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

Form 10-Q

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

For the quarterly period ended September 30, 2016

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.)**
25134 Rye Canyon Loop Suite 300 Valencia, California	**91355**
(Address of principal executive offices)	**(Zip Code)**

(661) 775-5300
(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of November 1, 2016, there were 478,376,869 shares of the registrant's common stock, $0.01 par value per share, outstanding.

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended September 30, 2016

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

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,530	$ 59,074
Accounts receivable	3,137	23
Inventory	5,124	—
Deferred costs from collaboration	—	13,539
Deferred costs from commercial product sales	279	—
Prepaid expenses and other current assets	4,534	4,018
Total current assets	48,604	76,654
Property and equipment - net	46,825	48,749
Other assets	702	1,009
Total assets	$ 96,131	$ 126,412
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,093	$ 15,599
Accrued expenses and other current liabilities	14,164	7,929
Facility financing obligation	70,888	74,582
Deferred sales from collaboration	—	17,503
Deferred payments from collaboration	462	140,231
Deferred revenue	2,014	—
Recognized loss on purchase commitments - current	8,340	12,475
Warrant liability	4,871	—
Total current liabilities	105,832	268,319
Note payable to our principal stockholder	49,521	49,521
Sanofi loan facility and loss share obligation	71,210	62,371
Senior convertible notes - long term	27,629	27,613
Recognized loss on purchase commitments - long term	63,229	53,692
Other liabilities	17,397	15,225
Total liabilities	334,818	476,741
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.01 par value - 700,000,000 and 550,000,000 shares authorized at September 30, 2016 and December 31, 2015, respectively; 478,362,548 and 428,670,943 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	4,784	4,287
Additional paid-in capital	2,548,090	2,508,633
Accumulated other comprehensive loss	(21)	(20)
Accumulated deficit	(2,791,540)	(2,863,229)
Total stockholders' deficit	(238,687)	(350,329)
Total liabilities and stockholders' deficit	$ 96,131	$ 126,412

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Net revenue - collaboration	$161,781	$ —	$161,781	$ —
Net revenue - commercial product sales	573	—	573	—
Total net revenue	162,354	—	162,354	—
Expense:				
Product costs - collaboration	22,742	—	22,742	—
Cost of goods sold	4,331	8,115	15,567	15,688
Research and development	3,917	6,341	13,357	23,455
Selling, general and administrative	13,135	11,547	31,595	32,649
Total expenses	44,125	26,003	83,261	71,792
Income (loss) from operations	118,229	(26,003)	79,093	(71,792)
Change in fair value of warrant liability	13,185	—	7,879	—
Interest income	28	2	70	8
Interest expense on notes	(4,166)	(4,145)	(12,567)	(17,899)
Interest expense on note payable to our principal stockholder	(729)	(729)	(2,172)	(2,164)
Loss on extinguishment of debt	—	(1,049)	—	(1,049)
Other (expense) income	(27)	67	(613)	1,470
Income (loss) before income tax benefit (expense)	126,520	(31,857)	71,690	(91,426)
Income tax benefit (expense)	—	—	—	—
Net income (loss)	$126,520	$ (31,857)	$ 71,690	$ (91,426)
Net income (loss) per share - basic	$ 0.26	$ (0.08)	$ 0.16	$ (0.23)
Net income (loss) per share - diluted	$ 0.26	$ (0.08)	$ 0.16	$ (0.23)
Shares used to compute basic net income (loss) per share	478,137	405,199	454,188	401,734
Shares used to compute diluted net income (loss) per share	482,744	405,199	454,366	401,734

See notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income (loss)	$126,520	$(31,857)	$71,690	$(91,426)
Other comprehensive (loss) income:				
Cumulative translation (loss) gain	—	1	(1)	(5)
Comprehensive income (loss)	$126,520	$(31,856)	$71,689	$(91,431)

See notes to condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 71,690	$ (91,426)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and accretion	3,097	10,094
Stock-based compensation expense	4,130	6,378
Loss on disposal of property and equipment	—	27
Interest on note payable to our principal stockholder	2,172	2,193
Loss on foreign currency exchange	3,035	—
Warrant fair value adjustment	(7,879)	—
Series A Warrant issuance costs included in financing	653	—
Loss on extinguishment of debt	—	1,049
Interest incurred through borrowings under Sanofi Loan Facility	4,125	798
Other, net	717	(5)
Changes in operating assets and liabilities:		
Accounts receivable	(3,114)	48,757
Inventory	(5,124)	(13,732)
Deferred costs from collaboration	13,539	(13,539)
Deferred costs from commercial product sales	(279)	—
Prepaid expenses and other current assets	(516)	6,979
Other assets	307	(672)
Accounts payable	(10,288)	(2,698)
Accrued expenses and other current liabilities	6,575	(5,922)
Deferred sales from collaboration	(17,503)	17,038
Deferred payment from collaboration	(135,056)	—
Deferred revenue	2,014	—
Recognized loss on purchase commitments	2,367	—
Net cash used in operating activities	(65,338)	(34,681)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,144)	(9,969)
Proceeds from sale of property and equipment	17	78
Net cash used in investing activities	(1,127)	(9,891)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	772	13,524
Proceeds from direct placement	50,000	—
Issuance costs associated with direct placement	(2,690)	—
Payment of 2015 notes	—	(64,287)
Principal payments on notes payable to Deerfield	(5,000)	—
Payment of debt issuance costs on 2018 notes	—	(831)
Milestone payment	—	(4,219)
Other	—	40
Proceeds from issuance of common stock pursuant to at-the-market issuance	—	14,536
Issuance costs of at-the-market issuance	—	(271)
Payment of employment taxes related to vested restricted stock units	(161)	(1,833)
Net cash provided by (used in) financing activities	42,921	(43,341)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(23,544)	(87,913)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	59,074	120,841
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 35,530	$ 32,928
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	7,198	11,439
Payment of 2015 Notes and interest through issuance of common stock	—	8,253
Reclassification of deferred payments from collaboration to Sanofi loan facility and loss share obligation	4,713	28,150
Cost incurred for construction in progress included in accounts payable and accrued liabilities	—	192

See notes to condensed consolidated financial statements.

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

1. Description of Business and Basis of Presentation

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, 2015 filed with the SEC on March 15, 2016 (the "Annual Report").

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and nine months ended September 30, 2016 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. The more significant estimates reflected in these accompanying financial statements involve assessing inventory, long-lived assets and deferred costs for impairment, accrued expenses, deferred sales and payments from collaboration, purchase commitments, valuation of stock-based compensation and warrants 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 as well as revenue sold through to the end customer. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Business

MannKind is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes. The Company's only marketed 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") on June 27, 2014 to improve glycemic control in adult patients with diabetes.

Basis of Presentation

The Company's primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, raising capital, and commercial manufacturing. In 2016, the Company commenced commercial sales and marketing activities related to Afrezza. It is costly to develop and conduct clinical studies for therapeutic products, as well as to establish and maintain commercial sales and marketing capabilities. As of September 30, 2016, the Company had an accumulated deficit of $2.8 billion and has reported negative cash flow from operations since inception, other than for the nine months ended September 30, 2014, the year ended December 31, 2014, and for the three months ended March 31, 2015, as a result of receipt of the upfront payment and milestone payments from Sanofi-Aventis U.S. LLC ("Sanofi") related to a license and collaboration agreement previously in effect.

In May 2016, pursuant to a previously filed Form S-3 Registration Statement, which was declared effective by the SEC on April 27, 2016, the Company sold in a registered public offering 48,543,692 shares of its common stock, together with warrants to purchase up to 48,543,692 shares of the Company's common stock. Net proceeds from this offering were approximately $47.4 million after deducting placement agent fees and expenses and paying for offering expenses, excluding any future proceeds from the exercise of the warrants. (See Note 14 — Warrants).

At September 30, 2016, the Company's capital resources consisted of cash and cash equivalents of $35.5 million. The Company expects to continue to incur significant expenditures to support commercial manufacturing and sales and marketing of Afrezza and the development of its product candidates. The facility agreement (the "Facility Agreement") with Deerfield Private Design Fund II, L.P. ("Deerfield Private Design Fund") and Deerfield Private Design International II, L.P. (collectively, "Deerfield") and the First Amendment to Facility Agreement and Registration Rights Agreement (the "First Amendment") that resulted in the issuance of an additional tranche of notes (see Note 13 — Facility Agreement) requires the Company to maintain at least $25.0 million in cash and

cash equivalents or available borrowings under the loan arrangement, dated as of October 2, 2007, between the Company and The Mann Group LLC (as amended, restated, or otherwise modified as of the date hereof, "The Mann Group Loan Arrangement"), as of the last day of each fiscal quarter.

On August 11, 2014, the Company executed a license and collaboration agreement (the "Sanofi License Agreement") with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to Sanofi), pursuant to which Sanofi was responsible for global commercial, regulatory and development activities for Afrezza. The Sanofi License Agreement became effective on September 23, 2014. The Company manufactured Afrezza at its manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product pursuant to a supply agreement dated August 11, 2014 (the "Sanofi Supply Agreement").

Under the Sanofi License Agreement, worldwide profits and losses, which were determined based on the difference between the net sales of Afrezza and the costs and expenses incurred by the Company and Sanofi that were specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of Afrezza, were shared 65% by Sanofi and 35% by the Company until Sanofi ceased distributing Afrezza. In connection with the Sanofi License Agreement, an affiliate of Sanofi provided the Company with a secured loan facility (the "Sanofi Loan Facility") of up to $175.0 million to fund the Company's share of net losses under the Sanofi License Agreement.

The Sanofi License Agreement and Sanofi Supply Agreement terminated, effective April 4, 2016, following which the Company assumed responsibility for the worldwide development and commercialization of Afrezza from Sanofi. Under the terms of the transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until the Company began distributing MannKind-branded Afrezza product to major wholesalers during the week of July 25, 2016.

Additional funding sources that are, or in certain circumstances may be, available to the Company, include approximately $30.1 million principal amount of available borrowings under The Mann Group Loan Arrangement. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under The Mann Group Loan Arrangement (see Note 5 — Related-Party Arrangements). The Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company is seeking and will need to raise additional capital, whether through a sale of equity or debt securities, a strategic business collaboration with a pharmaceutical company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the development and commercialization of Afrezza and its product candidates and to support its other ongoing activities. However, the Company cannot provide assurances that such additional capital will be available on acceptable terms or at all.

