ended September 30, 2020 or the three or nine months ended September 30, 2019.

Under the Insulin Supply Agreement with Amphastar, payment obligations are denominated in Euros. We are required to record the foreign currency translation impact of the U.S. dollar to Euro exchange rate associated with the recognized gain or loss on purchase commitments. The foreign currency translation gain decreased $7.7 million for the three months ended September 30, 2020 to a loss of $3.9 million, compared to a gain of $3.8 million for the same period in the prior year. The foreign currency translation gain decreased $8.5 million for the nine months ended September 30, 2020 to a loss of $4.0 million, compared to a gain of $4.5 million for the same period in the prior year. This impact was due to the translation of the U.S. dollar to Euro exchange rates.

Other Income (Expense)

The following tables provide a comparison of the other income (expense) categories for the three and nine months ended September 30, 2020 and 2019 (dollars in thousands):

	Three Months Ended September 30,			
	2020	2019	$ Change	% Change
Interest income	$ 18	$ 220	$ (202)	(92%)
Interest expense on notes	(1,057)	(4,126)	$ (3,069)	(74%)
Interest expense on promissory notes	(1,318)	(1,162)	$ 156	13%
Gain on extinguishment of debt	—	3,529	$ (3,529)	(100%)
Other income (expense)	14	(52)	$ 66	127%
Total other expense	$ (2,343)	$ (1,591)	$ 752	47%

	Nine Months Ended September 30,			
	2020	2019	$ Change	% Change
Interest income	$ 165	$ 794	$ (629)	(79%)
Interest expense on notes	(3,212)	(5,283)	$ (2,071)	(39%)
Interest expense on promissory notes	(3,858)	(3,351)	$ 507	15%
Gain on extinguishment of debt	—	3,529	$ (3,529)	(100%)
Other income (expense)	24	(84)	$ 108	129%
Total other expense	$ (6,881)	$ (4,395)	$ 2,486	57%

Interest income decreased by $0.2 million and $0.6 million, or 92% and 79%, for the three and nine months ended September 30, 2020, respectively, compared to the same period in the prior year, due to lower short-term interest rates.

Interest expense on notes decreased by $3.1 million and $2.1 million, or 74% and 39%, for the three and nine months ended September 30, 2020, respectively, compared to the same period in the prior year. The decrease was primarily due to a $3.4 million milestone obligation that was achieved in the third quarter of 2019, partially offset by interest expense from the MidCap Credit Facility.

The gain on extinguishment of debt for the three and nine months ended September 30, 2019 was primarily due to the cancellation of the 2021 notes in exchange for cash, common stock, 2024 convertible notes and non-interest bearing notes in August 2019 pursuant to an exchange agreement. There was no gain on extinguishments for the three and nine months ended September 30, 2020.

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 commercial product sales.

As of September 30, 2020, we had $122.6 million principal amount of outstanding debt consisting of:

- $40.0 million principal amount under the MidCap Credit Facility bearing interest at an annual rate equal to one-month LIBOR plus 6.75%, subject to a one-month LIBOR floor of 2.00%, and payable in equal monthly installments beginning in August 2021 through maturity in August 2024;
- $5.0 million principal amount of 2024 convertible notes bearing interest at 5.75% per annum, with interest payable in cash or equity semiannually in arrears on February 15 and August 15 of each year, and maturing in November 2024, all of which is convertible into shares of our common stock at the option of the holder at a conversion price of $3.00 per share;
- $2.6 million principal amount of the December 2020 note, which was prepaid in October 2020 with the issuance of 1,377,356 shares of our common stock;

- $70.1 million principal amount of indebtedness under the Mann Group promissory notes bearing interest at a fixed rate of 7.00% per annum compounded quarterly and maturing in November 2024, $35.0 million of which is convertible into shares of our common stock at the option of the 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 or in shares; and
- $4.9 million from a loan under the Paycheck Protection Program of the CARES Act, all or a portion of which may be forgiven. The PPP Loan matures in April 2022 and bears interest at a rate of 0.98% per annum. Principal and interest payments can be deferred up to ten months after the end of the Company's covered period unless the Company is notified earlier of its loan forgiveness status. In the event the SBA does not authorize loan forgiveness, the deferred principal and interest will be payable to the lender and the Company will then make equal monthly payments as required to fully amortize the remaining principal amount by April 9, 2022.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the MidCap Credit Facility, the 2024 convertible notes, the Mann Group promissory notes or unforgiven amounts of the PPP Loan if required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2024 convertible notes, the holders of such debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2024 convertible notes and the Mann Group convertible note are fully convertible at any time 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 pay interest on the 2024 convertible notes or under the MidCap Credit Facility, or if we fail to repay or repurchase the 2024 convertible notes, the Mann Group promissory notes, borrowings under the MidCap Credit Facility or unforgiven amounts of the PPP Loan, 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, $70.0 million of which remains payable upon achievement of such milestones. See Note 11 – *Commitments and Contingencies* and Note 6 – *Borrowings* for further information related to the Milestone Rights.

