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

Form 10-Q

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

For the quarterly period ended June 30, 2019

Or

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

For the transition period from _____ to _____.

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

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

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, 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 Act). Yes ☐ No ☒

As of July 16, 2019, there were 189,616,126 shares of the registrant's common stock, $0.01 par value per share, outstanding.

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended June 30, 2019

TABLE OF CONTENTS

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

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,968	$ 71,157
Restricted cash	5,316	527
Short-term investments	24,909	—
Accounts receivable, net	4,974	4,017
Inventory	3,963	3,597
Prepaid expenses and other current assets	2,704	2,556
Total current assets	49,834	81,854
Property and equipment, net	27,146	25,602
Right-of-use and other assets	4,815	249
Total assets	$ 81,795	$ 107,705
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,533	$ 5,379
Accrued expenses and other current liabilities	16,452	15,022
Facility financing obligation	8,974	11,298
Deferred revenue - current	32,370	36,885
Recognized loss on purchase commitments - current	11,649	6,657
Total current liabilities	76,978	75,241
Senior convertible notes	19,031	19,099
Note payable to related party	71,981	72,089
Accrued interest - note payable to related party	9,132	6,835
Recognized loss on purchase commitments - long term	81,978	91,642
Deferred revenue - long term	8,399	10,680
Milestone rights liability	7,201	7,201
Operating lease liabilities	3,094	—
Total liabilities	277,794	282,787
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.01 par value - 280,000,000 shares authorized, 189,447,055 and 187,029,967 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	1,894	1,870
Additional paid-in capital	2,769,396	2,763,067
Accumulated other comprehensive loss	(19)	(19)
Accumulated deficit	(2,967,270)	(2,940,000)
Total stockholders' deficit	(195,999)	(175,082)
Total liabilities and stockholders' deficit	$ 81,795	$ 107,705

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net revenue - commercial product sales	$ 6,065	$ 3,753	$ 11,141	$ 7,155
Revenue - collaborations and services	8,937	87	21,309	150
Revenue - other	—	53	—	53
Total revenues	15,002	3,893	32,450	7,358
Expenses:				
Cost of goods sold	4,327	5,095	8,347	9,103
Cost of revenue - collaborations and services	2,139	—	3,676	—
Research and development	1,632	2,967	3,299	5,611
Selling, general and administrative	16,609	21,731	42,282	42,349
(Gain) loss on foreign currency translation	1,247	(5,363)	(688)	(2,379)
Total expenses	25,954	24,430	56,916	54,684
Loss from operations	(10,952)	(20,537)	(24,466)	(47,326)
Other (expense) income:				
Interest income	255	55	573	161
Interest expense on notes	(564)	(1,709)	(1,157)	(3,503)
Interest expense on note payable to related party	(1,109)	(1,046)	(2,189)	(2,160)
Gain (loss) on extinguishment of debt	—	772	—	(53)
Other income (expense)	(17)	30	(31)	61
Total other expense	(1,435)	(1,898)	(2,804)	(5,494)
Loss before provision for income taxes	(12,387)	(22,435)	(27,270)	(52,820)
Provision for income taxes	—	(240)	—	(240)
Net loss	$ (12,387)	$ (22,675)	$ (27,270)	$ (53,060)
Net loss per share - basic and diluted	$ (0.07)	$ (0.16)	$ (0.15)	$ (0.41)
Shares used to compute basic and diluted net loss per share	188,054	140,054	187,744	130,535

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (12,387)	$ (22,675)	$ (27,270)	$ (53,060)
Other comprehensive income (loss):				
Cumulative translation loss	—	$ (3)	—	—
Comprehensive loss	$ (12,387)	$ (22,678)	$ (27,270)	$ (53,060)

See notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
BALANCE, JANUARY 1, 2018	119,053	$ 1,191	$ 2,638,992	$ (18)	$ (2,854,898)	$ (214,733)
Adjustment to adopt ASU 2016-09	—		—	—	1,873	1,873
Issuance of common shares from the release of restricted stock units	60	1	(82)	—	—	(81)
Issuance of common shares under Employee Stock Purchase Plan	137	1	—	—	—	1
Stock-based compensation expense	—	—	1,943	—	—	1,943
Issuance of shares pursuant to conversion of Facility Financing Obligation	3,549	35	9,372	—	—	9,407
Issuance of shares pursuant to conversion of Related Party Notes	3,000	30	8,130	—	—	8,160
Cumulative translation gain	—	—	—	3	—	3
Amortization of shelf fees	—	—	(5)	—	—	(5)
Issuance of at-the-market placement	214	2	632	—	—	634
Issuance costs associated with at-the-market placement	—	—	(25)	—	—	(25)
Net loss	—	—	—	—	(30,385)	(30,385)
BALANCE, MARCH 31, 2018	126,013	$ 1,260	$ 2,658,957	$ (15)	$ (2,883,410)	$ (223,208)
Issuance of common shares from the release of restricted stock units	108	$ 1	$ (105)	$ —	$ —	$ (104)
Exercise of Stock Options	3		2			2
Stock-based compensation expense	—	—	2,209	—	—	2,209
Issuance of shares pursuant to conversion of Facility Financing Obligation	3,061	31	5,969	—	—	6,000
Issuance of shares pursuant to conversion of Senior Convertible Notes	2,250	22	4,420	—	—	4,442
Cumulative translation loss	—	—	—	(3)	—	(3)
Amortization of shelf fees	—	—	(7)	—	—	(7)
Issuance of shares under Market Price Stock Purchase Plan	184	2	333	—	—	335
Issuance of direct placement — common stock		—	27,860	—	—	27,860
Issuance costs associated with direct placement	14,000	140	(1,610)			(1,470)
Net loss	—	—	—	—	(22,675)	(22,675)
BALANCE, JUNE 30, 2018	145,619	$ 1,456	$ 2,698,028	$ (18)	$ (2,906,085)	$ (206,619)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
BALANCE, JANUARY 1, 2019	187,030	$ 1,870	$ 2,763,067	$ (19)	$ (2,940,000)	$ (175,082)
Exercise of stock options	3	—	3	—	—	3
Issuance of common shares from the release of restricted stock units	63	1	(2)	—	—	(1)
Issuance of common shares under Employee Stock Purchase Plan	296	3	314	—	—	317
Stock-based compensation expense	—	—	1,104	—	—	1,104
Issuance of shares pursuant to conversion of Senior Convertible Notes	386	4	534	—	—	538
Net loss	—	—	—	—	(14,883)	(14,883)
BALANCE, MARCH 31, 2019	187,778	$ 1,878	$ 2,765,020	$ (19)	$ (2,954,883)	$ (188,004)
Exercise of stock options	14	—	$ 15	—	—	$ 15
Issuance of common shares from the release of restricted stock units	87	1	(1)	—	—	—
Stock-based compensation expense	—	—	2,568	—	—	2,568
Issuance of at-the-market placement	1,568	15	1,835	—	—	1,850
Issuance costs associated with at-the-market placement	—	—	(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)

See notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (27,270)	$ (53,060)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation, amortization and accretion	739	1,459
Amortization of right-of-use assets	618	—
Stock-based compensation expense	3,672	4,152
Loss on extinguishment of debt	—	53
(Gain) Loss on foreign currency translation	(688)	(2,379)
Interest on note payable to related party	2,297	2,219
Write-off of inventory	—	779
Other, net	—	106
Changes in operating assets and liabilities:		
Accounts receivable, net	(957)	(170)
Inventory	(366)	(1,798)
Prepaid expenses and other current assets	(150)	440
Right-of-use and other assets	(356)	79
Accounts payable	2,154	2,253
Accrued expenses and other current liabilities	460	818
Deferred revenue	(6,795)	2,049
Recognized loss on purchase commitments	(3,984)	(5,800)
Operating lease payments	(699)	—
Net cash used in operating activities	(31,325)	(48,800)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,493)	—
Purchase of short-term investments	(24,909)	—
Net cash used in investing activities	(26,402)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of stock options	18	—
Proceeds from direct placement of common stock	—	28,000
Issuance cost associated with direct placement	—	(1,610)
Principal payments on facility financing obligation	(2,500)	—
Payment of employment taxes related to vested restricted stock units	—	(184)
Proceeds from issuance of common stock pursuant to at-the-market issuance	1,850	634
Issuance cost of at-the-market transactions	(41)	(25)
Proceeds from executive stock purchase plan	—	335
Net cash (used) provided by financing activities	(673)	27,150
NET DECREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(58,400)	(21,650)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	71,684	48,355
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 13,284	$ 26,705
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	$ —	$ 1,860
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Payment of note obligations through common stock issuance	$ —	$ 20,405
Payment of note payable to related party through common stock issuance	$ —	$ 8,160
Accrued but unpaid debt issuance costs	$ —	$ 156
Payment of interest on senior convertible notes through common stock issuance	$ 538	$ —
Property and equipment in progress in accounts payable	$ 790	$ —
Common stock issuance to settle employee stock purchase plan liability	$ 317	—
Addition of right-of-use assets upon adoption of new lease guidance	$ 5,192	$ —

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 subsidiaries ("MannKind," the "Company," "we" or "us"), have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the "SEC"). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2018 filed with the SEC on February 26, 2019 (the "Annual Report").

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and six months ended June 30, 2019 may not be indicative of the results that may be expected for the full year.

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. The more significant estimates reflected in these accompanying condensed consolidated financial statements include revenue recognition and gross-to-net adjustments, assessing long-lived assets for impairment, inventory costing and recoverability, recognized loss on purchase commitments, 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 diseases such as diabetes and pulmonary arterial hypertension. The Company's only approved product, Afrezza (insulin human) Inhalation Powder, is a 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.

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. As of June 30, 2019, the Company had an accumulated deficit of $3.0 billion.