Reclassifications

Certain amounts from previous periods in the condensed consolidated statement of cash flows have been reclassified to conform to the 2016 presentation. Specifically interest on note payable to our principal stockholder has been reclassified from other liabilities. Additionally, on the condensed consolidated statement of operations, product manufacturing has been renamed to cost of goods sold.

Revenue Recognition – Net Revenue – Collaboration

On April 5, 2016 the Company assumed responsibility for the worldwide development and commercialization of Afrezza from Sanofi. Under terms of the transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until the Company began distributing MannKind-branded Afrezza product to major wholesalers during the week of July 25, 2016. As previously disclosed, profits and losses incurred by the Company and Sanofi that were specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of Afrezza, were shared 65% by Sanofi and 35% by the Company until Sanofi ceased selling Afrezza.

The Company analyzed the agreements entered into with Sanofi at their inception to determine whether the consideration, paid or payable to the Company, or a portion thereof, could be recognized as revenue. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Under the terms of the Sanofi License Agreement, Sanofi Supply Agreement and the Sanofi Loan Facility, the Company determined that the arrangement contained significant deliverables including (i) licenses to develop and commercialize Afrezza and to use the Company's trademarks, (ii) development activities, and

(iii) manufacture and supply services for Afrezza. Due to the proprietary nature of the manufacturing services to be provided by the Company, the Company determined that all of the significant deliverables should be combined into a single unit of accounting. The Company believes that the manufacturing services are proprietary due to the fact that since the late 1990's, the Company has developed proprietary knowledge and patented equipment and tools that are used in the manufacturing process of Afrezza. Due to the complexities of particle formulation and the specialized knowledge and equipment needed to handle the Afrezza powder, neither Sanofi nor, to the Company's knowledge, any third-party contract manufacturing organization currently possesses the capability of manufacturing Afrezza.

In order for revenue to be recognized, the seller's price to the buyer must be fixed or determinable. Prior to the third quarter of 2016, because the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement and the Sanofi Supply Agreement, the Company believed this requirement for revenue recognition had not been met.

Therefore, the Company had recorded the $150.0 million up-front payment and the two milestone payments of $25.0 million each as deferred payments from collaboration. In addition, as of December 31, 2015 the Company had recorded $17.5 million in Afrezza product shipments to Sanofi as deferred sales from collaboration and recorded $13.5 million as deferred costs from collaboration. Deferred costs from collaboration represented the costs of product manufactured and shipped to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi.

During the three months ended September 30, 2016, the Company determined that the remaining costs under the Sanofi License Agreement and the Sanofi Supply Agreement were reasonably estimable. Accordingly, the fixed or determinable fee requirement for revenue recognition was met and there are no future obligations to Sanofi. Therefore, the Company recognized $161.8 million of net revenue – collaboration for the three and nine months ended September 30, 2016. The revenue recognized includes the upfront payment of $150.0 million and the two milestone payments of $25.0 million each, net of $64.8 million of net loss share with Sanofi, as well as $17.4 million in sales of Afrezza and $9.2 million from sales of raw insulin, both to Sanofi. These payments and sales were made pursuant to the contractual terms of the agreements with Sanofi.

Revenue Recognition – Net Revenue – Commercial Product Sales

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the accounting requirements for revenue recognition are not met, the Company defers the recognition of revenue by recording deferred revenue on the balance sheet until such time that all criteria are met.

The Company sells Afrezza in the United States to Integrated Commercialization Solutions ("ICS") Direct and wholesale pharmaceutical distributors and, through them, to retail pharmacies, which are collectively referred to as "customers". These sales are subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. For the three and nine months ended September 30, 2016, net revenue – commercial product sales consisted of $0.6 million of net sales of Afrezza dispensed to patients. The net sales took place in the third quarter as a result of the Company's re-launch in July 2016.

With respect to sales to customers, the Company has entered into a Commercial Outsourcing Services Agreement with ICS, a third party logistics provider, under which ICS will distribute MannKind product to wholesalers on its behalf. To enable the Company to distribute product in all necessary jurisdictions, on July 1, 2016 the Company entered into a first amendment to its contract with ICS for an interim period. Under this amendment, ICS, through ICS Direct, will purchase product from the Company and title and risk of loss transfers to ICS Direct. However, because (1) the Company indemnifies and holds harmless ICS for all accounts receivable arising out of commercial product sales under the first amendment that are not collected from the customers according to payment terms, and (2) ICS Direct may return product to the Company under the right of return described below, the Company has concluded that it cannot recognize revenue upon transfer of product to ICS or further, to ICS Direct.

The Company provides the right of return to ICS Direct and its wholesale distributors and, through them, to its retail pharmacy customers for unopened product for a limited time before and after its expiration date. Once the product has been prescribed and dispensed to the patient, any right of return ceases to exist.

Given the Company's limited sales history for Afrezza, the Company cannot reliably estimate expected returns of the product at the time of shipment into the distribution channel. Accordingly, the Company defers recognition of revenue on Afrezza product shipments until the right of return no longer exists, which occurs at the earlier of the time Afrezza is dispensed from pharmacies to patients or expiration of the right of return. The Company recognizes revenue based on Afrezza patient prescriptions dispensed as estimated by syndicated data provided by a third party. The Company also analyzes additional data points to ensure that such third-party data is reasonable including data related to inventory movements within the channel and ongoing prescription demand.

On September 26, 2016, the Company provided notice to ICS of its election to terminate the interim period agreement effective December 15, 2016. We expect this termination election will not impact our recognition of revenue. After that date, ICS will no longer take title to inventory. However, the Commercial Outsourcing Services Agreement will continue to apply and ICS will continue to distribute MannKind product to wholesalers on its behalf.

The Company recorded $2.0 million in deferred revenue on its condensed consolidated balance sheet, of which $1.6 million (net of estimated gross-to-net adjustments) represents product shipped to our third-party logistics provider and wholesale distributors, but not dispensed to patients as of September 30, 2016. Deferred revenue also includes $0.4 million that we have received for the sale of surplus raw materials to a third party, where delivery was made after September 30, 2016. In addition, the costs of Afrezza associated with the deferred revenue are recorded as deferred costs until such time the related deferred revenue is recognized.

Gross-to-net Adjustments

Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, estimated rebates and patient discount programs, and are based on estimated amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company's agreements with its customers and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company records product sales deductions in the statement of operations at the time product revenue is recognized.

Product Returns

The Company does not provide a reserve for product refunds for sales of Afrezza due to its revenue recognition policy of deferring recognition of revenue on product shipments of Afrezza until the right of return no longer exists.

Wholesaler Distribution Fees

The Company pays distribution fees to certain wholesale distributors based on contractually determined rates. The Company accrues the distribution fees on shipment to the respective wholesale distributors and recognizes the distribution fees as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts

The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Rebates

The Company participates in federal and state government-managed Medicare and Medicaid rebate programs and intends to pursue participation in certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating federal and state government entities. Rebates provided through these other qualifying programs will be included in the Medicaid/Medicare rebate accrual and are considered Medicaid/Medicare rebates for the purposes of this discussion. The Company accounts for these rebates by establishing an accrual equal to the estimate of rebate claims attributable to a sale and determines its estimate of the rebates accrual based on historical payor data provided by a third-party vendor along with additional data including a forecasted participation rate for Medicare and Medicaid. From that data, as well as input received from the commercial team, an estimated participation rate for Medicare and Medicaid is determined and applied at the mandated rate for those sales. Any new information regarding changes in the programs' regulations and guidelines or any changes in the Company's government price reporting calculations that would impact the amount of the rebates will also be taken into account in determining or modifying the appropriate reserve. The time period between the date the product is sold into the channel and the date such rebates are paid ranges from approximately six to nine months. As such, continuous monitoring of these estimates will be performed on a periodic basis and if necessary, adjusted to reflect new facts and circumstances. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Discount and Co-Pay Assistance Programs

The Company offers discount card programs to patients for Afrezza in which patients receive discounts on their prescriptions or a reduction in their co-pay amounts that are reimbursed by the Company. The Company estimates the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Deferred costs from collaboration

Deferred costs from collaboration represents the costs of product manufactured and sold to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi. During the third quarter of 2016, the costs related to the Sanofi product sales were recognized as product costs – collaboration in the condensed consolidated statement of operations.

Deferred costs from commercial product sales

Deferred costs from commercial product sales represents the cost of product (including labor, overhead and costs to ship to third party logistics) shipped to ICS and wholesale distributors, but not dispensed by pharmacies to patients.

Cost of goods sold

Cost of goods sold includes the costs related to Afrezza product dispensed by pharmacies to patients as well as under-absorbed labor and overhead, foreign currency exchange impact and inventory write-offs, which are recorded as expenses in the period in which they are incurred rather than as a portion of the inventory cost.

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 of inventory items 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 purchased.

Fair Value of Financial Instruments

The carrying amounts reported in the accompanying financial statements for cash, accounts receivable, accounts payable and accrued expenses and other current liabilities approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to our principal stockholder, senior convertible notes, the Facility Agreement, the Sanofi Loan Facility and warrant liability are discussed in Note 8 — Fair Value of Financial Instruments.

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. 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. At the point that it becomes probable that the performance conditions will be met, the Company will record a cumulative catchup of the expense from the grant date to the current date, and the Company will then amortize the remainder of the expense over the remaining service period.

Warrants

The Company accounts for its warrants as either equity or liabilities based upon the characteristics and provisions of each instrument and evaluation of sufficient authorized shares available to satisfy the obligations. Warrants classified as derivative liabilities are recorded on the Company’s condensed consolidated balance sheets at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized in the condensed consolidated statements of operations. The Company estimates the fair value of its derivative liabilities using a third party valuation analysis that utilizes a Monte Carlo pricing valuation model and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date,

as well as expected volatility, expected life, yield, and risk-free interest rate. Warrants classified as equity are recorded within additional paid in capital at the issuance date and are not re-measured in subsequent periods, unless the underlying assumptions change to trigger liability accounting.

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.

In May 2014, the FASB issued ASU No. 2014-09 related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard requires a company to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. The Company is assessing the potential impact of the new standards on its consolidated financial statements and has not yet selected a method of adoption.