These liabilities and other factors raise substantial doubt about our ability to continue as a going concern. Our financial statements and related notes thereto included elsewhere in this report do not include adjustments that might result from any unfavorable outcome of this uncertainty.

During the nine months ended September 30, 2020, we used $28.4 million of cash for our operating activities as a result of our net loss of $30.8 million, in addition to a net cash outflow from changes in balances of operating assets and liabilities of $14.9 million, partially offset by non-cash charges of $17.4 million. The change in operating asset and liabilities was primarily a result of deferred revenue amortization of $24.4 million, partially offset by a milestone payment from UT of $12.5 million.

During the nine months ended September 30, 2019, we used $83.4 million of cash for our operating activities as a result of our net loss of $37.6 million. The net cash outflow was primarily due to result of deferred revenue amortization of $29.5 million and paid-in-kind interest on Promissory note of $32.8 million, partially offset by a milestone payment from UT of $12.5 million.

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

Cash used investing activities of $22.6 million for the nine months ended September 30, 2019, was primarily due to a purchase of short-term treasury bills of $44.9 million partially offset by proceeds of from sales of treasury bills of $25.0 million.

Cash provided by financing activities of $31.2 million for the nine months ended September 30, 2020 was primarily due to the receipt of $15.1 million in gross proceeds from at the market offerings for an aggregate of 9,401,827 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.

Cash provided by financing activities of $64.8 million for the nine months ended September 30, 2019 was primarily due to net proceeds from the Midcap Credit Facility of $39.1 million and net proceeds from exchange of Mann Group promissory notes which was offset by payments for financing facility of $6.9 million.

Future Liquidity Needs

We are not currently profitable and have rarely generated positive net cash flows 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 collaboration and development costs for product candidates in our pipeline. As of September 30, 2020, we had an accumulated deficit of $3.0 billion and $122.6 million of total principal amount of outstanding borrowings, with limited capital resources of $52.4 million in cash and cash equivalents. These financial conditions raise substantial doubt about our ability to continue as a going concern.

Our capital resources may not be sufficient to continue to meet our current and anticipated obligations over the next twelve months if we cannot increase our operating cash inflows by growing our prescription and revenue base and by obtaining access to the remaining $25.0 million borrowings that may become available under the MidCap Credit Facility (which, in turn, requires us to grow Afrezza revenue before we can access such funds). The various stay-at-home orders implemented around the country in response to the COVID-19 pandemic have negatively impacted the sales of Afrezza by limiting the access of our sales force to physicians. The COVID-19 pandemic is expected to continue to negatively impact our near-term revenues from Afrezza, which potentially shortens our cash runway.

Our ability to draw the $25.0 million Tranche 3 of the MidCap Credit Facility depends on our ability to achieve certain trailing 12-month Afrezza net revenue targets, which we are unlikely to achieve. The availability of Tranche 3 also depends on TreT achieving certain development milestones, which is likely to be negatively impacted by the COVID-19 pandemic. In the event our capital resources are not sufficient, we may need to raise additional capital by selling equity or debt securities, entering into strategic business collaboration agreements with other companies, seeking other funding facilities or licensing arrangements, selling assets or by other means. However, we cannot provide assurances that additional capital will be available 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 or make it difficult to comply with the covenants contained in the MidCap Credit Facility, which could negatively affect our liquidity. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, 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.

The impact of the COVID-19 pandemic on Afrezza sales also increased the risk of non-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. In August 2020, we entered into an amendment to the MidCap Credit Facility, pursuant to which the parties agreed that no breach of this covenant between July 31, 2020 and November 30, 2020 will be deemed to occur if we have unrestricted cash of at least $40.0 million. Thereafter, if we fail to meet the minimum Afrezza net revenue covenant, any outstanding borrowings, together with accrued interest, under the MidCap Credit Facility could be declared immediately due and payable. 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.

We may not have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2024 convertible notes, the holders of such debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. 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 the 2024 convertible notes or the MidCap Term Loan, or if we fail to repay or repurchase the 2024 convertible notes, MidCap Term Loan, PPP Loan 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 are unable to meet our current and anticipated obligations over the next twelve months through our existing capital resources, or obtain new sources of capital when needed, we may have to delay or reduce the scope of our manufacturing operations, reduce or eliminate one or more of our development programs, or make significant changes to our operating plan. These factors raise substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of September 30, 2020 and December 31, 2019, we did not have any off-balance sheet arrangements.