At June 30, 2019, the Company's capital resources consisted of cash and cash equivalents and restricted cash of $13.3 million and short-term investments of $24.9 million. The Company expects to continue to incur significant expenditures to support commercial manufacturing, sales and marketing of Afrezza, collaboration work and the development of product candidates in the Company's pipeline. The facility agreement (as amended, the "Facility Agreement" or "Facility Financing Obligation") with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (collectively, "Deerfield") that resulted in the issuance of 9.75% Senior Convertible Notes due 2019 ("2019 notes") (see Note 7 — Borrowings) as well as 8.75% Senior Convertible Notes (holder "Bruce & Co.") due 2019 ("Tranche B notes") which were repaid in full as of May 2019, requires the Company to maintain at least $25.0 million in cash and cash equivalents, including short-term investments, as of the end of each fiscal quarter after December 31, 2018.

At June 30, 2019, the Company had $99.2 million principal amount of outstanding borrowings. The Company has entered into certain transactions related to these borrowings that are more fully described in Note 6 — Related-Party Arrangements, and Note 7 – Borrowings.

The Company's currently available cash and financing sources will not be sufficient to continue to meet its current and anticipated cash requirements within one year from the date these financial statements are issued. The Company plans to raise additional capital through a sale of equity or debt securities, strategic business collaboration agreements with other companies, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the development and commercialization of Afrezza and other product candidates and to support its other ongoing activities. The Company cannot provide assurances that such additional capital will be available on acceptable terms or at all. Successful completion of these plans is dependent on factors outside of the Company's control. As such, management cannot be certain that such plans will be effectively implemented within one year after the date that the financial statements are issued. These factors raise substantial doubt about the Company's ability to continue as a going concern. The 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 subsidiaries. Intercompany balances and transactions have been eliminated.

Segment Information – Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating in the United States of America.

Revenue Recognition — The Company 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, up until December 31, 2018, 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"). These Customers 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 health care providers and 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 a point in time (based on the terms of the relevant contracts which are at delivery for wholesale distributors and at shipment 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. On a net basis, it is not probable that the Company will receive the consideration from these products. Therefore, the Company excludes such amounts from both gross and net revenue. The cost of product associated with the free goods program is included in the cost of goods sold.

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 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.

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 which 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 analyses also contemplates application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of June 30, 2019 and, therefore, the transaction price was not reduced further during the six months ended June 30, 2019. 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 incentive fees, 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 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 rate is estimated to be in the single-digits.

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 which 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 state Medicaid programs and Medicare. 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 which is included in accrued expenses and other current liabilities. 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 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 which 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: nonrefundable, 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 8 — Collaborations 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 approval and sales performance-based 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 to collaboration partners licenses to its intellectual property, supplies bulk fumaryl diketopiperazine (“FDKP”) 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.

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 also excludes the write-off of the cost of insulin held in inventory at the end of 2015.

Restricted Cash – 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.

Short-term Investments —The Company's short-term investments consist of U.S. Treasury securities stated at amortized cost which 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. The Company did not record any material gains or losses on these securities during the six months ended June 30, 2019.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. 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.

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 inventory also excludes the cost of insulin which was previously written off, in association with the insulin purchase agreement.

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.

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 is $93.6 million as of June 30, 2019. No new contracts were identified in 2019 or 2018 that required a new loss on purchase commitment accrual.

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.

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, restricted stock units, performance-based awards 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 subject to an estimated forfeiture rate. 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. Restricted stock units 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 six months ended June 30, 2019 and 2018 excludes the common stock equivalents of the following potentially dilutive securities because their inclusion, as the Company is in a net loss position, would be anti-dilutive:

	Six months ended June 30,	
	2019	2018
Vesting of restricted stock units	1,166,006	1,219,419
Conversion of convertible notes into common stock	3,629,627	14,154,500
Conversion of convertible related party notes into common stock	21,909,541	21,909,541
Exercise of common stock warrants	31,856	31,856
Employee stock purchase plan	367,792	248,067
Exercise of common stock options	15,512,639	11,368,356
Exercise of warrants associated with public offering	26,666,667	—
Exercise of warrants associated with direct placement	—	14,000,000
	69,284,128	62,931,739

Leases —The Company adopted Accounting Standards Codification ("ASC") Topic 842 – Leases ("the new lease guidance") on January 1, 2019. Under Topic 842, the Company is required to recognize the assets and liabilities that arise from most operating leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements.

Upon adoption of the new lease guidance, the Company recognized a lease liability to make lease payments and a right-of-use-asset representing its right to use the underlying asset for the applicable lease term using the optional transition method. In doing so, the Company elected the package of three practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company also elected the practical expedient that permits not separating lease and non-lease components for all classes of underlying assets. For short-term leases, the Company has elected not to apply the recognition requirements of this guidance. The Company did not elect to use the hindsight practical expedient.

Upon the adoption as of January 1, 2019, the impact on total assets and total liabilities was an increase of $5.2 million. The standard did not materially impact net earnings and had no net impact on cash flow. See Note 11 — Commitments and Contingencies for further information related to leases.

Recently Issued Accounting Standards – From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condensed consolidated financial position or results of operations upon adoption.

2. Accounts Receivable

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

	June 30, 2019	December 31, 2018
Accounts receivable, gross	$ 6,059	$ 5,198
Wholesaler distribution fees and prompt pay discounts	(716)	(868)
Reserve for returns	(369)	(313)
Accounts receivable, net	$ 4,974	$ 4,017

As of June 30, 2019 and December 31, 2018, the allowance for doubtful accounts was *de minimis*. As of June 30, 2019 and December 31, 2018, the Company had three wholesale distributors representing approximately 97% and 89% of gross accounts receivable, respectively.

3. Inventories

Inventories consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Raw materials	$ 1,140	$ 1,337
Work-in-process	1,333	1,605
Finished goods	1,490	655
Total inventory	$ 3,963	$ 3,597

Work-in-process and finished goods as of June 30, 2019 and December 31, 2018 include conversion costs but not insulin cost because the insulin used in its production was previously written off in 2015. 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 performed an assessment of projected sales and evaluated the lower of cost or net realizable value and the potential excess inventory on hand at June 30, 2019. 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 three and six months ended June 30, 2019, there was no inventory write-off. For the three and six months ended June 30, 2018, the Company recorded a $0.2 million and $0.8 million charge, respectively, to write-off inventory that may expire prior to being sold which was recorded as cost of goods sold.

4. Property and Equipment

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

	Estimated Useful Life (Years)	June 30, 2019	December 31, 2018
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	34,967	34,967
Machinery and equipment	3-15	61,217	61,217
Furniture, fixtures and office equipment	5-10	2,954	2,954
Computer equipment and software	3	8,355	8,355
Construction in progress	—	2,625	342
Total property and equipment, gross		128,382	126,099
Less accumulated depreciation		(101,236)	(100,497)
Total property and equipment, net		$ 27,146	$ 25,602

Depreciation expense related to property and equipment for the three and six months ended June 30, 2019 and 2018 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Depreciation Expense	$ 371	$ 445	$ 739	$ 886

5. Accrued Expenses and Other Current Liabilities

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

	June 30, 2019	December 31, 2018
Salary and related expenses	$ 7,223	$ 8,110
Current portion of milestone rights liability	1,643	1,643
Professional fees	711	741
Discounts and allowances for commercial product sales	2,819	2,656
Sales and marketing services	321	88
Accrued interest	733	492
Deferred lease liability	1,432	257
Other	1,570	1,035
Total accrued expenses and other current liabilities	$ 16,452	$ 15,022

6. Related-Party Arrangements

	June 30, 2019	December 31, 2018
Principal amount	$ 71,506	$ 71,506
Unamortized premium	520	639
Unaccreted debt issuance costs	(45)	(56)
Net carrying amount	$ 71,981	$ 72,089

(See also Note 13 — Subsequent Events) In October 2007, the Company entered into a loan agreement (the "Mann Group Loan Arrangement") with The Mann Group LLC ("The Mann Group"), which has been amended from time to time. On March 11, 2018, the Company amended and restated the Mann Group Loan Arrangement to, among other things, (i) reflect the current outstanding principal balance of the existing loan of $71.5 million, after giving effect to the partial cancelation of principal in exchange for shares of the Company's common stock described below; (ii) extend the maturity date of the loan to July 1, 2021; (iii) for periods beginning after April 1, 2018 require interest to compound quarterly; and (iv) permit the principal and any accrued and unpaid interest under the Mann Group Loan Arrangement to be converted, at the option of The Mann Group, at any time on or prior to close of business on the business day immediately preceding the stated maturity date, into shares of the Company's common stock. The conversion rate of 250 shares per $1,000 principal amount of the Note, which is equal to $4.00 per share subject to adjustment under certain circumstances as described in the Mann Group Loan Arrangement.

The Company analyzed this amendment and concluded that the transaction represented an extinguishment of the related party note and recorded a $0.8 million loss on extinguishment of debt. As a result of the extinguishment the Company recorded a debt premium of $0.8 million and debt issuance costs of $0.1 million during 2018.

On March 11, 2018, the Company and The Mann Group entered into a common stock purchase agreement pursuant to which the Company agreed to issue to The Mann Group and The Mann Group agreed to purchase 3,000,000 shares of the Company's common stock at a price per share of $2.72 which represented the closing price of the Company's common stock on March 9, 2018. As payment for the purchase price for the shares, The Mann Group agreed to cancel $8.2 million in principal amount under the Mann Group Loan Arrangement, with the principal payment to be reflected in the amended and restated Mann Group Loan Arrangement. The purchased shares were issued in a private placement.

Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. Under the agreement, accrued and unpaid interest may be capitalized and paid-in-kind. The Mann Group can require the Company to prepay up to $200.0 million in advances that have been outstanding for at least 12 months, less approximately $105.0 million aggregate principal amount that has been cancelled in connection with three common stock purchase agreements. If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice, or the number of days to maturity of the note if less than 90 days, to prepay such advances. However, pursuant to a letter agreement entered into on August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. In addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under the Mann Group Loan Arrangement until the Company's payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group's option, and the interest rate will increase to the one-year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under the Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

As of June 30, 2019 and December 31, 2018, the Company had accrued unpaid interest related to the above note of $9.1 million and $6.8 million, respectively. As of June 30, 2019 there were no additional amounts available for future borrowings. Interest expense (excluding the amortization of debt premium and debt issuance costs) for the three and six months ended June 30, 2019 and 2018 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Interest expense on note payable to related party (excluding amortization of debt premium and debt issuance costs)	$ 1,109	$ 1,040	$ 2,189	$ 2,160

Amortization of the premium and accretion of debt issuance costs related to the related party notes for the three and six months ended June 30, 2019 and 2018 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Amortization of debt premium	$ 61	$ 57	$ 120	$ 67
Accretion expense - debt issuance cost	$ 6	$ 6	$ 11	$ 8

The Company has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws (see Note 11 —Commitments and Contingencies).

7. Borrowings

Carrying amount of borrowings consist of the following, exclusive of $9.1 million accrued interest owed to the related party that will be capitalized and paid-in-kind (in thousands):

	June 30, 2019	December 31, 2018
Facility financing obligation	$ 8,974	$ 11,298
Senior convertible notes	19,031	19,099
Note payable to related party	71,981	72,089
Total debt - net carrying amount	$ 99,986	$ 102,486

These borrowings are further described below:

Facility Financing Obligation – On July 1, 2013, the Company entered into the Facility Agreement, which permitted it to borrow $160.0 million through the issuance of the 2019 notes, $100.0 million of which were converted into shares of the Company's common stock during 2013 and 2014. The Company and Deerfield amended the Facility Agreement in 2014 to permit the Company to borrow an additional $20.0 million through the issuance of Tranche B notes. The remaining $80.0 million in principal amount that was not converted during 2013 and 2014 ($60.0 million in 2019 notes and $20.0 million in Tranche B notes) is subject to a repayment schedule that began in July 2016 and will end in August 2019. As of June 30, 2019, the Facility Financing Obligation consisted of $9.0 million principal amount and $0.2 million unamortized issuance cost. The table below summarizes all principal payments since July 2016, indicating whether the amount was settled in cash or in exchange for the issuance of shares of the Company's common stock:

Date	2019 notes	Tranche B notes
July 2016	$5.0 million (cash)	
April 2017	$5.0 million (equity exchange)	$4.0 million (cash) $1.0 million (equity exchange)
June 2017	$5.0 million (equity exchange)	
November 2017	$5.6 million (equity exchange)	
January 2018	$3.2 million (equity exchange)	
March 2018	$1.3 million (equity exchange)	$5.0 million (equity exchange)
June 2018	$3.0 million (equity exchange)	$3.0 million (equity exchange)
July 2018	$2.0 million (cash) $10.0 million (equity exchange)	$2.0 million (equity exchange)
September 2018	$8.0 million (equity exchange)	$2.5 million (equity exchange)
October 2018	$3.0 million (cash)	
May 2019		$2.5 million (cash)
July 2019	$2.4 million (cash)	
	$1.6 million (equity exchange)	

The Facility Agreement includes customary representations, warranties and covenants, including a restriction on the incurrence of additional indebtedness. On July 18, 2019, outstanding 2019 notes in the principal amount of $4.0 million were repaid. The Facility Agreement also required the Company to deposit $5.0 million in an escrow account, which is classified as restricted cash in the condensed consolidated balance sheets as of June 30, 2019, until August 31, 2019. See Note 13 – Subsequent Events. As discussed in Note 1 – Description of Business and Summary of Significant Accounting Policies, the Company will need to raise additional capital to support its current operating plans.

Accretion of debt issuance cost and debt discount during the three and six months ended June 30, 2019 and 2018, are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Amortization of debt discount	$ 69	$ 385	$ 141	$ 698
Accretion expense - debt issuance cost	$ 21	$ 10	35	$ 17

Milestone Rights — On July 1, 2013, in conjunction with the execution of the Facility Agreement, the Company issued to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÀRL, (the "Milestone Purchasers") certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, $75.0 million of which remains payable upon achievement of such milestones (the "Milestone Rights").

As of June 30, 2019 and December 31, 2018, the remaining Milestone Rights liability balance was $8.9 million which is based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. The Company currently estimates that it will reach the next milestone in the third quarter of 2019, 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 $1.6 million, which represents the fair value related to this payment that was determined in 2013 (the most recent measurement date). Accordingly, $1.6 million in value related to the next milestone payment was recorded in accrued expenses and other current liabilities as of June 30, 2019 and December 31, 2018, resulting in $7.2 million being recorded in Milestone Rights liability, which is non-current, in the accompanying condensed consolidated balance sheets as of June 30, 2019 and December 31, 2018, respectively.

The Milestone Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to Afrezza. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to Afrezza in violation of the terms of the Milestone Agreement. The Company has initially recorded the Milestone Rights at their estimated fair value.

Security Agreement — In connection with the Facility Agreement and Milestone Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the "Security Agreement") with Deerfield and Horizon Santé FLML SÁRL (collectively, the "Purchasers"), pursuant to which the Company and MannKind LLC each granted the Purchasers a security interest in substantially all of their respective assets, including respective intellectual property, accounts receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Security Agreement includes customary covenants by the Company and MannKind LLC, remedies of the Purchasers and representations and warranties by the Company and MannKind LLC. The security interests granted by the Company and MannKind LLC will terminate upon repayment of the Facility Financing Obligation in full, if applicable.

Embedded Derivatives — The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. The Company analyzed the Tranche B notes and identified embedded derivatives which required separate accounting. All of the embedded derivatives were determined to have a *de minimis* value as of December 31, 2018 and no value as of June 30, 2019 due to the repayment of the Tranche B notes in full in May 2019.

Senior Convertible Note — (See also Note 13 – Subsequent Events) In October 2017, the Company entered into exchange agreements with the holders of the Company's 5.75% Senior Convertible Notes due 2018 (the "2018 notes"), pursuant to which the Company agreed to exchange all of the outstanding 2018 notes in the aggregate principal amount of $27.7 million for (i) new 5.75% $23.7 million aggregate principal amount of Senior Convertible notes due 2021 (the "2021" notes or "senior convertible note") and (ii) an aggregate of 973,236 shares of its common stock. In addition, the conversion rate was adjusted from $34 per share to $5.15 per share. The senior convertible notes were issued at the closing of the exchange on October 23, 2017. The Company analyzed this exchange and concluded that the exchange represents an extinguishment of the 2018 notes and recorded a $0.8 million loss on extinguishment of debt during the last quarter of fiscal year 2017. In addition, unamortized debt issuance costs of $0.3 million and unamortized debt premium of $0.2 million were also written-off during the last quarter of fiscal year 2017.

In May 2018, the Company entered into a privately-negotiated exchange agreement (the "Exchange Agreement") with certain holders of its senior convertible notes, pursuant to which the Company agreed to issue 2,250,000 shares of its common stock in exchange for the cancellation of $5.0 million principal amount of the senior convertible notes and unpaid accrued interest thereon. The exchange price for these exchange shares was $2.2567 per share. The exchange was completed on May 31, 2018. As a result, the Company recognized approximately $0.8 million as extinguishment gain which was calculated based on the difference between the reacquisition price and the net carrying amount of the payment on the debt.

As of June 30, 2019 and December 31, 2018, there was $18.7 million principal amount of senior convertible notes outstanding. The senior convertible notes are the Company's general, unsecured, senior obligations, except that they are subordinated in right of payment to the Facility Financing Obligation. The senior convertible notes rank equally in right of payment with the Company's other unsecured senior debt. The senior convertible notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash or, at the option of the Company — subject to certain conditions and limitations — in shares of the Company's common stock (the "Interest Shares"), on February 15 and August 15. Accrued interest related to these notes is recorded in accrued expenses and other current liabilities on the accompanying condensed consolidated balance sheets.

The senior 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 an initial conversion rate of 194.1748 shares per $1,000 principal amount of senior convertible notes, which is equal to the initial conversion price of approximately $5.15 per share. The conversion rate is subject to adjustment under certain circumstances described in an indenture governing the senior convertible notes.

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of senior convertible notes will have the option to require the Company to repurchase all or any portion of that holder's senior convertible notes. The fundamental change repurchase price will be 100% of the principal amount of the senior 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 senior convertible notes to be mandatorily converted in whole or 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 exceeds 120% of the conversion price then in effect for at least 10 trading days in any 20 consecutive trading day period, ending within five business days prior to the date of the mandatory conversion notice. The redemption price is equal the sum of 100% of the principal amount of the senior convertible notes to be redeemed, plus accrued and unpaid interest. Under the terms of the indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the indenture is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the term of the senior convertible notes under existing commitments. Applying the Company's sequencing policy, the Company performed an analysis at the time of the offering of the senior convertible notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each reporting date since was sufficient to deliver the number of shares that could be required to be delivered during the term of the senior convertible notes under existing commitments.

The senior convertible notes provide that upon acceleration of certain indebtedness, including the Facility Financing Obligation, the holders may elect to accelerate the Company's repayment obligations under the notes if such acceleration is not cured, waived, rescinded or annulled.

As a result of the exchange of the senior convertible notes during the last quarter of 2017, the Company recorded approximately $0.8 million in debt premium, which is recorded with the senior convertible notes, in the accompanying condensed consolidated balance sheets. The premium is being accreted to interest expense using the effective interest method over the term of the senior convertible notes.

Amortization of the premium and accretion of debt issuance costs related to the 2021 notes for the three and six months ended June 30, 2019 and 2018 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Amortization of debt premium	$ 36	$ 40	$ 72	$ 83
Accretion expense - debt issuance cost	2	$ 1	$ 4	$ 1

Refer to Note 6 – Related Party Arrangements for information regarding the Note payable to related party.