In August 2014, the FASB issued ASU No. 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. The adoption of this standard is not expected to materially impact the Company's consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330, inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments indicate that after adoption an entity should measure inventory within the scope of the ASU at the lower of cost and net realizable value. The amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of ASU No. 2015-11 will have no impact on the Company's consolidated financial statements because the Company currently measures inventory at the lower of cost and net realizable value.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update is intended to improve the recognition and measurement of financial instruments. The ASU affects public and private companies, not-for-profit organizations, and employee benefit plans that hold financial assets or owe financial liabilities. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is evaluating the impact the adoption of ASU No. 2016-01 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The Company is evaluating the impact the adoption of ASU No. 2016-02 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. For public business entities, the amendments in this standard are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company is evaluating the impact the adoption of ASU No. 2016-09 will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new standard seeks to reduce diversity in practice related to the classification of certain transactions in the Statement of Cash Flows. For public business entities, the amendments in this standard are effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company is evaluating the impact the adoption of ASU No. 2016-15 will have on its consolidated financial statements.

2. Inventories

Inventories consist of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	$ 2,666	$ —
Work-in-process	1,774	—
Finished goods	684	—
Total Inventory	$ 5,124	$ —

As of December 31, 2015, the Company recorded a write-off of all of its inventory. As of September 30, 2016, raw materials consists only of insulin which the Company intends to sell to Sanofi under the Insulin Put Option as described in Note 11. Work-in-process and finished goods as of September 30, 2016 includes conversion costs but not materials cost because the materials used in its production were previously written-off.

3. Property and Equipment

Property and equipment — net consist of the following (dollar amounts in thousands):

	Estimated Useful Life (Years)	September 30, 2016	December 31, 2015
Land	—	$ 3,435	$ 3,435
Buildings	39-40	21,590	21,590
Building improvements	5-40	60,584	60,584
Machinery and equipment	3-15	67,996	68,434
Furniture, fixtures and office equipment	5-10	4,114	4,114
Computer equipment and software	3	9,519	9,519
Construction in progress	—	203	586
		167,441	168,262
Less accumulated depreciation		(120,616)	(119,513)
Total property and equipment — net		$ 46,825	$ 48,749

The December 31, 2015 balances have been reclassified to the current year presentation by allocating an impairment of $140.4 million to the individual asset groups. An additional impairment of $0.7 million was charged to the individual asset groups for the nine months ended September 30, 2016.

Depreciation expense related to property and equipment for the three and nine months ended September 30, 2016 and 2015 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Depreciation expense	$ 597	$ 3,165	$1,775	$8,282

4. Accrued Expenses and Other Current Liabilities

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

	September 30, 2016	December 31, 2015
Salary and related expenses	$ 7,533	$ 5,662
Sales and marketing services	4,036	—
Professional fees	1,300	931
Discounts and allowances for commercial product sales	623	—
Other services	260	309
Accrued interest	212	615
Other	200	174
Construction in progress	—	238
Accrued expenses and other current liabilities	$ 14,164	$ 7,929

5. Related-Party Arrangements

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. The Mann Group Loan Arrangement has been amended from time to time. On October 31, 2013, the promissory note underlying The Mann Group Loan Arrangement was amended to, among other things, extend the maturity date of the loan to January 5, 2020, extend the date through which the Company can borrow under The Mann Group Loan Arrangement to December 31, 2019, increase the aggregate borrowing amount under The Mann Group Loan Arrangement from $350.0 million to $370.0 million and provide that repayments or cancellations of principal under The Mann Group Loan Arrangement will not be available for reborrowing.

As of September 30, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million, and the amount available for future borrowings was $30.1 million. 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. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized as additional borrowings at any time and would be classified as non-current upon mutual agreement of both parties. As of September 30, 2016, the Company had accrued $8.6 million of interest in other long term liabilities. 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 two 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 in 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. 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.

During the nine months ended September 30, 2016, there were no additional borrowings under or amendments to The Mann Group Loan Arrangement.

In May 2015, the Company entered into a sublease agreement with the Alfred Mann Foundation for Scientific Research (the "Mann Foundation"), a California not-for-profit corporation. The lease is for approximately 12,500 square feet of office space in Valencia, California and expires in April 2017. The office space contains the Company's principal executive offices.

Lease payments to the Mann Foundation for the three and nine months ended September 30, 2016 and 2015 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Lease Payments	$ 67	$ 65	$ 200	$ 109

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).

6. Senior Convertible Notes

Senior convertible notes consist of the following (in thousands):

	September 30, 2016	December 31, 2015
Principal amount	$ 27,690	$ 27,690
Unamortized premium	486	660
Unaccreted debt issuance costs	(547)	(737)
Net carrying amount	$ 27,629	$ 27,613

The 5.75% senior convertible notes due 2018 (the "2018 notes") are the Company's general, unsecured, senior obligations, except that the 2018 notes are subordinated in right of payment to the outstanding notes issued pursuant to the Facility Agreement and the Company's borrowings under the Sanofi Loan Facility with an affiliate of Sanofi. The 2018 notes rank equally in right of payment with the Company's other unsecured senior debt. The 2018 notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash on February 15 and August 15 of each year, beginning February 15, 2016, with interest accruing from August 15, 2015. The 2018 notes mature on August 15, 2018.

The 2018 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 147.0859 shares per $1,000 principal amount of 2018 notes, which is equal to a conversion price of approximately $6.80 per share, the same conversion price as that of the 2015 notes on the date of exchange. The conversion rate is subject to adjustment under certain circumstances described in an indenture governing the 2018 notes dated August 10, 2015 with US Bank (as successor trustee to Wells Fargo, National Association), including in connection with a make-whole fundamental change. If certain fundamental changes occur, such as share price being over $4.82 on date of conversion, the Company will be obligated to pay a make-whole premium on any 2018 notes converted in connection with such fundamental change by increasing the conversion rate on such 2018 notes. In such instances, the amount of the fundamental change make-whole premium will be based on the Company's common stock price and the effective date of the applicable fundamental change. The Company can force conversion at $6.80 or 747.1 thousand shares.

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2018 notes will have the option to require the Company to repurchase all or any portion of that holder's 2018 notes. The fundamental change repurchase price will be 100% of the principal amount of the 2018 notes to be repurchased plus accrued and unpaid interest, if any.

On or after the date that is one year following the original issue date of the 2018 notes, the Company will have the right to redeem for cash all or part of the 2018 notes if the last reported sale price of its common stock exceeds 130% of the conversion price then in effect for 20 or more trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date of the redemption notice. The redemption price will equal the sum of 100% of the principal amount of the 2018 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, including the make-whole shares, 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 2018 notes under existing commitments. Applying the Company's sequencing policy, the Company performed an analysis

at the time of the offering of the 2018 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the term of the 2018 notes under existing commitments.

The 2018 notes provide that upon an acceleration of certain indebtedness, including the 9.75% Senior Convertible Notes due 2019 (the "2019 notes") and the 8.75% Senior Convertible Notes due 2019 (the "Tranche B notes") issued to Deerfield pursuant to the Facility Agreement (see Note 13 — Facility Agreement), the holders may elect to accelerate the Company's repayment obligations under the notes if such acceleration is not cured, waived, rescinded or annulled. There can be no assurance that the holders would not choose to exercise these rights in the event such events were to occur.

The Company incurred approximately $0.8 million in issuance costs, which are recorded as an offset to the 2018 notes, in the accompanying condensed consolidated balance sheets. These costs are being accreted to interest expense using the effective interest method over the term of the 2018 notes.

Amortization of the premium related to the 2018 notes was $59,000 and $174,000 during the three and nine months ended September 30, 2016, respectively. Amortization of the premium related to the 2018 notes was $29,000 during the three and nine months ended September 30, 2015. Accretion of debt issuance expense related to the 2018 notes during the three and nine months ended September 30, 2016 was $65,000 and $190,000, respectively. There was no accretion of debt issuance expense related to the 2018 notes during the three and nine months ended September 30, 2015.

7. Collaboration Arrangement

Sanofi License Agreement and Sanofi Supply Agreement

See Note 1 under Basis of Presentation, for accounting considerations related to the Company's license and collaboration agreement with Sanofi which was terminated effective April 4, 2016.

Sanofi Loan Facility

On September 23, 2014, the Company entered into the Sanofi Loan Facility, consisting of a senior secured revolving promissory note and a guaranty and security agreement (the "Security Agreement") with an affiliate of Sanofi which provides the Company with a secured loan facility of up to $175.0 million to fund the Company's share of net losses under the Sanofi License Agreement. In the event of certain future defaults under the Sanofi Loan Facility for which the Company is not able to obtain waivers, the lender under the Sanofi Loan Facility may accelerate all of the Company's repayment obligations, and take control of the Company's pledged assets, potentially requiring the Company to renegotiate the terms of its indebtedness on terms less favorable to the Company, or to immediately cease operations.

The obligations of the Company under the Sanofi Loan Facility are guaranteed by the Company's wholly-owned subsidiary, MannKind LLC, and are secured by a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which the Company purchases or has purchased such insulin, and a second priority security interest in the Company's assets that secure the Company's obligations under the Facility Agreement, as amended. In addition, the Company granted to Sanofi, as additional security for the obligations under the Sanofi Loan Facility, a first priority mortgage on the Company's facility in Valencia, California, which has a carrying value of $17.4 million as of September 30, 2016.

Advances under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum and are payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. The Company is required to make mandatory prepayments on the outstanding loans under the Sanofi Loan Facility from its share of any profits (as defined in the Sanofi License Agreement) under the Sanofi License Agreement within 30 days of receipt of its share of any such profits. No advances may be made under the Sanofi Loan Facility if Deerfield has commenced enforcement proceedings in connection with an event of default under the Facility Agreement.

The outstanding principal of all loans under the Sanofi Loan Facility, if not prepaid, will become due and payable on September 23, 2024 unless accelerated pursuant to the terms of the Sanofi Loan Facility. Additionally, if the Company sells its Valencia facility, the Company is required to prepay the loans under the Sanofi Loan Facility from the net cash proceeds of the sale within five business days of receipt. The maturity date of September 23, 2024 for repayment of the outstanding principal amount of the loans under the Sanofi Loan Facility is not affected by the termination of the Sanofi License Agreement.