Contractual Obligations

See Note 6 – *Borrowings* and Note 11 – *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 is determined, for any one-month period, on the basis of one-month LIBOR in effect at the beginning of such period plus 6.75%, subject to a one-month LIBOR floor of 2.00%. 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 7.00%, the interest rate under the 2024 convertible notes is fixed at 5.75%, and the interest rate under the PPP Loan is fixed at 0.98%. See Note 6 – *Borrowings* for information about the principal amount of outstanding debt.

If a change in the one-month LIBOR interest rate equal to 10% of the one-month LIBOR interest rate on September 30, 2020 were to have occurred, this change would not have a material effect on our interest payment obligation.

Foreign Currency Exchange Risk

On July 1, 2019, the Company entered into a 90-day foreign currency hedging transaction to mitigate its exposure to foreign currency exchange risks associated with the then-existing third quarter amount of €1.9 million. The Company realized a *de minimis* currency loss during third quarter of 2019. This amount was 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 September 30, 2020, we realized a $3.9 million currency loss, which was included in loss on foreign currency translation in the accompanying condensed consolidated statements of operations. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If a change in the U.S. dollar to Euro exchange rate equal to 10% of the U.S. dollar to Euro exchange rate on September 30, 2020 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $9.5 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, or the Exchange Act, as of September 30, 2020. 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 September 30, 2020, 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. We will continue to vigorously defend against the claims advanced.

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*

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

We may need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.*

This report includes disclosures stating that our existing cash resources and our accumulated deficit raise substantial doubt about our ability to continue as a going concern. As of September 30, 2020, we had cash and cash equivalents of $52.4 million and accumulated deficit of $3.0 billion. 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;
- 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;
- our ability to satisfy the milestone conditions necessary to access additional borrowings under the MidCap Credit Facility;
- 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 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 or make it difficult to comply with the covenants contained in the MidCap Credit Facility, which could negatively affect our liquidity.

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 continue to 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. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. 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.

Our prospects are heavily dependent on the successful commercialization of our only approved product, Afrezza. 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 development of our only approved product, Afrezza. We anticipate that in the near term our prospects and ability to generate significant revenues will heavily depend on our ability to successfully commercialize Afrezza in the United States. In addition, 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.

Successful commercialization of Afrezza is subject to many risks, including some that are outside our control. There are numerous examples of unsuccessful product launches, second launches that underperform original expectations and other 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 relative to alternative products, the availability of alternative treatments and lack of coverage or adequate reimbursement. We will need to maintain and 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 for the treatment diabetes 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 payor 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.

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 commercialize success with Afrezza in the United States, our business, financial condition and results of operations will be materially and adversely affected.

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, and there is substantial doubt about our ability to continue as a going concern.”

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 recent 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. The 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.*

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.

For example, the ongoing COVID-19 pandemic 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 significant restrictions. In parts of the country, the number of COVID-19 cases is increasing, raising the possibility that recurring cycles of restrictions will be imposed in the future. 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 into 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, who normally conduct in-person office visits with healthcare providers, were required to work from home for varying periods of time since mid-March 2020, which has had an impact to 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 payors, 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 TreT 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 or to comply with the covenants contained in the MidCap Credit Facility, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to rapidly evolve. 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 continue to be successful in establishing or maintaining 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. 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 and our focus on the development and commercialization of Afrezza, we will likely 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.

A significant portion of the research that we have conducted involves new technologies, including our Technosphere platform technology. 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 September 30, 2020, we had an accumulated deficit of $3.0 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. In addition, under our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin through 2026. As of September 30, 2020, there was €80.9 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 September 30, 2020, we had $122.6 million principal amount of outstanding debt, consisting of:

- $40.0 million principal amount under the MidCap Credit Facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.75%, subject to a one-month LIBOR floor of 2.00%, and payable in equal monthly installments beginning in August 2021 through maturity in August 2024;
- $5.0 million principal amount of the 2024 convertible notes bearing interest at 5.75% per annum, with interest payable in cash or equity semiannually in arrears on February 15 and August 15 of each year, and maturing in November 2024, all of which is convertible into shares of our common stock at the option of the holder at a conversion price of $3.00 per share;
- $2.6 million principal amount of the December 2020 note, which was prepaid in October 2020 with the issuance of 1,377,356 shares of our common stock;

- $70.1 million principal amount of indebtedness under the Mann Group promissory notes bearing interest at a fixed rate of 7.00% per annum compounded quarterly and maturing in November 2024, $35.0 million of which is convertible into shares of our common stock at the option of the 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 or in shares.
- $4.9 million from a loan under the Paycheck Protection Program of the CARES Act. The PPP Loan matures in April 2022 and bears interest at a rate of 0.98% per annum. On November 9, 2020, we may be required to pay the lender $1.4 million of principal and interest, which includes six months of payments deferred in accordance with the terms of the PPP Loan, and equal monthly payments of principal and interest thereafter as required to fully amortize the remaining principal amount by April 9, 2022.