8. Collaborations and Licensing Arrangements

Revenue from collaborations and services for the three and six months ended June 30, 2019 and 2018 are as follows (in thousands):

	Three Months ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
UT License Agreement	$ 7,779	$ —	$ 15,394	$ —
UT Research Agreement	1,058	—	5,716	—
Receptor Collaboration and License Agreement	63	62	125	125
Cipla License and Distribution Agreement	37	25	74	25
	$ 8,937	$ 87	$ 21,309	$ 150

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 and associated inhalation delivery devices. Under the UT License Agreement, UT will be responsible for global development, regulatory and commercial activities with respect to Treprostinil (internally designated "TreT"). The Company will manufacture clinical supplies and initial 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 a $12.5 million milestone payment on March 29, 2019. The Company may receive additional milestone payments of up to $37.5 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. 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. During the three and six months ended June 30, 2019, the Company recognized $7.8

million and $15.4 million, respectively, as revenue - collaborations and services. The total deferred revenue consists of $40.8 million of which $32.4 million is current and $8.4 million is long term. 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 regarding that revenue will be completed within the next 12 months, and includes payments received as well as payments receivable.

The Company has evaluated the UT License Agreement in accordance with the revenue recognition requirements pursuant to ASC 606:

> 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 covered 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 if and when it is exercised.
>
> The Company expects to complete the activities specified in the development plan and to achieve the remaining milestone events for total consideration of approximately $100.4 million, which includes an upfront payment, four milestone payments and various pass-through costs. Future commercial supply remains at UT's option, is valued at a stand-alone selling price and is therefore not accounted for the current arrangement. The Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation.

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. 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 if and when it is exercised.

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 is recognized using an output method (based on project milestones achieved and surveys of performance completed to date). The Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation. The revenue for the engineering consulting services is recognized using a ratable method until the obligation is satisfied and the Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation. During the three and six months ended June 30, 2019, the Company recognized $1.1 million and $5.7 million as revenue - collaborations and services, respectively. As of June 30, 2019 the deferred revenue balance was $0.5 million.

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 $1.3 million in signing fees and upfront license fees. Under the CLA, the Company may also receive nonrefundable 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.

The $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. Deferred revenue related to this contract was $0.4 million at June 30, 2019 of which $0.3 million was recorded in current liabilities.

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. Therefore, the receipt of such payments is highly susceptible to factors outside of the Company's influence, the uncertainty regarding the receipt of these payments is not expected to be resolved for years, and the Company has limited experience with similar contracts. There was no change to the accounting for this contract as a result of the initial application of the new revenue guidance. See Note 1 – Description of Business and Summary of 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 six months ended June 30, 2019 and 2018 the additional research and formulation services provided to Receptor were *de minimis*.

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 certain additional regulatory milestone payments, 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. The Company also recognized $0.2 million as income tax expense for a payment made to the India tax authority in 2018. Deferred revenue related to this contract was $2.0 million at June 30, 2019, of which $0.1 million was recorded in current liabilities.

Biomm Supply and Distribution Agreement – In May 2017, the Company and Biomm S.A. entered into a supply and distribution agreement for the commercialization of Afrezza in Brazil. Under this agreement, Biomm is responsible for preparing and filing the necessary applications for regulatory approval 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"). Afrezza was approved by ANVISA during the second quarter of 2019; registration by CMED is still pending. The Company will manufacture and supply Afrezza to Biomm, and Biomm will be responsible for promoting and distributing Afrezza within Brazil.

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.

9. 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, note payable to related party (also referred to as The Mann Group Loan Arrangement), senior convertible notes, the Facility Financing Obligation and the Milestone Rights liability are disclosed below.

Cash Equivalents and restricted cash— Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase that are readily convertible into cash. As of June 30, 2019 and December 31, 2018, the Company held $8.0 million and $71.2 million, respectively, of cash and cash equivalents. Restricted cash is held in an escrow account as well as used to collateralize a letter of credit. The Company held $5.3 million and $0.5 million in restricted cash as of June 30, 2019 and December 31, 2018, respectively. Both are comprised of money market funds. 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. As of June 30, 2019 the Company held $24.9 million of short-term investments in U.S. Treasury bills or notes. 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).

Note Payable to Related Party — The fair value measurement of the note payable is based on discounted cash flow model and it is sensitive to the change in yield (Level 3 in the fair value hierarchy). If the yield increases by approximately 2% from 23% to 25%, the fair value of the note payable with the conversion feature would change from $59.5 million to $57.9 million, or a decrease of $1.6 million and 2.7%; if the yield decreases 2% from 23% to 21%, the fair value of the note payable with conversion feature would change from $59.5 million to $61.2 million, or an increase of $1.7 million or 2.9%. If the yield increases by approximately 4% from 23% to 27%, the fair value of the note payable with the conversion feature would change from $59.5 million to $56.3 million, or a decrease of $3.2 million and 5.4%; if the yield decreases 4% from 23% to 19%, the fair value of the note payable with conversion feature would change from $59.5 million to $62.9 million, or an increase of $3.4 million and 5.7%.

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

	June 30, 2019		
	Carrying Amount	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
Facility financing obligation	$ 9.0	$ 9.0	$ 9.0
Senior convertible notes	19.0	18.0	18.0
Note payable to related party	72.0	59.5	59.5
Milestone rights	8.9	18.5	18.5
Total financial liabilities	$ 108.9	$ 105.0	$ 105.0

	December 31, 2018		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
Facility financing obligation	$ 11.3	$ 11.4	$ 11.4
Senior convertible notes	19.1	17.5	17.5
Note payable to related party	72.1	55.0	55.0
Milestone rights	8.9	18.1	18.1
Total financial liabilities	$ 111.4	$ 102.0	$ 102.0

Milestone Rights Liability — The fair value measurement of the Milestone Rights liability is sensitive to the discount rate and the timing and probability of making milestone payments. If the achievement of each of the milestones which require payments were to be six months later than in the current forecast, the fair value of the liability would decrease by 6%. If the probabilities of meeting the $50.0 million to $200.0 million milestones were to decrease by 5% or 10%, the fair value of the liability would decrease by 13% and 24%, respectively. Over the long term, these inputs are interrelated because if the Company's performance improves, the timing of meeting the milestones would likely be earlier, the probability of making payments on the milestones would likely be higher and the discount rate would likely decrease, all of which would increase the fair value of the liability. The inverse is also true.

Embedded Derivatives — The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. The Company analyzed the Tranche B notes and identified embedded derivatives, which required separate accounting. All of the embedded derivatives were determined to have a *de minimis* value at December 31, 2018 and no value as of June 30, 2019 due to the repayment of the Tranche B notes in full in May 2019.

10. Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2019 and 2018 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock-based compensation	$ 2,568	$ 2,209	$ 3,672	$ 4,152

During the three months ended June 30, 2019, the Company issued 533,361 restricted units to the Company's board of directors which vest immediately. The grant date fair value of the restricted stock units was $0.7 million with a weighted average grant date fair value per share of $1.32. These restricted stock units will not be delivered to the Company's board of directors until separation of services.

During the three months ended June 30, 2019, the Company granted certain employees stock options to purchase an aggregate of 4,985,363 shares of common stock at a weighted average exercise price of $1.32 per share. The options vest over a four year period. The total grant date fair value of these awards is $6.6 million as determined using a Black-Scholes option pricing model.

During the six months ended June 30, 2019, the Company granted certain employees stock options to purchase an aggregate of 5,333,303 shares of common stock at a weighted average exercise price of $1.33 per share. The options vest over a four year period. The grant date fair value of these awards is $6.1 million with a weighted average grant date fair value of $1.15 per share, as determined using a Black-Scholes option pricing model.

In the Condensed Statements of Stockholders' Deficit and the Condensed Consolidated Statements of Cash Flows, the prior quarter's stock-based compensation expense is inclusive of expenses associated with restricted stock unit awards in order to conform to the current quarter presentation.

As of June 30, 2019, there were $2.2 million and $12.5 million of unrecognized compensation expense related to restricted stock units and options, respectively, which vest over the vesting period except for certain options that are subject to performance conditions. The Company evaluates performance conditions as the probability that the performance conditions will be met and uses that information to estimate the date at which those performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

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 June 30, 2019, 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 Sanofi's election to terminate a license and collaboration agreement (the "Sanofi License Agreement") between the Company and sanofi-aventis U.S. LLC ("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 has appealed this ruling, and following an oral hearing before the Supreme Court of Israel, has decided to withdraw his appeal. Subsequently, in November 2018, the Company filed a motion to dismiss the certification motion. At a case conference in February 2019, the court directed the parties to negotiate a procedure for determining whether the plaintiff can distinguish the claims in the Israeli litigation from those in a U.S. case against the Company based on the same events (which was dismissed by the U.S. district court for the Central District of California in August 2016). In July 2019, the plaintiff asked the court to be allowed to amend his claim. This motion will be heard in September 2019. The Company will continue to vigorously defend against the claims advanced.

Contingencies — In connection with the Facility Agreement, on July 1, 2013, the Company also entered into a Milestone Agreement with the Milestone Purchasers, pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, $75.0 million of which remains payable upon achievement of such milestones (see Note 7 – Borrowings).

Commitments — On July 31, 2014, the Company entered into a supply agreement (the "Insulin Supply Agreement") with Amphastar France Pharmaceuticals S.A.S., a French corporation ("Amphastar"), pursuant to which Amphastar manufactures for and supplies to the Company certain quantities of recombinant human insulin for use in Afrezza. Under the terms of the Insulin Supply Agreement, Amphastar is responsible for manufacturing the insulin in accordance with the Company's specifications and agreed-upon quality standards.

In December 2018, the Insulin Supply Agreement with Amphastar was amended to extend the term over which the Company is required to purchase insulin, without reducing the total amount of insulin to be purchased. Under the amendment, annual minimum quantities of insulin to be purchased for calendar years 2018 through 2024 total an aggregate purchase price of €90.3 million. As of June 30, 2019, the remaining purchase amount is €82.3 million. See also Note 13 – Subsequent Events.