The Company's total cumulative portion of the loss sharing, including interest, was $71.2 million, of which $71.5 million was borrowed under the Sanofi Loan Facility as of September 30, 2016. For the three months ended September 30, 2016, the Company's portion of the profit sharing was $0.3 million under the Sanofi License Agreement, which is required to be applied as a prepayment against the balance owed under the Sanofi Loan Facility. The total amount owed to Sanofi is $71.2 million, which includes $5.8 million in paid-in-kind interest capitalized as principal.

The Sanofi Loan Facility includes customary representations, warranties and covenants by the Company, including restrictions on its ability to incur additional indebtedness, grant certain liens and make certain changes to its organizational documents. Events of default under the Sanofi Loan Facility include: the Company's failure to timely make payments due under the Sanofi Loan Facility; inaccuracies in the Company's representations and warranties to the noteholder; the Company's failure to comply with any of its covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; the Company's insolvency or the occurrence of certain bankruptcy-related events; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, Sanofi may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including the Company's failure to timely make payments due under the Sanofi Loan Facility; the Company's failure to comply with the negative covenants under the Sanofi Loan Facility limiting the Company's ability to incur additional indebtedness or grant certain liens; the Company's insolvency or the occurrence of certain bankruptcy-related events; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect) occur and are continuing, the noteholder may accelerate all of the Company's repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor. There can be no assurance that the noteholder would not choose to exercise these rights in the event such events were to occur.

8. 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.

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.

Cash Equivalents

Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of September 30, 2016 and December 31, 2015, the Company held cash equivalents of $33.7 million and $55.8 million, respectively, 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).

Note Payable to Principal Stockholder

The fair value of the note payable to our principal stockholder cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment. Therefore the fair value is based upon carrying value.

Financial Liabilities

The following tables set forth the fair value of our financial instruments (in millions):

	As of September 30, 2016			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Senior convertible notes	$ —	$ —	$ 21.7	$ 21.7
Facility financing obligation	—	—	74.9	74.9
Milestone rights	—	—	15.3	15.3
Sanofi Loan Facility	—	—	61.8	61.8
Warrant liability	—	—	4.9	4.9
Total financial liabilities	$ —	$ —	$178.6	$178.6

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Senior convertible notes	$ —	$ —	$ 21.3	$ 21.3
Facility financing obligation	—	—	78.4	78.4
Milestone rights	—	—	14.4	14.4
Sanofi Loan Facility	—	—	36.5	36.5
Total financial liabilities	$ —	$ —	$150.6	$150.6

Senior Convertible Notes

The estimated fair value of the 2018 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company's stock price and yields on U.S. Treasury notes and actively traded bonds, and non-observable, such as the Company's longer-term historical volatility, and estimated yields implied from any available market trades of the Company's issued debt instruments. As there is no current active and observable market for the 2018 notes, the Company determined the estimated fair value using a convertible bond valuation model within a lattice framework. The convertible bond valuation model combined expected cash flows based on terms of the notes with market-based assumptions regarding risk-free rate, risk-adjusted yields (20%), stock price volatility (90.0%) and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible (Level 3 in the fair value hierarchy).

Facility Agreement

As discussed in Note 13 — Facility Agreement, the Company issued 2019 notes and subsequently issued Tranche B notes (the "Facility Financing Obligation") in connection with the Facility Agreement. As there is no current observable market for the 2019 notes or Tranche B notes, the Company determined the estimated fair value using a bond valuation model based on a discounted cash flow methodology. The bond valuation model combined expected cash flows associated with principal repayment and interest based on the contractual terms of the debt agreement discounted to present value using a selected market discount rate. On September 30, 2016 the market discount rate was recalculated at 12% for the principal amount of $20.0 million of 2019 notes, and 11% for the remaining principal amount of $40.0 million on the 2019 notes and 11% for the Tranche B notes, which reflected an increase in the market price of benchmark U.S. Treasury securities as compared to prior measurement date (Level 3 in the fair value hierarchy).

In addition to the 2019 notes and Tranche B notes, the Company also issued certain rights to receive payments of up to $90.0 million upon occurrence of specified strategic and sales milestones (the "Milestone Rights"). These rights are not reflected in the Facility Financing Obligation. The estimated fair value of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (13.5%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of September 30, 2016, the carrying value of the Milestone Rights is $8.9 million, classified as a long-term liability in other liabilities and the fair value is estimated at $15.3 million.

Sanofi Loan Facility

As discussed in Note 7 — Collaboration Arrangement, the Sanofi Loan Facility consists of a senior secured revolving promissory note and a guaranty and security agreement with an affiliate of Sanofi which provides the Company with a secured loan facility of up to $175.0 million to fund the Company's share of net losses under the Sanofi License Agreement. The estimated fair value was determined using a discounted cash flow model in which time outstanding and discount rate were primary variables. This method considered the key elements of the contractual terms of the Sanofi Loan Facility, market-based estimated cost of capital, and time value of money, namely the amount of time to settlement and the estimated discount rate (10%) appropriate for the liability (Level 3 in the fair value hierarchy). As of September 30, 2016, the carrying value of the Sanofi Loan Facility is $71.5 million and the fair value is estimated at $61.8 million.

Warrant Liability

Warrant liabilities are measured at fair value using a Monte Carlo pricing valuation model. The assumptions used in the valuation model for the common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero percent based on the Company's expectation that it will pay no dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; and (d) an expected volatility based upon the Company's historical volatility over the remaining contractual term of the warrants and probability of a dilutive financing that may trigger a price protection clause. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities is the expected volatility. Significant increases in volatility would result in a higher fair value measurement (Level 3 in the fair value hierarchy). See Note 14 – Warrants for further discussion.

9. Accounting for Stock-Based Compensation

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock-based compensation	$ 1,502	$ 2,600	$4,130	$ 6,378

During the three months ended March 31, 2016, the Company issued stock awards to employees with a four-year vesting schedule. The grant date fair value of the 2,364,200 restricted stock units and 4,920,267 stock options issued was $2.2 million and $3.0 million, respectively, with a grant date fair value per share of $0.92 and $0.61, respectively.

During the three months ended June 30, 2016, the Company issued stock awards to employees with a four-year vesting schedule. The grant date fair value of the 1,088,050 restricted stock units and 1,140,200 stock options issued was $1.0 million and $0.7 million respectively, with a grant date fair value per share of $0.91 and $0.62, respectively.

During the three months ended September 30, 2016, the Company issued stock awards to employees with a four-year vesting schedule. The grant date fair value of the 374,900 restricted stock units and 272,900 stock options issued was $0.3 million and $0.1 million, respectively, with a grant date fair value per share of $0.84 and $0.55, respectively.

As of September 30, 2016, there was $5.0 million and $5.8 million of unrecognized compensation cost related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 3 years.

During the three months ended June 30, 2016, the Company granted certain employees stock options to purchase an aggregate of 4,015,000 shares of common stock at a weighted average exercise price of $0.91 per share. These awards vest in four equal tranches upon the achievement of certain product sales targets. The grant date fair value of these awards is $2.5 million with a grant date fair value of $0.63 per share, as determined using a Black-Scholes option pricing model. As of June 30, 2016, no compensation cost was recognized related to these awards as, at that time, it was not considered probable of achievement within the next twelve months.

During the three months ended September 30, 2016, the Company granted certain employees stock options to purchase an aggregate of 470,000 shares of common stock at a weighted average exercise price of $0.84 per share. These awards vest in four equal tranches upon the achievement of certain product sales targets. The grant date fair value of these awards is $0.3 million with a grant date fair value of $0.55 per share, as determined using a Black-Scholes option pricing model.

As of September 30, 2016, the Company reviewed the probability of achieving the performance conditions for each of the four vesting tranches and determined that it was probable that the Company would achieve the first vesting tranche in September 2017. Therefore, the Company recorded a non-material cumulative catchup of the expense from the grant date through September 30, 2016 and will record the unrecognized compensation cost related to the first tranche in the amount of $0.4 million through September 30, 2017. The Company further determined that no compensation costs would be recognized for the second, third and fourth vesting tranches as it had not been determined that it was probable.

10. Net Income (Loss) Per Common Share

Generally, basic net income (loss) per share excludes dilution for potentially dilutive securities and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (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 antidilutive. During 2015, 9,000,000 shares of the Company's common stock, which were loaned to Bank of America pursuant to the terms of a share lending agreement, were issued and outstanding, with the holder of the borrowed shares having all the rights of a holder of the Company's common stock. As the share borrower was required to return all borrowed shares to the Company, the borrowed shares were not considered outstanding for the purpose of computing and reporting basic or diluted loss per share during the periods presented for 2015. These shares were returned to the Company in the third quarter of 2015.

The following tables summarize the components of the basic and diluted net income (loss) per common share computations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Basic EPS:				
Net income (loss) (numerator)	$126,520	$ (31,857)	$ 71,690	$ (91,426)
Weighted average common shares (denominator)	478,137	405,199	454,188	401,734
Net income (loss) per share	$ 0.26	$ (0.08)	$ 0.16	$ (0.23)
Diluted EPS:				
Net income (loss) (numerator)	$126,520	$ (31,857)	$ 71,690	$ (91,426)
Weighted average common shares	478,137	405,199	454,188	401,734
Effect of dilutive securities - common shares issuable	4,607	—	178	—
Adjusted weighted average common shares (denominator)	482,744	405,199	454,366	401,734
Net income (loss) per share	$ 0.26	$ (0.08)	$ 0.16	$ (0.23)

Common shares issuable represents incremental shares of common stock which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes. For the three and nine months ended September 30, 2016, 78,085,579 and 82,158,388 incremental shares of common stock, respectively, were not included in the calculation of diluted earnings per share because the inclusion of these shares would have been antidilutive. For the three and nine months ended September 30, 2015, 30,416,127 incremental shares of common stock were not included in the calculation of diluted loss per share for both periods because the inclusion of these shares would have been antidilutive.

11. Commitments and Contingencies

Guarantees and Indemnifications

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

Litigation

The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of September 30, 2016, 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 of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in the Company's stock price, several complaints were filed in the U.S. District Court for the Central District of California (the "District Court") against the Company and certain of its officers and directors on behalf of certain purchasers of its common stock, which were consolidated into a single action. The amended complaint alleged that the Company and certain of its officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The Company and the named defendants brought a motion to dismiss the class action that was pending against them, which the District Court granted in August 2016 without leave to amend the complaint. The lead plaintiff has appealed the decision to the Ninth Circuit Court of Appeals. The Company will vigorously oppose the appeal.