All or a portion of the PPP Loan may be forgiven by the SBA upon application to our lender by us beginning 60 days after loan approval, but not later than ten months after the end of our covered period, and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered interest and covered utilities during the 24 week period (or eight-week period at our option) beginning on the date of loan approval. Not more than 40% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven will be reduced if our full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA. Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan.

The PPP Loan application required us to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP, the certification described above does not contain any objective criteria. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the PPP has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that we satisfied all eligible requirements for the PPP Loan, we are found to be in violation of any of the laws or governmental regulations that apply to us in connection with the PPP Loan, including the False Claims Act, or it is otherwise determined that we were not eligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. If we fail to take all actions necessary and promptly file all required reporting to ensure than no less than 90% of the PPP Loan is forgiven in accordance with the loan forgiveness provisions of the PPP, we will be in violation of the consent given by MidCap with respect to such additional indebtedness, which could lead to an event of default under the MidCap Credit Facility. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

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 2021. 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 yet to be established. 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, an advance of $25.0 million will be available to us until June 30, 2021, subject to the satisfaction of certain milestone conditions associated with Afrezza net revenue and certain milestone conditions related to our collaboration with United Therapeutics. As described in Part I, Item 2 of this Quarterly Report, it is unlikely that the milestone conditions for funding Tranche 3 related to Afrezza trailing net revenue will be achieved. In addition, the COVID-19 pandemic is expected to negatively impact TreT clinical development activities being conducted by United Therapeutics. These factors make it unlikely that we will be able to satisfy the milestone conditions necessary for us to draw the remaining advance under the MidCap Credit Facility.

Under the MidCap Credit Facility, we must comply with a minimum cash covenant of $15.0 million at all times, which will increase to $20.0 million following the funding of an additional advance. The minimum cash covenant increased to $40.0 million for any trailing twelve-month reporting period between July 31, 2020 and November 30, 2020 if the Afrezza trailing 12 month net sales target is not met during this period in accordance with an amendment to the MidCap Credit Facility. 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. In August 2020, we entered into an amendment to the MidCap Credit Facility, pursuant to which the parties agreed that no breach of this covenant between July 31, 2020 and November 30, 2020 will be deemed to occur if we have unrestricted cash of at least $40.0 million. Thereafter, if we fail to meet this covenant, any outstanding borrowings, together with accrued interest, under the MidCap Credit Facility could be declared immediately due and payable.

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

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2024 convertible notes, the holders of such debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. 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 the 2024 convertible notes or the MidCap Term Loan, or if we fail to repay or repurchase the 2024 convertible notes, MidCap Term Loan, PPP Loan 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.*

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 the production of Afrezza 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 Afrezza, we need access to sufficient, reliable and affordable supplies of insulin, FDKP, our Afrezza inhaler, the related cartridges and other materials. Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar. We must rely on 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 we fail as an effective manufacturing organization or fail to engage third-party manufacturers with this capability, we may be unable to support commercialization of this product.

We use our Danbury, Connecticut facility to formulate both the Afrezza and TreT inhalation powders, fill plastic cartridges with the powders, package the cartridges in blister packs, and place the blister packs into foil pouches. We utilize a contract packager to assemble the final kits of Afrezza foil-pouched blister packs along with inhalers and the package inserts. The final responsibility for TreT packaging has not yet been determined.

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 initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

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 Afrezza 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 Afrezza and we would lose potential revenues.

If Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payors 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 payors 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 payors, 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 payors 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.*

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 payors 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. At the federal level, the Trump administration's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Moreover, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services ("HHS") has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. More recently, President Trump signed an executive order (one of several intended to encourage lower drug prices) on July 24, 2020 directing HHS to make rules that would exclude from the safe harbor protections of the Anti-Kickback Statute rebates paid by manufacturers to insurers, pharmacies and pharmacy benefit managers for Medicare Part D drugs, provided such rules do not increase federal spending or out-of-pocket costs to patients. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have stated that they will continue to seek new legislative and/or administrative measures to control drug costs. 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 payors 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 to address 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.