2019	€	2.3 million
2020	€	15.9 million
2021	€	15.9 million
2022	€	19.8 million
2023	€	19.8 million
2024	€	8.6 million

Unless terminated earlier, the term of the Insulin Supply Agreement expires on December 31, 2024 and can be renewed for additional, successive two year term 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. On April 1, 2019, the Company entered into a foreign currency hedging transaction to mitigate its exposure to foreign currency exchange risks. The hedging transaction hedges against short-term currency fluctuations for the remaining current year purchase requirement amount of €3.9 million and is renewable every 90 days. The Company realized a *de minimis* currency loss during second quarter of 2019. This amount is recorded in other income and expense.

Warrants - On April 5, 2018, the Company entered into securities purchase agreements with certain institutional investors. Pursuant to the terms of the purchase agreements, the Company sold to the purchasers in a registered offering an aggregate of 14,000,000 shares of its common stock and warrants to purchase up to an aggregate of 14,000,000 shares of its common stock at a combined purchase price of $2.00 per share and accompanying warrant. The shares of the common stock and the warrants were immediately separable. The Company determined that these warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital. The warrants were exercisable at a price of $2.38 per share and all warrants expired unexercised on April 9, 2019.

On December 19, 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 are exercisable at a price of $1.60 per share and will expire on December 26, 2019. The net proceeds to the Company from the offering were approximately $37.3 million. The offering closed on December 26, 2018. The Company determined that the December warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital.

Vehicle Leases – During the second quarter of 2018, the Company entered into a lease agreement with Enterprise Fleet Management Inc. for the lease of approximately 119 vehicles. The lease requires monthly payments of approximately $83,000 per month including the cost of maintaining the vehicles, taxes and insurance. This amount excludes other variable payments such as storage fees. 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 the second quarter of 2019, 23 vehicles were removed from the fleet, resulting in a fleet size of 96 vehicles; no gain or loss was recorded. The revised monthly payment inclusive of maintenance fees, insurance and taxes is $69,000 and the reduction of the right of use asset and lease obligation is approximately $0.3 million in our condensed consolidated balance sheets. The lease expense is included in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations for the three and six months ended June 30, 2019.

Upon adoption of the new lease guidance, the agreement was classified as an operating lease which resulted in recording right-of-use assets and lease liabilities of approximately $1.6 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 — On May 5, 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 for three and six months ended June 30, 2019.

On November 29, 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 3% annual increases, plus the estimated operating costs 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 the new guidance, 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.

Operating lease costs under all operating leases including office space and equipment for the three and six months ended June 30, 2019 was approximately $0.3 million and $0.8 million, respectively. Cash paid for all operating leases for the three and six months ended June 30, 2019 was $0.2 million and $0.7 million, respectively. Variable lease costs were approximately $0.1 million and $0.2 million for the three and six months ended June 30, 2019, respectively. The weighted average discount rate used was 7.2%. The weighted-average remaining lease term for all operating leases is 3.6 years.

Rent expense under all operating leases for the three and six months ended June 30, 2018 including office space and equipment was approximately $0.1 million and $0.2 million, respectively, prior to the adoption of ASC topic 842.

Future minimum office and vehicle lease payments as of June 30, 2019 and December 31, 2018, are as follows:

	June 30, 2019	December 31, 2018
2019 (Remainder)	$ 742,078	$ 1,595,421
2020	1,503,192	1,623,835
2021	1,532,458	1,653,101
2022	1,254,828	1,305,096
2023	87,957	87,957
	$ 5,120,513	$ 6,265,410

The 2018 amounts above are inclusive of office and vehicle lease payments in order to conform to the current year presentation.

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

13. Subsequent Event

July 2019 Exchange Agreement

On July 18, 2019, the Company entered into an exchange agreement with Deerfield pursuant to which the Company agreed to, among other things, (i) repay approximately $2.4 million in aggregate principal amount under the 2019 notes held by Deerfield (the "Tranche 4 Notes") and pay accrued and unpaid interest on the entire principal amount of the Tranche 4 Notes that had been outstanding, and (ii) issue an aggregate of 1,514,423 shares of the Company's common stock (the "Exchange Shares") to Deerfield in exchange for approximately $1.6 million in aggregate principal amount of Tranche 4 Notes. The exchange price per Exchange Share was $1.04, which was the closing price of the Company's common stock on July 17, 2019 as reported on the Nasdaq Stock Market. The principal amount repaid and exchanged under the Tranche 4 Notes represented the principal amount that would have otherwise become due and payable on July 18, 2019 under the Tranche 4 Notes.

Warrants Repurchase

On July 18, 2019, the Company repurchased for approximately $433,000 a December warrant to acquire 3,333,334 shares of the Company's common stock. Following the repurchase of the December warrant, it was cancelled and is no longer issued and outstanding.

Amphastar Amendment

On August 2, 2019, the Company and Amphastar amended the Insulin Supply Agreement to extend the term an additional two years (to December 31, 2026) and to restructure the annual purchase commitments as follows:

	As of June 30, 2019	As amended August 2, 2019
2019	€ 2.3 million	€ —
2020	€ 15.9 million	€ 6.6 million
2021	€ 15.9 million	€ 6.6 million
2022	€ 19.8 million	€ 8.5 million
2023	€ 19.8 million	€ 10.9 million
2024	€ 8.6 million	€ 14.6 million
2025	€ —	€ 15.5 million
2026	€ —	€ 19.4 million

In connection with this amendment, the Company is obligated to pay amendment fees of $1.5 million by September 15, 2019 and $1.25 million by December 15, 2019.

MidCap Credit Facility

On August 6, 2019 (the "Closing Date"), MannKind Corporation ("MannKind") entered into a Credit and Security Agreement (the "MidCap Credit Facility"), by and among MannKind, MannKind LLC, the Company's wholly owned subsidiary ("MannKind LLC", and together with MannKind, collectively, the "Company"), the lenders party thereto from time to time and MidCap Financial Trust ("MidCap"), as agent.

The MidCap Credit Facility provides a secured term loan facility in 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") will be available to the Company until April 15, 2020, subject to the Company's satisfaction of certain conditions described in the MidCap Credit Facility, including the Company achieving Afrezza Net Revenue (as defined in the MidCap Credit Facility) of at least $30.0 million on a trailing twelve month basis. Under the terms of the MidCap Credit Facility, 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 TreT .

Tranche 1 and, if borrowed, Tranche 2 and Tranche 3, each accrue interest at an annual rate equal to LIBOR plus 6.75%, subject to a LIBOR floor of 2.00%. Interest on each term loan advance is due and payable monthly in arrears. Principal on each term loan advance under Tranche 1 and Tranche 2 is payable in 36 equal monthly installments beginning September 1, 2021, until paid in full on August 1, 2024, and principal on each 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 $375,000 origination fee.

Upon termination of the MidCap Credit Facility, the Company is required to pay an exit fee equal to 6.00% of the principal amount of all term loans advanced to the Company under the MidCap Credit Facility.

The Company's obligations under the MidCap Credit Facility are secured by a security interest on substantially all of its assets, including intellectual property. Additionally, the Company's future subsidiaries, if any, may be required to become co-borrowers or guarantors under the credit facility.

The MidCap Credit Facility contains customary affirmative covenants and customary negative covenants limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, dispose of assets, undergo a change in control, merge or consolidate, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The Company must also comply with a financial covenant relating to trailing twelve month minimum Afrezza Net Revenue requirements (as defined in the MidCap Credit Facility), tested on a monthly basis, and a minimum cash covenant of $15.0 million at all times prior to the funding of Tranche 2, and $20.0 million at all times following the funding of Tranche 2 or Tranche 3.

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 MannKind'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 MannKind'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 "Tranche 1 Warrants"). 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.

Exchange of 2021 Convertible Notes for 2024 Convertible Notes and the Indenture for the 2024 Convertible Notes

On August 6, 2019, MannKind entered into a privately-negotiated exchange agreement (the "2021 Note Exchange Agreement") with Bruce & Co., Inc., for itself and on behalf of the beneficial owners of the holders of MannKind's outstanding 2021 notes, pursuant to which MannKind agreed to, among other things, (i) repay $1,470,147 in cash to such holders ($1,500,000 less the amount of interest accruing under the 2021 notes between August 6, 2019 and August 15, 2019), (ii) issue 4,017,857 shares of MannKind's common stock to such holders (at a conversion price of $1.12 per share), (iii) issue new 5.75% Convertible Senior Subordinated Exchange Notes due 2024 (the "2024 convertible notes") to such holders pursuant to the provisions of an indenture (the "Indenture") in an aggregate principal amount of $5,000,000 and (iv) issue two non-interest bearing promissory notes to such holders, each in the amount of $2,630,750, one of which will mature on June 30, 2020 (the "June 2020 note") and the other of which will mature on December 31, 2020 (the "December 2020 note", and together with the June 2020 note, the "2020 notes"), 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 at the option of MannKind. In addition, MannKind may elect to pay the 2020 notes at any time on or prior to their respective maturity dates, if certain conditions are met, in shares of MannKind's common stock at a price per share equal to the last reported sale price on the trading day immediately prior to the payment date. The exchange pursuant to the 2021 Note Exchange Agreement was effected on August 6, 2019.

The 2024 convertible notes were issued pursuant to an indenture, dated as of August 6, 2019, between MannKind and U.S. Bank National Association, as trustee. The 2024 convertible notes are MannKind'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 MannKind'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 MannKind if certain conditions are met, in shares of MannKind'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 will be 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 MannKind'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. The conversion rate will be subject to adjustment under certain circumstances described in the Indenture.

The Indenture includes customary events of default, including:

(1) the Company fails to pay when due the principal of or premium, if any, on any of the 2024 convertible notes at maturity, upon repurchase, acceleration or otherwise;

(2) the Company fails to pay an installment of interest on any of the 2024 convertible notes for 30 days after the date when due;

(3) the Company fails to deliver when due all shares of the Company's common stock, together with cash instead of fractional shares, and/or other property, if applicable, deliverable upon conversion of the 2024 convertible Notes, which failure continues for 10 days;

(4) the Company fails to perform or observe any other term, covenant or agreement contained in the 2024 convertible notes or the Indenture for a period of 60 days after written notice of such failure, requiring the Company to remedy the same, shall have been given to the Company;

(5) (i) the Company fails to make any payment by the end of the applicable grace period, if any, after the maturity of any indebtedness for borrowed money in an amount in excess of $25,000,000 or (ii) there is an acceleration of any indebtedness for borrowed money in an amount in excess of $25,000,000 because of a default with respect to such indebtedness without such indebtedness having been discharged or such acceleration having been cured, waived, rescinded or annulled, in the case of either (i) or (ii) above, for a period of 30 days after written notice to the Company;

(6) the Company fails to provide a fundamental change company notice; and

(7) certain events of bankruptcy, insolvency or reorganization of the Company.