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement 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. The Company will vigorously defend against the claims advanced.

Subsequent to the filing of the federal securities class action against the Company, two shareholder derivative complaints were filed in the Superior Court for the State of California, County of Los Angeles against certain of the Company's directors and officers. The complaints allege breaches of fiduciary duties by the defendants and other violations of law. Among other allegations, the complaints allege that the defendants caused the Company to make false and misleading statements or omissions of material fact regarding the Company's business and the prospects for sales of Afrezza, thereby artificially inflating the price of the Company's common stock. Following the dismissal of the federal securities class action, each derivative complaint was voluntarily dismissed by its plaintiff.

Contingencies

In connection with the Facility Agreement, on July 1, 2013 the Company also entered into a Milestone Rights Purchase Agreement (the "Milestone Agreement") with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, 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, including the first commercial sale of an Afrezza product in the United States and the achievement of specified net sales figures (see Note 13 – Facility Agreement).

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. The Company has agreed to purchase annual minimum quantities of insulin under the Insulin Supply Agreement of an aggregate total of approximately €120.1 million, of which €92.4 million is remaining at September 30, 2016. The annual minimum quantity for 2016 is €6.1 million, of which €6.1 million has been purchased as of September 30, 2016. The Company may request to purchase additional quantities of insulin over annual minimum quantities and will incur aggregate cancellation fees of approximately $5.3 million if not purchased. The Company also has other firm commitments with other suppliers for an aggregate of $0.9 million. Based on the Company's firm purchase commitments outstanding, the Company has recorded a recognized loss on purchase commitments of $71.6 million and $66.2 million as of September 30, 2016 and December 31, 2015, respectively. The $5.4 million increase for the nine months ended September 30, 2016 related to the recognized loss on purchase commitments was primarily due to an increase of $9.2 million for a change in estimate as a result of the sale of raw insulin for Sanofi, offset by a decrease of $1.1 million for a reduction in the recognized loss on purchase commitments for other materials related to a change in estimate associated with the renegotiation of certain agreements and a foreign currency translation loss of $3.0 million.

Unless earlier terminated, the term of the Insulin Supply Agreement with Amphastar expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months' written notice given prior to the end of the initial term or any additional two year term. The Company and Amphastar each have normal and customary termination rights, including termination for 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.

Under the terms of the Sanofi Supply Agreement, in the event that Sanofi terminates the Sanofi License Agreement for various reasons (including the reasons cited in its notice of termination to the Company), then upon written notice from the Company within 30 days following the termination date, Sanofi is obligated to purchase up to $50 million of the Company's insulin inventory as a percentage of each lot received or receivable by the Company (the "Insulin Put Option"). On April 14, 2016, the Company provided Sanofi with written notice that it was exercising the Insulin Put Option. In the second quarter of 2016, $9.2 million was received for the sale of insulin inventory in connection with the Insulin Put Option, which was initially recorded as deferred sales from collaboration. This amount was recognized as net revenue – collaboration in the condensed consolidated statements of operations for the three and nine months ended September 30, 2016.

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 their 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. Tax years since 2011 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

13. Facility Agreement

As of September 30, 2016, there was $55.0 million principal amount of 2019 notes and $20.0 million principal amount of Tranche B notes outstanding. The 2019 notes accrue interest at an annual rate of 9.75% and the Tranche B notes accrue interest at an annual rate of 8.75%. The Facility Agreement principal repayment schedule is comprised of annual payments beginning on July 1, 2016 and ending December 9, 2019. The repayment dates correspond to the dates on which the 2019 notes or Tranche B notes, as applicable, were issued. Principal payments of $20.0 million are due during the year ending December 31, 2017.

In conjunction with the Facility Agreement, the Company entered into a Milestone Rights Agreement with Deerfield which requires the Company to make contingent payments to Deerfield, totaling up to $90.0 million, upon the Company achieving specified commercialization milestones. The Milestone Rights were initially recorded as a short-term liability equal to $3.2 million included in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet and a long-term liability equal to $13.1 million included in other liabilities. As of September 30, 2016, the remaining liability balance of $8.9 million is classified as a long-term liability in other liabilities.

Accretion of debt issuance cost and debt discount in connection with the Facility Agreement during the three and nine months ended September 30, 2016 and 2015 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Accretion expense - debt issuance cost	$ 9	$ 9	$ 26	$ 26
Accretion expense - debt discount	$ 428	$ 397	$ 1,280	$ 1,142

The Facility Agreement contains a financial covenant that requires the Company's cash and cash equivalents, which include available borrowings under The Mann Group Loan Arrangement, on the last day of each fiscal quarter to not be less than $25.0 million. The Company will need to raise additional capital to support its current operating plans. Due to the uncertainties related to maintaining sufficient resources to comply with the aforementioned covenant, the 2019 notes and Tranche B notes have been classified as current liabilities in the accompanying condensed consolidated balance sheet as of September 30, 2016. In the event of non-compliance, Deerfield may declare all or any portion of the 2019 notes and/or Tranche B notes to be immediately due and payable.

14. Warrants

In May 2016, the Company sold in a registered offering an aggregate of 48,543,687 shares of common stock together with A Warrants exercisable for up to an aggregate of 36,407,765 shares of common stock and B Warrants exercisable for up to an aggregate of 12,135,921 shares of common stock with a total fair value of $44.7 million. Each of the warrants has an exercise price of $1.50 per share. The A Warrants became exercisable upon issuance and will expire two years thereafter. The B Warrants will become exercisable beginning in May 2017 and will expire 30 months after the date of issuance. The shares of common stock and the warrants are immediately separable and issued separately. There have been no warrants exercised as of September 30, 2016.

The Company determined that the A Warrants require liability classification primarily due to a price-protection clause that applies in the event of certain dilutive financings. The fair value of the A Warrants was recorded as warrant liability in the condensed consolidated balance sheet at issuance and is adjusted to fair value at each reporting period until exercise or expiration. The Company determined that the B Warrants met the criteria for equity classification and has accounted for such warrants in additional paid-in capital.

As of September 30, 2016 and May 12, 2016, the fair value of the A Warrants liability was $4.9 million and $12.8 million, respectively. As of May 12, 2016, the fair value of the B Warrants at issuance was $5.0 million. The fair value of the A Warrants liability as of September 30, 2016 was estimated using a Monte Carlo valuation pricing model with the following underlying assumptions: (a) a risk-free interest rate of 0.66%; (b) an assumed dividend yield of zero percent; (c) an expected term of 1.6 years; and (d) an expected volatility of 90%. The fair value of the A Warrants liability as of May 12, 2016 was estimated using a Monte Carlo valuation pricing model with the following underlying assumptions: (a) a risk-free interest rate of 0.76%; (b) an assumed dividend yield of zero percent; (c) an expected term of 2.0 years; and (d) an expected volatility of 95%. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities is the expected volatility. Significant increases in volatility would result in a higher fair value measurement (Level 3 in the fair value hierarchy).

For the three and nine months ended September 30, 2016, the Company recognized a change in fair value of warrant liability of $13.2 million and $7.9 million, respectively, in the condensed consolidated statements of operations to reflect the fair value adjustments of the A Warrant liability from the date of issuance.

15. Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Sales and marketing	$ 7,005	$ 507	$ 11,022	$ 1,616
General and administrative	6,130	11,040	20,573	31,033
Total selling, general and administrative	$ 13,135	$ 11,547	$ 31,595	$ 32,649

16. Restructuring Charges

In September 2016, the Company initiated a restructuring of its organization in order to conserve resources for commercial sales and marketing of Afrezza and to align product manufacturing in support of these commercial efforts ("2016 Restructuring"). In connection with the 2016 Restructuring, the Company reduced its total workforce by approximately 18% to 155 employees. The Company recorded charges of approximately $1.5 million, primarily for employee severance as well as other related termination benefits and recognized a liability of $1.5 million as of September 30, 2016, which approximates fair value. The Company expects to substantially pay out the obligation for the 2016 Restructuring in the fourth quarter of 2016. The $1.5 million of costs associated with the 2016 Restructuring are included in cost of goods sold, research and development and selling, general and administrative in the condensed consolidated statements of operations as $0.4 million, $0.7 million and $0.4 million, respectively, for the three and nine months ended September 30, 2016.

In September 2015, the Company initiated a restructuring of the organization as a result of its shift to commercial production of Afrezza ("2015 Restructuring"). In connection with the 2015 Restructuring, the Company reduced its total workforce by approximately 26% to 198 employees. The Company recorded charges of approximately $3.2 million, primarily for employee severance as well as other related termination benefits and recognized a liability of $3.2 million as of September 30, 2015, which approximates fair value. The $3.2 million of costs associated with the 2015 Restructuring are included in operating expenses for research and development and selling, general and administrative in the condensed consolidated statements of operations as $2.0 million and $1.2 million, respectively, for the three and nine months ended September 30, 2015. During the quarter ended December 31, 2015, the Company recorded additional charges related to employee severance and other related termination benefits in the amount of $2.8 million, meaning it had recorded restructuring charges of $6.0 million for the year ended December 31, 2015. This additional $2.8 million of costs are included in research and development and selling, general and administrative in the condensed consolidated statements of operations as $0.7 million and $2.1 million, respectively. As of September 30, 2016 and December 31, 2015, the Company had a remaining accrual balance for the 2015 Restructuring of $1.7 million and $3.0 million, respectively. The Company expects to substantially pay out the remainder of this obligation by the third quarter of 2017.

A reconciliation of beginning and ending liability balances for the restructuring charges is as follows (in thousands):

Description	2016 Restructuring	2015 Restructuring	Total
Accrual - September 30, 2015	$ —	$ 3,149	$ 3,149
Costs incurred and charged to expense	—	2,891	2,891
Costs paid or settled	—	(3,012)	(3,012)
Accrual - December 31, 2015	—	3,028	3,028
Costs incurred and charged to expense	1,475	547	2,022
Costs paid or settled	—	(1,865)	(1,865)
Accrual - September 30, 2016	$ 1,475	$ 1,710	$ 3,185

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, 2015 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 discovery, development and commercialization of therapeutic products for diseases such as diabetes. According to the Centers for Disease Control and Prevention, 29.1 million people in the United States had diabetes in 2012. Globally, the International Diabetes Federation has estimated that approximately 415.0 million people had diabetes in 2015 and approximately 642.0 million people will have diabetes by 2040.