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 payors, such as government health administration authorities and private insurance plans. Third-party payors 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 payors' drug formularies, which are the lists of medications for which third-party payors 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 payors 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. In addition, because each third-party payor 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 payor 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 coverage of, and adequate payment levels reimbursement for, Afrezza or any of our other product candidates that receive marketing approval from third-party payors, 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.

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

The testing, manufacturing, marketing and sale 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. 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, in order to commercialize Afrezza successfully, 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 of 2017 ("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, 2019 we had federal and state net operating loss carryforwards of $2.1 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 to the end of the previous tax year regarding 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, 2019. There is a risk that changes in ownership may occur in tax years after December 31, 2019. 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.

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.

We and certain of our executive officers and directors have been named as defendants in ongoing securities lawsuits that could result in substantial costs and divert management's attention.*

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. We will continue to vigorously defend against the claims advanced. If we are not successful in our defense, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition.

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 TreT. 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, infrastructure and data security.*

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.

Legal, political and economic uncertainty surrounding the exit of the U.K. from the European Union may be a source of instability in international markets, create significant currency fluctuations and pose additional risks to our business.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020. This event is commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020, (the "Transition Period"), during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period.

The uncertainty concerning the U.K's legal, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise). These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business.

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. For example, with the approval of Afrezza, the FDA has 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 long-term trial and have not yet commenced this trial.

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. For example, stability failure of Afrezza could lead to product recall or other sanctions.

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;
- 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. 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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, as defined by such law, and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to physicians 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;
- 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 remain judicial and congressional challenges to certain provisions of the PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed Executive Orders and other directives designed to eliminate the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Act includes 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”. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation, and other efforts to repeal and replace the PPACA will impact the PPACA and our business.

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. The CARES Act suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 to address 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 payors. 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 payors, 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;
- 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 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. 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, as defined by such law, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; 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 payor, 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 payors 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. 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 average manufacturer price ("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 payors. 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.

In addition, in certain countries, including the United States, applications are generally published 18 months after the application's priority date. In any event, 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"), or the Leahy-Smith Act, the United States moved to a first inventor to file system. In general, the Leahy-Smith Act 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 2020, 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 extend 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. 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 Leahy-Smith Act 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, we have identified certain patents having claims that may trigger an allegation of infringement in connection with the commercial manufacture and sale of Afrezza. If a court were to determine that Afrezza was infringing any of these patent rights, we would have to establish with the court that these 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.

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.

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;
- our future estimates of Afrezza sales, 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 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;
- 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 Stock 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, 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.

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.

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 October 26, 2020, we had 232,600,608 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 some or all of our 2024 convertible notes or 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.

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

As previously reported, in August 2019 we issued a $2.6 million principal amount note due December 2020 in exchange for the cancellation of existing indebtedness. On October 9, 2020, we prepaid the December 2020 note through the issuance of 1,377,356 shares of our common stock, pursuant to our election and in accordance with the terms of the December 2020 note. We relied on an exemption from registration provided by Section 3(a)(9) of the Securities Act for the issuance of such shares.

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 Common Stock issued November 16, 2015 (incorporated by reference to Exhibit 4.17 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
4.5	Form of Common Stock Purchase Warrant issued December 26, 2018 (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 December 21, 2018).
4.6	Amendment to Common Stock Purchase Warrant, dated December 22, 2019, by and between MannKind Corporation and CVI Investments, Inc. (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 December 23, 2019).
4.7	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).
4.8	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).
4.9	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).
4.10	Promissory Note due September 30, 2020 made by MannKind Corporation in favor of Bruce & Co., Inc., dated August 6, 2019 (incorporated by reference to Exhibit 4.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.11	Promissory Note due December 31, 2020 made by MannKind Corporation in favor of Bruce & Co., Inc., dated August 6, 2019 (incorporated by reference to Exhibit 4.5 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.12	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).
4.13	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).
4.14	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).

Exhibit Number	Description of Document
10.1	Amendment No. 2 to Credit and Security Agreement, dated August 21, 2020, by and among MannKind Corporation, MannKind LLC 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 August 25, 2020).
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	Interactive Data Files pursuant to Rule 405 of Regulation S-T.
104	The cover page has been formatted in Inline XBRL.

SIGNATURE

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

Dated: November 4, 2020	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 September 30, 2020 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: November 4, 2020

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 September 30, 2020 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: November 4, 2020

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 September 30, 2020, 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 4th day of November, 2020.

/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 September 30, 2020, 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 4th day of November, 2020.

/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.