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.

If MannKind undergoes certain fundamental changes, except in certain circumstances, each holder of 2024 convertible notes will have the option to require MannKind 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.

MannKind 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.

Exchange of Mann Group Note

On August 5, 2019, MannKind entered into a privately-negotiated exchange agreement (the "Mann Group Exchange Agreement") with The Mann Group, pursuant to which MannKind agreed to, among other things, (i) repay $3,000,000 in cash to the Mann Group, (ii) issue 7,142,857 shares of MannKind's common stock to the Mann Group (at a conversion price of $1.12 per share), (iii) issue a new convertible promissory note (the "Mann Group Convertible Note") to the Mann Group in an aggregate principal amount of $35,000,000 and (iv) issue a new non-convertible promissory note (the "Mann Group Non-Convertible Note," together with the Mann Group Convertible Note, the "New Mann Group Loan Arrangement") to the Mann Group in an aggregate principal amount of $35,050,750, in exchange for the cancellation of the $70.1 million in principal amount and accrued interest on the amended and restated promissory note dated March 11, 2018 held by the Mann Group.

The Mann Group Convertible Note and Mann Group Non-Convertible Note will 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 MannKind'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, 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 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.

August 2019 Exchange Agreement

On August 6, 2019, the Company entered into an Exchange Agreement (the "Deerfield Exchange Agreement") with Deerfield pursuant to which the Company agreed to, among other things, (i) repay $2,000,000 of the aggregate principal amount under the 2019 notes held by Deerfield (the "Deerfield Tranche 1 Notes") and pay all accrued and unpaid interest on the Deerfield Tranche 1 Notes then-outstanding, (ii) issue an aggregate of 2,678,571 shares of MannKind's common stock to Deerfield in exchange for $3,000,000 aggregate principal amount of Deerfield Tranche 1 Notes and (iii) cancel the Deerfield Tranche 1 Notes. The principal amount being repaid and exchanged under the Deerfield Tranche 1 Notes represents the final outstanding principal amount that would otherwise have become due and payable on August 31, 2019.

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, 2018 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 patients with diseases such as diabetes and pulmonary arterial hypertension. Our only approved product, Afrezza, is a 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.

As of June 30, 2019, we had an accumulated deficit of $3.0 billion and a stockholders' deficit of $196.0 million. We had a net loss of $12.4 million and $27.3 million for the three and six months ended June 30, 2019, respectively. We have funded our operations primarily through the sale of equity and convertible debt securities; the receipt of upfront and milestone payments under the Sanofi License Agreement and under the UT License Agreement; and borrowings under the Facility Agreement with Deerfield, under the Mann Group Loan Arrangement and under a senior secured revolving promissory note that we entered into with an affiliate of Sanofi in September 2014 in connection with the Sanofi License Agreement (the "Sanofi Loan Facility"), which was terminated in 2016. In August 2019, we entered into the MidCap Credit Facility, which will allow us to borrow up to $75.0 million to provide additional funding for our operations. As discussed below in "Liquidity and Capital Resources," if we are unable to obtain additional funding, there is substantial doubt about our ability to continue as a going concern.

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 successfully commercialize Afrezza and manufacture sufficient quantities of Afrezza, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights. Additional 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.

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, 2018. See Note 1 – Description of Business and Significant Accounting Policies in the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited) for descriptions of the new accounting policies and impact of adoption.

RESULTS OF OPERATIONS

Three and six months ended June 30, 2019 and 2018

Revenues

The following tables provide a comparison of the revenue categories for the three and six months ended June 30, 2019 and 2018 (dollars in thousands):

	Three Months Ended June 30,			
	2019	2018	$ Change	% Change
Revenues:				
Net revenue - commercial product sales:				
Gross revenue from product sales	$ 10,339	$ 6,702	$ 3,637	54%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(4,274)	(2,949)	(1,325)	45%
Net revenue - commercial product sales	6,065	3,753	2,312	62%
Revenue - collaborations and services	8,937	87	8,850	10,172%
Revenue - other	—	53	(53)	(100%)
Total revenues	$ 15,002	$ 3,893	$ 11,109	285%

	Six Months Ended June 30,			
	2019	2018	$ Change	% Change
Revenues:				
Net revenue - commercial product sales:				
Gross revenue from product sales	$ 18,546	$ 11,898	$ 6,648	56%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(7,405)	(4,743)	(2,662)	56%
Net revenue - commercial product sales	11,141	7,155	3,986	56%
Revenue - collaborations and services	21,309	150	21,159	14,106%
Revenue - other	—	53	(53)	(100%)
Total revenues	$ 32,450	$ 7,358	$ 25,092	341%

Gross revenue from the sales of Afrezza for the quarter ended June 30, 2019 increased by $3.6 million, or 54%, compared to the same quarter in the prior year, primarily driven by higher product demand and price increases, as well as a more favorable mix of Afrezza cartridges. The gross-to-net adjustment was $4.3 million (or 41% of gross revenue) for the quarter ended June 30, 2019 compared to $2.9 million (or 44% of gross revenue) for the same quarter in the prior year. The lower percentage was primarily due to lower commercial and government rebates, partially offset by a higher rate of product returns.

Net revenue from collaborations and services for the quarter ended June 30, 2019 increased by $8.9 million compared to the same quarter in the prior year, primarily attributable to the UT License Agreement ($7.8 million) and the UT Research Agreement ($1.1 million).

Gross revenue from the sales of Afrezza for the six months ended June 30, 2019 increased by $6.6 million, or 56%, compared to the same period in the prior year, primarily driven by higher product demand and price increases, as well as a more favorable mix of Afrezza cartridges. The gross-to-net adjustment was $7.4 million (or 40% of gross revenue) for the six months ended June 30, 2019 compared to $4.7 million (or 40% of gross revenue) for the same period in the prior year. During this period, lower commercial and government rebates were offset by a higher rate of product returns.

Net revenue from collaborations and services for the quarter ended June 30, 2019 increased by $21.2 million compared to the same period in the prior year, primarily attributable to the UT License Agreement ($15.4 million) and the UT Research Agreement ($5.7 million).

Commercial product gross profit

The following tables provide a comparison of the commercial product gross profit categories for the three and six months ended June 30, 2019 and 2018 (dollars in thousands):

	Three Months Ended June 30,			
	2019	2018	$ Change	% Change
Commercial product gross profit:				
Net revenue - commercial product sales	$ 6,065	$ 3,753	$ 2,312	62%
Cost of goods sold	4,327	5,095	$ (768)	-15%
Commercial product gross profit	$ 1,738	$ (1,342)	$ 3,080	230%

	Six Months Ended June 30,			
	2019	2018	$ Change	% Change
Commercial product gross profit:				
Net revenue - commercial product sales	$ 11,141	$ 7,155	$ 3,986	56%
Cost of goods sold	8,347	9,103	$ (756)	-8%
Commercial product gross profit	$ 2,794	$ (1,948)	$ 4,742	243%

Commercial product gross profit for the three and six months ended June 30, 2019 increased by $3.1 million or 230%, and $4.7 million or 243%, respectively, compared to the same periods in the prior year. The increases were primarily attributable to higher commercial sales.

Expenses

The following tables provide a comparison of the expense categories for the three and six months ended June 30, 2019 and 2018 (dollars in thousands):

	Three Months Ended June 30,			
	2019	2018	$ Change	% Change
Expenses:				
Cost of goods sold	$ 4,327	$ 5,095	$ (768)	(15%)
Cost of revenue - collaborations and services	2,139	—	2,139	100%
Research and development	1,632	2,967	(1,335)	(45%)
Selling	9,380	12,338	(2,958)	(24%)
General and administrative	7,229	9,393	(2,164)	(23%)
Loss on foreign currency translation	1,247	(5,363)	6,610	(123%)
Total expenses	$ 25,954	$ 24,430	$ 1,524	6%

	Six Months Ended June 30,			
	2019	2018	$ Change	% Change
Expenses:				
Cost of goods sold	$ 8,347	$ 9,103	$ (756)	(8%)
Cost of revenue - collaborations and services	3,676	—	3,676	100%
Research and development	3,299	5,611	(2,312)	(41%)
Selling	28,029	23,317	4,712	20%
General and administrative	14,253	19,032	(4,779)	(25%)
Loss on foreign currency translation	(688)	(2,379)	1,691	(71%)
Total expenses	$ 56,916	$ 54,684	$ 2,232	4%

Cost of goods sold for the quarter ended June 30, 2019 decreased by $0.8 million compared to the same quarter in the prior year, primarily due to a $0.4 million decrease in foreign exchange currency loss and a $0.2 million decrease in inventory write-offs, partially offset by costs due to higher sales.

Cost of goods sold for the six months ended June 30, 2019 decreased by $0.8 million compared to the same period in the prior year primarily due to a $0.8 million decrease in inventory write-offs, partially offset by costs due to higher sales.

Cost of revenue - collaborations and services was $2.1 million and $3.7 million for the three and six months ended June 30, 2019, respectively, compared to zero for the same periods in the prior year. Cost of revenue - collaborations and services for both periods in 2019 was attributable to resource costs related to conducting activities under the UT License Agreement and UT Research Agreement.

Research and development expenses for the quarter ended June 30, 2019 decreased by $1.3 million, or 45%, compared with the same quarter in the prior year. This was primarily attributable to $0.5 million decreases in both clinical trial spending and personnel costs.