Our only marketed product, Afrezza, is a rapid-acting inhaled insulin to improve glycemic control in adult patients with diabetes. Afrezza was approved by the U.S. Food and Drug Administration ("FDA") on June 27, 2014. It consists of a dry formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream. Peak insulin levels are achieved within 12–15 minutes of administration.

In February 2015, Afrezza became available by prescription in United States retail pharmacies. All sales and marketing activities related to Afrezza were conducted by Sanofi pursuant to the Sanofi License Agreement, and we were responsible for manufacturing Afrezza to supply Sanofi's demand for the product pursuant to the Sanofi Supply Agreement.

Following the termination of the Sanofi License Agreement in April 2016, we assumed responsibility for worldwide development and commercialization of Afrezza, which included, among other activities, establishing a channel strategy, distribution agreements, a contract sales force, co-pay assistance programs, a voucher program, data agreements, and payor relationships. Under terms of the transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until we began distributing MannKind-branded Afrezza product to major wholesalers during the week of July 25, 2016. We began recognizing commercial product sales revenue during the three months ended September 30, 2016.

We intend to continue the commercialization of Afrezza in the United States through our own commercial organization. Our current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary foreign regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are appropriate commercial opportunities.

In May 2016, pursuant to a previously filed Form S-3 Registration Statement, which was declared effective by the Securities and Exchange Commission (the "SEC") on April 27, 2016, we sold in a registered public offering 48,543,692 shares of our common stock, together with A Warrants exercisable for up to an aggregate of 36,407,769 shares of our common stock and B Warrants exercisable for up to an aggregate of 12,135,923 shares of our common stock. Net proceeds from this offering were approximately $47.4 million after deducting placement agent fees and expenses and paying for offering expenses, and excluding any future proceeds from the exercise of the warrants.

As of September 30, 2016, we had an accumulated deficit of $2.8 billion and a stockholders' deficit of $238.7 million. We have funded our operations primarily through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement, borrowings under The Mann Group Loan Arrangement, receipt of upfront and milestone payments under the Sanofi License Agreement and borrowings under the Sanofi Loan Facility to fund our portion of the loss share. As discussed below in "Liquidity and Capital Resources", if we are unable to obtain additional funding, there will continue to be substantial doubt about our ability to continue as a going concern.

Our business is subject to significant risks, including but not limited to our ability to successfully market and sell Afrezza, our ability to successfully manufacture sufficient quantities of Afrezza and the risks inherent in our future clinical trials and the regulatory

approval process for our product candidates. Additional significant risks also include raising capital, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

REVENUE RECOGNITION

Net Revenue – Collaboration

As discussed above, in April 2016 we assumed responsibility for the worldwide development and commercialization of Afrezza from Sanofi and began distributing our branded product to major wholesalers during the three months ended September 30, 2016. Profits and losses that were specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of Afrezza were shared 65% by Sanofi and 35% by MannKind until Sanofi ceased selling Afrezza. One of the four basic criteria of revenue recognition is that a seller's price to a buyer must be fixed or determinable. Prior to the three months ended September 30, 2016, we did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement and the Sanofi Supply Agreement. Thus, we believed the fixed or determinable requirement for revenue recognition had not been met and recorded no revenue from our collaboration with Sanofi prior to the three months ended September 30, 2016. However, during the three months ended September 30, 2016, we determined that, due to the termination of the Sanofi License Agreement, the remaining costs under the Sanofi License Agreement were fixed or determinable and that future activity under the Sanofi Supply Agreement was reasonably estimable and thus recognized revenue from collaboration. There are no future obligations to Sanofi.

Net Revenue – Commercial Product Sales

We sell Afrezza in the United States to ICS Direct and wholesale pharmaceutical distributors and, through them, to retail pharmacies, which we collectively refer to as our customers. These sales are subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Net revenue – commercial product sales consists of net sales of Afrezza dispensed to patients. The net sales took place during the three months ended September 30, 2016 as a result of our Afrezza launch in July 2016.

Given the limited sales history of Afrezza, we cannot reliably estimate expected returns of the product at the time of shipment into the distribution channel. Accordingly, we defer recognition of revenue on Afrezza product shipments until the right of return no longer exists, which occurs at the earlier of the time Afrezza is dispensed through patient prescriptions or expiration of the right of return.

We record revenue by estimating Afrezza patient prescriptions dispensed using an analysis of third-party syndicated data. We also analyze additional data points to ensure that such third-party data is reasonable including data related to inventory movements within the channel and ongoing prescription demand.

The Company recorded $2.0 million in deferred revenue on its condensed consolidated balance sheet, of which $1.6 million (net of estimated gross-to-net adjustments) represents product shipped to our third-party logistics provider and wholesale distributors, but not dispensed to patients as of September 30, 2016. Deferred revenue also includes $0.4 million that we have received for the sale of surplus raw materials to a third party, where delivery was made after September 30, 2016. In addition, the costs of Afrezza associated with the deferred revenue are recorded as deferred costs until such time the related deferred revenue is recognized.

Gross-to-net Adjustments

Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, estimated rebates and patient discount programs, and are based on estimated amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with our customers and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. We record product sales deductions in the statement of operations at the time product revenue is recognized. Total items deducted from gross product sales for the quarter ended September 30, 2016 were approximately $0.3 million, or 31.8% as a percentage of gross sales.

Product Returns

We do not provide a reserve for product refunds for sales of Afrezza due to our revenue recognition policy of deferring recognition of revenue on product shipments of Afrezza until the right of return no longer exists.

Wholesaler Distribution Fees

We pay distribution fees to certain wholesale distributors based on contractually determined rates and accrue those distribution fees on shipments to the respective wholesale distributors. Distribution fees are recognized as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts

We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the prompt pay discount amount and we recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Rebates

We participate in federal and state government-managed Medicare and Medicaid rebate programs and intend to pursue participation in certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating federal and state government entities. Rebates provided through these other qualifying programs will be included in the Medicaid/Medicare rebate accrual and are considered Medicaid/Medicare rebates for the purposes of this discussion. We account for these rebates by establishing an accrual equal to the estimate of rebate claims attributable to a sale and we determine our estimate of the rebates accrual based on historical payor data provided by a third-party vendor along with additional data including a forecasted participation rate for Medicare and Medicaid. From that data, as well as input received from the commercial team, an estimated participation rate for Medicare and Medicaid is determined and applied at the mandated rate for those sales. Any new information regarding changes in the programs' regulations and guidelines or any changes in our government price reporting calculations that would impact the amount of the rebates will also be taken into account in determining or modifying the appropriate reserve. The time period between the date the product is sold into the channel and the date such rebates are paid ranges from approximately six to nine months. As such, continuous monitoring of these estimates will be performed on a periodic basis and if necessary, adjusted to reflect new facts and circumstances. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Discount and Co-Pay Assistance Programs

We offer discount programs to patients for Afrezza in which patients receive discounts on their prescriptions or a reduction in their co-pay amounts that are reimbursed by us. We estimate the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

PRODUCT COSTS - COLLABORATION

Product costs – collaboration represents the costs of Afrezza manufactured and sold as well as insulin sold to Sanofi. Previously, these costs were recognized as deferred costs from collaboration.

COST OF GOODS SOLD

Cost of goods sold includes costs related to Afrezza product dispensed by pharmacies to patients, as well as under-absorbed labor and overhead, foreign currency exchange impact, loss on purchase commitments and inventory write-offs, which are recorded as expenses in the period in which they are incurred rather than as a portion of the inventory cost.

RESEARCH AND DEVELOPMENT EXPENSES

Historically our research and development expenses have consisted mainly of costs associated with research and development of our product candidates, including associated clinical trials, and manufacturing process development. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of equipment. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash.

Our research and development staff conducts our internal research and development activities, which include research, product development, clinical development, manufacturing process development and related activities. This staff is located in our facilities in Valencia, California and Danbury, Connecticut. We expense research and development costs as we incur them.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Our selling, general and administrative expenses are driven by salaries, benefits and stock-based compensation for administrative, finance, sales, marketing, business development, human resources, legal and information systems support personnel. In addition, selling, general and administrative expenses include professional service fees and business insurance costs.

RESULTS OF OPERATIONS

Three and nine months ended September 30, 2016 and 2015

Revenue

The following table provides a comparison of the revenue categories for the three and nine months ended September 30, 2016 and 2015 (dollars in thousands):

	Three and Nine Months Ended September 30,			
	2016	2015	$ Change	% Change
Revenue:				
Net revenue - collaboration	$161,781	$—	$161,781	100%
Net revenue - commercial product sales:				
Gross revenue from product sales	840	—	840	100%
Gross-to-Net Adjustments:				
Inventory management fees and cash discounts	(129)	—	(129)	-100%
Patient discount programs	(112)	—	(112)	-100%
Medicaid and Medicare rebates	(26)	—	(26)	-100%
Net revenue - commercial product sales	573	—	573	100%
Total net revenue	$162,354	$—	$162,354	100%

During the three and nine months ended September 30, 2016, we recognized net revenue – collaboration of $161.8 million, attributable to the collaboration with Sanofi. The collaboration payments recognized relate to activities from prior periods and were previously deferred. In the third quarter of 2016, due to the termination of the Sanofi License Agreement, we determined the costs related to the collaboration were reasonably estimable resulting in the accounting requirements for revenue recognition being met and there are no future obligations to Sanofi. The amount of revenue recognized was the upfront payment of $150.0 million and two milestone payments of $25.0 million each, net of $64.8 million of net loss share with Sanofi, as well as $17.4 million in sales of Afrezza and $9.2 million in sales of raw insulin, both to Sanofi. These amounts were exchanged as a result of the contractual terms of the agreements with Sanofi. During the three and nine months ended September 30, 2015, we did not recognize any revenues from collaboration.

We began distributing MannKind-branded Afrezza product to ICS Direct and wholesalers during the week of July 25, 2016. During the three and nine months ended September 30, 2016, we recognized net revenue – commercial product sales of $0.6 million, representing net sales of Afrezza dispensed to patients. During the three and nine months ended September 30, 2015, we did not recognize any revenues from commercial product sales. Estimated gross-to-net adjustments include estimates of wholesaler distribution and logistics fees, prompt pay discounts, estimated government rebates and patient discount programs.