Research and development expenses for the six months ended June 30, 2019 decreased by $2.3 million, or 41%, compared with the same period in the prior year. This was primarily attributable to $1.0 million decrease in personnel related costs and a $0.7 million decrease in clinical trial spending.

Selling expenses for the quarter ended June 30, 2019 decreased by $3.0 million, or 24%, compared to the same quarter in the prior year. The decrease was primarily attributable to a $1.7 million decrease in personnel related costs and a $1.0 million decrease in marketing spending.

Selling expenses for the six months ended June 30, 2019 increased by $4.7 million, or 20%, compared to the same period in the prior year. This was primarily attributable to a $9.3 million increase in costs for a television campaign for Afrezza, offset by a $1.9 million decrease in personnel related costs, a $1.6 million decrease in marketing spending and $0.4 million decrease in sponsorship.

General and administrative expenses for the quarter ended June 30, 2019 decreased by $2.2 million, or 23%, compared to the same quarter in the prior year. This decrease was primarily attributable to a $1.3 million decrease in professional fees and a $0.6 million decrease in personnel costs.

General and administrative expenses for the six months ended June 30, 2019 decreased by $4.8 million, or 25%, compared to the same period in the prior year. This decrease was primarily attributable to a $2.6 million decrease in personnel costs and a $2.0 million decrease in professional fees.

Other Income (Expense)

The following tables provide a comparison of the other income (expense) categories for the three and six months ended June 30, 2019 and 2018 (dollars in thousands):

	Three Months Ended June 30,			
	2019	2018	$ Change	% Change
Interest income	255	55	200	364%
Interest expense on notes	(564)	(1,709)	1,145	67%
Interest expense on note payable to related party	(1,109)	(1,046)	(63)	(6%)
Gain on extinguishment of debt	—	772	(772)	(100%)
Other income (expense)	(17)	30	(47)	(157%)
Total other income (expense)	$ (1,435)	$ (1,898)	$ 463	(24%)

	Six Months Ended June 30,			
	2019	2018	$ Change	% Change
Interest income	573	161	412	256%
Interest expense on notes	(1,157)	(3,503)	2,346	67%
Interest expense on note payable to related party	(2,189)	(2,160)	(29)	(1%)
Loss on extinguishment of debt	—	(53)	53	100%
Other income (expense)	(31)	61	(92)	(151%)
Total other income (expense)	$ (2,804)	$ (5,494)	$ 2,690	(49%)

Interest income increased by $0.2 million or 364% and $0.4 million or 256% for the three and six months ended June 30, 2019, respectively, compared to the same periods in the prior year, which was primarily attributable to a higher balance on our money market funds and short-term investments.

Interest expense on notes, which includes the Facility Financing Obligation and senior convertible notes, decreased by $1.1 million or 67% and $2.3 million or 67% for the three and six months ended June 30, 2019, compared to the same periods in the prior year, which was primarily attributable to a reduction in principal debt balances.

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, and from borrowings under certain loan arrangements, including the Mann Group Loan Arrangement, the Facility Agreement, and, most recently, the MidCap Credit Facility.

The following table summarizes our outstanding debt as of June 30, 2019 and as of the date of this report:

Holder	As of June 30, 2019				As of August 7, 2019			
	Principal amount	Annual interest rate	Maturity date	Conversion price	Principal amount	Annual interest rate	Maturity date	Conversion price
Bruce & Co.	$18.7 million	5.75%	October 2021	$5.15 per share	$5.0 million	5.75%	November 2024	$3.00 per share
					$2.6 million	—	June 2020	N/A
					$2.6 million	—	December 2020	N/A
Deerfield	$4.0 million	9.75%	July 2019	N/A	—	—	—	—
	$5.0 million	9.75%	August 2019	N/A				
The Mann Group	$80.6 million (including accrued interest paid-in-kind)	5.84%	July 2021	$4.00 per share	$35.0 million	7.00%	November 2024	$2.50 per share
					$35.1 million	7.00%	November 2024	N/A
MidCap	—	—	—	—	$40.0 million	LIBOR plus 6.75%	August 2024	N/A

On July 31, 2014, we entered into the Insulin Supply Agreement, pursuant to which we agreed to purchase certain annual minimum quantities of insulin. See Note 11 — Commitments and Contingencies, and Note 13 – Subsequent Events for further information related to the Insulin Supply Agreement.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2024 convertible notes, 2020 notes, the MidCap Credit Facility or the New Mann Group Loan Arrangement 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. The 2024 convertible notes and the New Mann Group Loan Arrangement are fully convertible at any time prior to maturity as further disclosed in Note 6 – Related Party Arrangements and Note 7 – Borrowings.

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 our term loan under the MidCap Credit Facility (“MidCap Term Loan”), or if we fail to repay or repurchase the 2024 convertible notes, 2020 notes, MidCap Term Loan or borrowings under the New Mann Group Loan Arrangement, 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 connection with the execution of the Facility Agreement, on July 1, 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, $75.0 million of which remains payable upon achievement of such milestones. See Note 11 — Commitments and Contingencies and Note 7 — Borrowings for further information related to the Milestone Rights.

These 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 six months ended June 30, 2019, we used $31.3 million of cash for our operating activities as a result of our net loss of $27.3 million, offset by a net cash inflow from changes in balances of operating assets and liabilities of $10.7 million and non-cash charges of $6.6 million. The net cash inflow was primarily due to a decrease in deferred revenue of $6.8 million, recognized loss on purchase commitments of $4.0 million, accounts receivable of $1.0 million, operating lease payments of $0.7 million and inventory of $0.4 million, offset by an increase accounts payable of $2.2 million. The non-cash charges included $3.7 million of stock-based compensation, $2.3 million of interest accrued through notes payable to related party and $0.7 million from gains on foreign currency exchange.

During the six months ended June 30, 2018, we used $48.8 million of cash for our operating activities as a result of our net loss of $53.1 million, offset by a net cash inflow resulting from change in balances of operating assets and liabilities of $2.1 million and non-cash charges of $6.4 million. The net cash inflow was primarily a result decreases in recognized loss on purchase commitments ($5.8 million) and lower inventory ($1.8 million) and accounts receivable ($0.2 million), offset by increases in accounts payable ($2.3 million), deferred payments from collaboration ($2.0 million) and accrued expenses and other current liabilities (($0.8 million) and decreases in prepaid expenses and other assets ($0.4 million). The non-cash charges included $4.2 million of stock-based compensation expense, $2.2 million of interest accrued on notes payable to the related party $1.5 million of depreciation, amortization and accretion, $0.8 million inventory write-off, $0.1 million loss on extinguishment of debt and other net assets of $0.1 million, offset by a $2.4 million foreign currency exchange gain. We recorded a write down of inventory charges of approximately $0.8 million for the six months ended June 30, 2018. These charges are presented separately in the accompanying condensed consolidated cash flow statement for 2018.

Cash used in investing activities of $26.4 million for the six months ended June 30, 2019, was primarily due to a purchase of short-term treasury bills. There was no investing activities for the six months ended June 30, 2018.

Cash used in financing activities of $0.7 million for the six months ended June 30, 2019 was primarily due to a principal payment of the Facility Financing Obligation of $2.5 million, offset by $1.9 million in proceeds from sales of our common stock under our Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald & Co. Cash provided from financing activities was $27.2 million for the six months ended June 30, 2018 which primarily related to $26.4 million in net proceeds from a registered direct offering of our common stock in April 2018.

Future Liquidity Needs

As of June 30, 2019, we had $8.0 million of cash and cash equivalents, $5.3 million of restricted cash and $24.9 million of short-term investments. Our cash position and short-term investments, together with our short-term debt obligations and anticipated operating expenses, raises substantial doubt about our ability to continue as a going concern. We expect to expend our capital resources for the manufacturing, sales and marketing of Afrezza and to develop our product pipeline candidates. We also intend to use our capital resources for general corporate purposes. We will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, support continued product growth and commercialization efforts, and to fund operations. We will seek to raise additional funds through various potential sources, such as equity and debt financings, or through collaboration and licensing agreements.

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. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any collaboration, license, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, or at all. If we are unable to raise additional capital when needed or on acceptable terms, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in raising additional capital when needed, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of June 30, 2019, we did not have any off-balance sheet arrangements.

Contractual Obligations

As of June 30, 2019, there were no 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, other than the following:

On June 18, 2019, we entered into a Eleventh Amendment to Facility Agreement (the "Eleventh Amendment") with Deerfield, pursuant to which the parties amended the Facility Agreement to defer the repayment of $5.0 million in principal amount of 2019 notes (the "July Payment") issued in tranche 1 under the Facility Agreement from July 1, 2019 to August 31, 2019, conditioned upon, among other things, our depositing of $5.0 million into an escrow account until the July Payment has been satisfied in full.

Also see Note 13 Subsequent Events.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

As of June 30, 2019, all our debt had fixed interest rates, so we did not have exposure to changes in our interest expense as a result of changes in interest rates. Specifically, the interest rate on amounts borrowed under The Mann Group Loan Arrangement was fixed at 5.84%; under the 2021 convertible notes, 5.75%; and under the 2019 notes, 9.75%. See Note 13 – Subsequent Events to the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited) for information about the principal amount of outstanding debt.

Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds, U.S. Treasury bills or notes and investment-grade corporate, government and municipal debt. None of these investments are entered into for trading purposes. Our cash is deposited in and invested through highly rated financial institutions in North America.

If a change in interest rates equal to 10% of the interest rates on June 30, 2019 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio.

Foreign Currency Exchange Risk

On April 1, 2019, we entered into a foreign currency hedging transaction to mitigate our exposure to foreign currency exchange risks associated with our insulin purchase obligation under the Insulin Supply Agreement. The hedging transaction hedges against short-term currency fluctuations for the remaining current year purchase obligation under the Insulin Supply Agreement of €3.9 million and is renewable every 90 days. We realized a *de minimis* currency loss during the second quarter of 2019. This amount is recorded in other income and expense.

We incur and will continue to incur significant expenditures for insulin supply obligations under our Insulin Supply Agreement with Amphastar. Such obligations are denominated in Euros. At the end of each reporting period, the recognized gain or loss on purchase commitment is converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. On April 2, 2018, we entered into a foreign currency short-term (90 days) hedging transactions to mitigate our foreign currency exchange risks associated with our insulin purchase obligation under the Insulin Supply Agreement. For the three months ended June 30, 2019, we realized a *de minimis* currency gain. This amount was recorded in other income and expense. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If a change in the U.S. dollar to Euro exchange rate equal to 10% of the U.S. dollar to Euro exchange rate on June 30, 2019 were to occur, this change would have resulted in a foreign currency impact to our pre-tax income (losses) of approximately $9.4 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 June 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, we 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. At a case conference in February 2019, the court directed the parties to negotiate a procedure for determining whether the plaintiff can distinguish the claims in the Israeli litigation from those in a U.S. case against us based on the same events (which was dismissed by the U.S. district court for the Central District of California in August 2016). In July 2019, the plaintiff asked the court to be allowed to amend his claim. This motion will be heard in September 2019. We will continue to vigorously defend against the claims advanced.

We are subject to legal proceedings and claims which 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 contain 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 will 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 stockholder's deficit raise substantial doubt about our ability to continue as a going concern. As of June 30, 2019, we had cash and cash equivalents of $13.3 million, short-term investment of $24.9 million and a stockholders' deficit of $196.0 million. We will 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 Afrezza is commercially successful;
- the degree to which we are able to generate revenue from our Technosphere drug delivery platform, including through our collaborations;
- the costs of developing and commercializing Afrezza on our own in the United States, including the costs of expanding our commercialization capabilities;
- the demand by any or all of the holders of our debt instruments to require us to repay or repurchase such debt securities if and when required;
- our ability to repay or refinance existing indebtedness, and the extent to which our notes with conversion options or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;

- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facility;
- our obligation to make milestone payments to Deerfield;
- 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. 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 will 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 market acceptance of Afrezza for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, relative pricing compared with 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 retain and find and 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 will 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.

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, approval, 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 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, especially in the current market, 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 development and commercialization of Afrezza, we will likely not be able to advance these programs unless we are able to enter into collaborations with third parties to fund these programs or to obtain funding to enable us to continue these programs.

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 to the revenues we can generate from Afrezza.

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

We are not currently profitable and have rarely generated positive net cash flow from operations. As of June 30, 2019, 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 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 the date of this report, there was €82.1 million remaining in aggregate purchase commitments under this agreement. We may not have the necessary capital resources on hand in order 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.*

As of the date of this report, we have $120.3 million principal amount of outstanding debt consisting of:

- $5.0 million principal amount of 2024 convertible notes bearing interest at 5.75% per annum, with interest payable in cash 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 holder at a conversion price of $3.00 per share;
- $5.3 million principal amount of 2020 notes, half of which mature in June 2020 and half of which mature in December 2020;
- $70.1 million principal amount of indebtedness under the New Mann Group Loan Arrangement 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; and
- $40.0 million principal amount under the MidCap Credit Facility, bearing interest at an annual rate equal to LIBOR plus 6.75%, subject to a LIBOR floor of 2.00%, and maturing in August 2024.

Under the MidCap Credit Facility, our interest rate on borrowed amounts is dependent on LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market and is widely used as a reference for setting the interest rate on loans globally, is currently scheduled to be phased out in 2021. Before LIBOR is phased out, we may need to renegotiate the MidCap Credit Facility to replace LIBOR with a new standard, which has yet to be established. The consequences of these developments cannot be entirely 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.

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.

The MidCap Credit Facility also contains a covenant relating to trailing twelve month minimum Afrezza Net Revenue requirements (as defined in the Credit Agreement), tested on a monthly basis, as described in more detail in the MidCap Credit Facility. If we fail to meet this covenant, we may lose the ability to borrow the Tranche 2 advance and the Tranche 3 advance if the other conditions for those advances are satisfied, and 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, 2020 notes, MidCap Term Loan or borrowings under The New Mann Group Loan Arrangement 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; and
- actions by regulators.

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; and
- 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.

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, 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, including Amphastar, 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. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of Afrezza may be delayed. Likewise, if Amphastar ceases to manufacture or is otherwise unable to deliver insulin for Afrezza, we will need to locate an alternative source of supply and the production of Afrezza may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations 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 Afrezza inhalation powder, fill plastic cartridges with the powder, 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 foil-pouched blister packs along with inhalers and the package insert. 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:

- 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. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to 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 released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional 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. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. In addition, on January 31, 2019, the United States Department of Health and Human Services Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drugs products to consumers which among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other proposed measures will 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. 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, or 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.

In addition, in many foreign countries, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, 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.

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;
- A 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of certain drug-device combination products, which has been suspended for calendar years 2016 through 2019;
- 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 the Centers for Medicare & Medicaid Services ("CMS") certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals and other healthcare providers 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.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders and other directives designed to delay 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, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 ("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". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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 July 2018, CMS published a 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. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, 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 2027 unless additional Congressional action is taken. 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. 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;

- California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act ("CCPA"), it will create new individual privacy rights for consumers (as that word is broadly defined in the law) and place increased privacy and security obligations on entities handling personal data of consumers or households. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, 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;

- 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, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- 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. To the extent that Afrezza or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may 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 Department of Health and Human Services 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.

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 work force, 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. Section 404 also requires our independent registered public accounting firm to attest to, and report on, our internal controls over financial reporting.

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, including those related to revenue recognition, 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 or reported cash flows. In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue *from Contracts with Customers (Topic 606)*, which was subsequently clarified by additional ASUs. The standard requires a company to recognize revenue to depict the transfer of goods or services when transferred to customers in the amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. We adopted the new standard for the year beginning January 1, 2018. Any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify 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.

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

As of December 31, 2018 we had federal and state net operating loss carryforwards of $2.1 billion and $2.4 billion, respectively, which we assess annually. The federal and state net operating loss carryforwards have begun to expire. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue 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 the net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met Section 382 study ownership change threshold has been identified through December 31, 2018. There is a risk that changes in ownership can and may occur in tax years after December 31, 2018. If a change in ownership were to occur, 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.

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 has appealed this ruling, and following an oral hearing before the Supreme Court of Israel, has decided to withdraw his appeal. Subsequently, in November 2018, we filed a motion to dismiss the certification motion. At a case conference in February 2019, the court directed the parties to negotiate a procedure for determining whether the plaintiff can

distinguish the claims in the Israeli litigation from those in a U.S. case against us based on the same events (which was dismissed by the U.S. district court for the Central District of California in August 2016). 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.

We expect that at least for the foreseeable future, our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of Afrezza. It will also serve as the initial production facility for 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, 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 and commercialization of Afrezza 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. 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, including beginning on December 22, 2018, 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.

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. To date, we have not enrolled any subjects in 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 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. 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. Enforcement action may include product seizures, injunctions, 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 initially 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.

Our suppliers are subject to FDA inspection.

We depend on suppliers for insulin and other materials that comprise Afrezza, including our Afrezza inhaler and cartridges. Each supplier must comply with relevant regulatory requirements and is subject to inspection by the FDA. 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 we or any potential third-party manufacturer or supplier fails to comply with these requirements or 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 of insulin, we will be required to evaluate the new supplier's ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and commercialization of Afrezza.

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 and the vesting of restricted stock unit awards and the purchase of shares of common stock 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 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;
- 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 and 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 July 16, 2019, we had 189,616,126 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 borrowings under The New Mann Group Loan Arrangement 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 will 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.

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. 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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 2, 2017).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 13, 2017).
3.4	Amended and Restated Bylaws (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
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	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference Exhibit 99.2 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 Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.5	Form of Tranche B Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.8 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50856), filed with the SEC on May 12, 2014).
4.6	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).
4.7	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.8	Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.9	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 10.39 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.10	Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.14 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
4.11	Exchange and Third Amendment to Facility Agreement, dated June 29, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on June 29, 2017).
4.12	Fourth Amendment to Facility Agreement, dated October 23, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 October 23, 2017).
4.13	Fifth Amendment to Facility Agreement, dated January 15, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., and Deerfield Private Design International II, L.P. (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 January 19, 2018.

Exhibit Number	Description of Document
4.14	Exchange and Sixth Amendment to Facility Agreement, dated January 18, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on January 19, 2018.
4.15	Exchange and Seventh Amendment to Facility Agreement, dated June 8, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 June 11, 2018).
4.16	Exchange and Eighth Amendment to Facility Agreement, dated July 12, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 July 13, 2018).
4.17	Ninth Amendment to Facility Agreement, dated September 5, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 September 5, 2018).
4.18	Tenth Amendment to Facility Agreement, dated September 26, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 September 27, 2018).
4.19	Eleventh Amendment to Facility Agreement, dated June 18, 2019 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 June 19, 2019).
4.20	Indenture, by and between MannKind and U.S. Bank (dated October 30, 2017 (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 October 30, 2017).
4.21	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2021 (incorporated by reference to Exhibit A of Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 30, 2017).
4.22	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).
4.23	Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated March 11, 2018 (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 March 12, 2018).
4.24	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).
10.1	Exchange Agreement, dated July 18, 2019, by and among MannKind Corporation, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 July 18, 2019).
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.

SIGNATURE

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

Dated: August 7, 2019

MANNKIND CORPORATION

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

By: /s/ STEVEN B. BINDER
Steven B. Binder
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

I, Michael E. Castagna, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 of MannKind Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: August 7, 2019

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

I, Steven B. Binder, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 of MannKind Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Steven B. Binder
Steven B. Binder
Chief Financial Officer

Date: August 7, 2019

Exhibit 32.1

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

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

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended June 30, 2019, 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 7th day of August, 2019.

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

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

Exhibit 32.2

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

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

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended June 30, 2019, 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 7th day of August, 2019.

/s/ Steven B. Binder
Steven B. Binder
Chief Financial Officer

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