Expenses

The following table provides a comparison of the expense categories for the three months ended September 30, 2016 and 2015 (dollars in thousands):

	Three Months Ended September 30,			
	2016	2015	$ Change	% Change
Expenses:				
Product costs - collaboration	$22,742	$ —	$22,742	100%
Cost of goods sold	4,331	8,115	(3,784)	-47%
Research and development	3,917	6,341	(2,424)	-38%
Selling, general and administrative	13,135	11,547	1,588	14%
Total expenses	$44,125	$26,003	$18,122	70%

During the three months ended September 30, 2016, we recognized $22.7 million of product costs – collaboration, which consists of $13.5 million in Afrezza manufacturing costs for product sold to Sanofi and $9.2 million for a change in estimate in our recognized loss on purchase commitments related to the sale of raw insulin to Sanofi. The Afrezza manufacturing costs were previously deferred on the condensed consolidated balance sheet at December 31, 2015. During the three months ended September 30, 2015, we did not recognize any product costs – collaboration.

The decrease in cost of goods sold of $3.8 million for the three months ended September 30, 2016 compared to the same period in the prior year is due to a $2.8 million decrease in under-absorbed labor and overhead due to the reduction in force and decreased depreciation from an asset impairment write-down in 2015, a $1.1 million gain on purchase commitments for other materials related to a change in estimate associated with the renegotiation of certain agreements, and inventory write offs of $1.0 million in 2015, offset by $1.0 million related to foreign currency exchange loss on the recognized loss on purchase commitments for insulin purchases. Cost of goods sold for the three and nine months ended September 30, 2016 also includes $0.1 million attributable to commercial product sales, which consists of the manufacturing costs for Afrezza dispensed to patients. This $0.1 million attributable to commercial product sales only includes conversion cost as we wrote off the cost of our raw materials held in inventory at the end of 2015.

The decrease in research and development expense of $2.4 million for the three months ended September 30, 2016 compared to the same period in the prior year is due to the expense associated with the 2015 reduction in force exceeding the expense associated with the 2016 reduction in force by $1.1 million and decreases in research and development project costs of $1.0 million, in facility spending of $0.8 million, in stock-based compensation expense of $0.6 million and in clinical trial expenses of $0.5 million, partially offset by an increase of $1.6 million in development work done for third parties.

The increase in selling, general and administrative expenses of $1.6 million for the three months ended September 30, 2016 compared to the same period in the prior year is due to an increase in costs for the support of sales and marketing of Afrezza of $5.4 million, partially offset by decreases in professional fees of $0.8 million, in facility spending of $0.7 million, in stock-based compensation expense of $0.5 million and expenses associated with the 2015 reduction in force of $1.7 million.

The following table provides a comparison of the expense categories for the nine months ended September 30, 2016 and 2015 (dollars in thousands):

	Nine Months Ended September 30,			
	2016	2015	$ Change	% Change
Expenses:				
Product costs - collaboration	$22,742	$ —	$ 22,742	100%
Cost of goods sold	15,567	15,688	(121)	-1%
Research and development	13,357	23,455	(10,098)	-43%
Selling, general and administrative	31,595	32,649	(1,054)	-3%
Total expenses	$83,261	$71,792	$ 11,469	16%

During the nine months ended September 30, 2016, we recognized $22.7 million of product costs – collaboration, which consists of $13.5 million in costs of manufacturing Afrezza for product sold to Sanofi and $9.2 million for a change in estimate in our recognized loss on purchase commitments related to the sale of raw insulin to Sanofi. The Afrezza manufacturing costs were previously deferred on the consolidated balance sheet at December 31, 2015. During the nine months ended September 30, 2015, we did not recognize any product costs - collaboration.

Cost of goods sold for the nine months ended September 30, 2016 was $15.6 million, of which $13.6 million was related to under-absorbed labor and overhead costs, which are expensed in the period in which they occur rather than relieved as a portion of inventory costs, $3.0 million related to a foreign currency exchange loss on the recognized loss on purchase commitments for insulin and $0.1 million attributable to commercial product sales, which consists of the manufacturing costs corresponding to Afrezza sold and recognized as product sales to patients offset by a $1.1 million gain on purchase commitments for other materials related to a change in estimate associated with the renegotiation of certain agreements. This $0.1 million attributable to commercial product sales only includes conversion cost as we wrote off the cost of our raw materials held in inventory at the end of 2015. Cost of goods sold for the nine months ended September 30, 2015 of $15.7 million were primarily related to under-absorbed labor and overhead costs expensed in the period.

The decrease in research and development expense of $10.1 million for the nine months ended September 30, 2016 compared to the same period in the prior year is due to the expense associated with the 2015 reduction in force exceeding the expense associated with the 2016 reduction in force by $4.6 million and decreases in facility spending of $2.8 million, in clinical trial expenses of $2.0 million, in research and development project costs of $1.8 million, in stock-based compensation expense of $0.8 million, in FDA fees of $0.6 million and a one-time technology transfer agreement expense reimbursement of $0.3 million in 2016, which were partially offset by a $1.6 million increase in development work done for third parties, a $0.8 million decrease in research and development tax credit and 2016 Sanofi research and development transition costs of $0.4 million.

The decrease in selling, general and administrative expenses of $1.1 million for the nine months ended September 30, 2016 compared to the same period in the prior year is due to decreases in salaries and personnel related expenses of $5.0 million, in facility expense related to the reduction in force in 2015 of $1.5 million, in stock-based compensation of $1.5 million, in consulting, professional fees, and other expenses of $2.4 million, which was offset by an $9.4 million increase in costs for the support of sales and marketing for Afrezza.

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the three months ended September 30, 2016 and 2015 (dollars in thousands):

	Three Months Ended September 30,			
	2016	2015	$ Change	% Change
Change in fair value of warrant liability	$13,185	$ —	$13,185	100%
Interest income	28	2	26	1300%
Interest expense on notes	(4,166)	(4,145)	(21)	1%
Interest expense on note payable to principal stockholder	(729)	(729)	—	0%
Loss on extinguishment of debt	—	(1,049)	1,049	-100%
Other (expense) income	(27)	67	(94)	-140%
Total other income (expense)	$ 8,291	$(5,854)	$14,145	-242%

Included in the three months ended September 30, 2016 is a $13.2 million benefit from a decrease in the fair value of the warrant liability from June 30, 2016. There is no change in fair value of warrant liability for the three months ended September 30, 2015 because the warrants were not outstanding in 2015.

The decrease in the loss on extinguishment of debt of $1.0 million for the three months ended September 30, 2016 compared to the same period in the prior year was due to the settlement of the 2015 notes through payment of cash and issuance of new debt.

The following table provides a comparison of the other income (expense) categories for the nine months ended September 30, 2016 and 2015 (dollars in thousands):

	Nine Months Ended September 30,			
	2016	2015	$ Change	% Change
Change in fair value of warrant liability	$ 7,879	$ —	$ 7,879	100%
Interest income	70	8	62	775%
Interest expense on notes	(12,567)	(17,899)	5,332	-30%
Interest expense on note payable to principal stockholder	(2,172)	(2,164)	(8)	0%
Loss on extinguishment of debt	—	(1,049)	1,049	-100%
Other (expense) income	(613)	1,470	(2,083)	-142%
Total other expense	$ (7,403)	$(19,634)	$12,231	-62%

Included in the nine months ended September 30, 2016 is a $7.9 million benefit from a decrease in the fair value of the warrant liability from May 12, 2016, the date the warrants were issued. There is no change in the fair value of warrant liability for the nine months ended September 30, 2015 because the warrants were not outstanding in 2015.

The decrease in the interest expense on notes of $5.3 million for the nine months ended September 30, 2016 compared to the same period in the prior year was primarily due to interest expense paid in 2015 for the achievement and re-measurement of the second milestone under the Milestone Agreement in the first quarter of 2015. There was no such payment in 2016.

The decrease in the loss on extinguishment of debt of $1.0 million for the nine months ended September 30, 2016 compared to the same period in the prior year was due to the settlement of the 2015 notes through payment of cash and issuance of new debt.

The decrease in other (expense) income of $2.1 million for the nine months ended September 30, 2016 compared to the same period in the prior year was primarily due to a one-time adjustment in 2015 to the sale price of patents we sold to a third party.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have primarily funded our operations through the sale of equity securities and convertible debt securities, borrowings under The Mann Group Loan Arrangement, borrowings under the Facility Agreement with Deerfield, receipt of upfront, milestone payments under the Sanofi License Agreement, and borrowings under the Sanofi Loan Facility.

As of September 30, 2016, we had $222.5 million principal amount of outstanding debt, consisting of:

- $27.7 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;
- $55.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and each $25.0 million of which is due and payable in July and December 2019;
- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, and $5.0 million of which is due and payable in December 2019;
- $49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at 5.84% and maturing and due on January 5, 2020; and
- $70.3 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

As of September 30, 2016, the amount available for future borrowings under The Mann Group Loan Arrangement was $30.1 million. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable. As of September 30, 2016, the accrued and unpaid interest under The Mann Group Loan Arrangement was $8.6 million.

All profits and losses from Afrezza sales by Sanofi or its affiliates were shared 65% by Sanofi and 35% by MannKind until Sanofi ceased distributing Afrezza pursuant to the terms of the Sanofi License Agreement. Our total share of the net losses are $71.2 million, classified as Sanofi loan facility and loss share obligation, of which $71.5 million has been borrowed under the Sanofi Loan Facility. Subsequent to September 30, 2016, we applied $0.3 million to the Sanofi Loan Facility as a prepayment equal to our share of the net profit for the third quarter of 2016. The balance remaining under the Sanofi Loan Facility is $71.2 million, which includes $5.8 million in paid-in-kind interest capitalized as additional principal. Additionally, if we sell our Valencia facility, which we no longer use as our corporate headquarters, we will be required to prepay the loans under the Sanofi Loan Facility from the net cash proceeds of the sale within five business days of receipt.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2018 notes, 2019 notes, Tranche B notes, The Mann Group Loan Arrangement or Sanofi Loan Facility when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective 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 2018 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum, paid-in kind on a quarterly basis (2.06% per quarter compounded). Loans under The Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum, due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group mutually agree. 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 2018 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or borrowings under The Mann Group Loan Arrangement or the Sanofi Loan Facility when required, 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 note holders 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, including the first commercial sale of an Afrezza product and the achievement of specified net sales figures.

The Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires our cash and cash equivalents, which includes available borrowings under The Mann Group Loan Arrangement, on the last day of each fiscal quarter to not be less than $25.0 million. In the event of default under the Facility Agreement, the holders of the 2019 notes and Tranche B notes may declare all or any portion of the 2019 notes and Tranche B notes to be immediately due and payable. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations.

In August 2015, we issued $27.7 million aggregate principal amount of 2018 notes. The 2018 notes are general, unsecured, senior obligations, except that the 2018 notes are subordinated in right of payment to the outstanding notes issued pursuant to the Facility Agreement and our borrowings under the Sanofi Loan Facility. The 2018 notes rank equally in right of payment with our other unsecured senior debt. The 2018 notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash on February 15 and August 15 of each year, beginning February 15, 2016, with interest accruing from August 15, 2015. The 2018 notes mature on August 15, 2018.

Pursuant to our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin, for an aggregate total purchase price of approximately €120.1 million, of which €92.4 million is remaining at September 30, 2016. The annual minimum quantity for 2016 is €6.1 million, of which €6.1 million has been purchased as of September 30, 2016. The Company may request to purchase additional quantities of insulin over annual minimum quantities and will incur aggregate cancellation fees of approximately $5.3 million if not purchased. We and Amphastar each have normal and customary termination rights, including termination for 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, we 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 us 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.

As a result of Sanofi's termination of the Sanofi License Agreement, we had the right to require Sanofi, upon giving Sanofi written notice within 30 days following the termination date, to purchase up to $50 million of our insulin inventory as a percentage of each lot received or receivable by us (the "Insulin Put Option"). In April 2016, we provided Sanofi with written notice of our election to exercise the Insulin Put Option. In the second quarter of 2016, we received $9.2 million for the sale of insulin inventory in connection with the Insulin Put Option, which was initially recorded as deferred payments from collaboration. This amount was subsequently recognized as net revenue – collaboration in the condensed consolidated statements of operations in the third quarter of 2016. The subsequent draw down of the remaining $40.8 million of purchases of raw insulin by Sanofi are scheduled to occur annually in the fourth quarter from 2016 through 2019.

Pursuant to the Sanofi License Agreement, we received milestone payments of $50.0 million in the first quarter of 2015 upon satisfaction of certain manufacturing milestones specified in the Sanofi License Agreement. As a result of the termination of the Sanofi License Agreement, we will not receive any additional milestone payments from Sanofi under the agreement.

During the nine months ended September 30, 2016, we used $65.3 million of cash for our operating activities as a result of a net decrease in operating assets and liabilities of $147.0 million offset by our net income of $71.7 million, adjusted by non-cash charges of $10.0 million. The non-cash charges included $3.1 million of depreciation and accretion, $4.1 million of stock-based compensation, $2.2 million interest accrued through borrowings from our principal stockholder, $3.0 million loss on foreign currency exchange, $4.1 million of interest accrued through borrowings under Sanofi Loan Facility and other non-cash charges of $0.7 million offset by $7.9 million from fair valuation of warrants. Also within adjustments to reconcile net income to net cash used was $0.7 million from Series A Warrant issuance costs included in financing. The changes in operating assets and liabilities were due to increases in accounts receivable of $3.1 million, inventory of $5.1 million, deferred costs from commercial product sales of $0.3 million, prepaid expenses and other current assets of $0.2 million, accrued expenses and other current liabilities of $6.6 million, deferred revenue of $2.0 million and purchase commitment liabilities of $2.4 million, offset by decreases in deferred costs from collaboration of $13.5 million, accounts payable of $10.3 million, deferred sales from collaboration of $17.5 million and deferred payment from collaboration of $135.0 million.

During the nine months ended September 30, 2015, we used $34.7 million of cash for our operating activities as a result of our net loss of $91.4 million, adjusted by non-cash charges of $20.5 million and a net decrease in operating assets and liabilities of $36.2 million. The non-cash charges included $10.1 million of depreciation and accretion, $6.4 million of stock-based compensation, $2.2 million interest accrued through borrowings from our principal stockholder, $1.0 million of loss on extinguishment of debt and $0.8 million of interest accrued through borrowings under Sanofi Loan Facility. The change in operating assets and liabilities were due to increases in inventory of $13.7 million, deferred costs of $13.5 million, other assets of $0.7 million and deferred revenue of $17.0 million offset by decreases in accounts receivable of $48.8 million, prepaid expenses and other current assets of $7.0 million, accounts payable of $2.7 million and accrued expenses and other current liabilities of $5.9 million.

We used $1.1 million of cash for investing activities during the nine months ended September 30, 2016, compared to $9.9 million for the nine months ended September 30, 2015. The $8.8 million decrease was due to reduced purchases of machinery and equipment.

Our financing activities provided $42.9 million of cash for the nine months ended September 30, 2016, as compared to $43.3 million used in the same period in 2015. For the nine months ended September 30, 2016, cash provided by financing activities was primarily from $47.3 million in net proceeds received from the sale of stock and warrants pursuant to a registered public offering of 48,543,687 common shares. Each share of common stock was sold together with a warrant to purchase 0.75 of a share of common stock (A Warrants) and a warrant to purchase 0.25 of a share of common stock (B Warrants) for a combined purchase price of $1.03. Additionally $0.8 million was received from exercises of stock options offset by $5.0 million for principal payments on notes payable to Deerfield, and the payment of employment taxes related to vesting restricted stock units of $0.2 million.

We used $43.3 million for financing activities during the nine months ended September 30, 2015, primarily for $64.3 million of principal payments on notes payable, $4.2 million for the achievement and payment of the second milestone to Deerfield for product launch on February 3, 2015 and $1.8 million for payment of employment taxes related to vested restricted stock units, offset by $13.5 million provided from exercises of stock options and $14.3 million provided by net proceeds for the issuance of common stock pursuant to our At Market Issuance Sales Agreement.

As of September 30, 2016, we had $35.5 million in cash and cash equivalents. We expect to expend our capital resources for the manufacturing, sales and marketing of Afrezza and to develop our product candidates. We also intend to use our capital resources for general corporate purposes.

If we enter into strategic business collaborations with respect to our product candidates or Afrezza for commercialization outside of the United States, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. 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 strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if 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 through equity or debt financing or entering business collaborations, 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, and there will continue to be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of September 30, 2016, we did not have any off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES

The preparation of our condensed consolidated financial statements in conformity with Generally Accepted Accounting Principles in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Item 7 of the Annual Report, in addition to the following policies:

Revenue **–** Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the accounting requirements for revenue recognition are not met, we defer the recognition of revenue by recording deferred revenue on the balance sheet until such time that all criteria are met.

We have entered into a Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc. (ICS), a third party logistics provider, under which ICS will distribute our product to wholesalers on its behalf. To enable us to distribute product in all necessary jurisdictions, on July 1, 2016 we entered into a first amendment to its contract with ICS for an interim period. Under this amendment, ICS, through ICS Direct, will purchase product from us and title and risk of loss transfers to ICS Direct. However, because (1) we are required to indemnify and hold harmless ICS for all accounts receivables arising out of product sales under the first amendment that are not collected from the customers according to payment terms, and (2) ICS Direct may return product to us under the right of return described below, we have concluded that we cannot recognize revenue upon transfer of product to ICS or further, to ICS Direct.

On September 26, 2016, we provided notice to ICS of our election to terminate the interim period agreement effective December 15, 2016. After that date, ICS will no longer take title to inventory. However, the Commercial Outsourcing Services Agreement will continue to be in effect and ICS will continue to distribute our product to wholesalers on our behalf.

We provide the right of return to our customers for unopened product for a limited time before and after its expiration date. Given our limited sales history for Afrezza and the inherent uncertainties in estimating product returns, we have determined that the shipments of Afrezza made to our customers thus far do not meet the criteria for revenue recognition at the time of shipment. We invoice our customers upon shipment of Afrezza to them and record accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price net of estimated gross-to-net adjustments. We then recognize revenue when Afrezza is dispensed at the pharmacies directly to the patients.

Given our limited sales history for Afrezza, we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on Afrezza product shipments until the right of return no longer exists, which occurs at the earlier of the time Afrezza is dispensed through patient prescriptions or expiration of the right of return. We recognize revenue based on Afrezza patient prescriptions dispensed as estimated by syndicated data provided by a third party. We also analyze additional data points to ensure that such third-party data is reasonable including data related to inventory movements within the channel and ongoing prescription demand. We commenced commercial sales of MannKind-branded Afrezza product in July 2016. In addition, the costs of Afrezza associated with the deferred revenue are recorded as deferred costs until such time the related deferred revenue is recognized.

Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, estimated rebates and patient discount programs, and are based on estimated amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with our customers and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. We record product sales deductions in the statement of operations at the time product revenue is recognized.

Product Returns

We do not provide a reserve for product refunds for sales of Afrezza due to our revenue recognition policy of deferring recognition of revenue on product shipments of Afrezza until the right of return no longer exists.

Wholesaler and Retail Pharmacy Distribution Fees

We offer distribution fees to certain wholesale distributors based on contractually determined rates. We accrue the distribution fees on shipment to the respective wholesale distributors and recognizes the distribution fees as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts

We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Rebates

We participate in federal and state government-managed Medicare and Medicaid rebate programs and intends to pursue participation in certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating federal and state government entities. Rebates provided through these other qualifying programs will be included in the Medicaid/Medicare rebate accrual and are considered Medicaid/Medicare rebates for the purposes of this discussion. We account for these rebates by establishing an accrual equal to the estimate of rebate claims attributable to a sale and determines our estimate of the rebates accrual based on payor data provided by a third-party and additional data including the date rebate agreements are executed so reimbursements may begin and estimated payor mix forecast data. From that data as well as input received from the commercial team, an estimated participation rate for Medicare and Medicaid is determined and applied at the mandated rate for those sales. Any new information regarding changes in the programs' regulations and guidelines or any changes in the our government price reporting calculations that would impact the amount of the rebates will also be taken into account in determining or modifying the appropriate reserve. The time period between the date the product is sold into the channel and the date such rebates are paid ranges from approximately six to nine months. As such, continuous monitoring of these estimates will be performed on a periodic basis and, if necessary, adjusted to reflect new facts and circumstances. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Discount Programs

We offer discount card programs to patients for Afrezza in which patients receive discounts on their prescriptions that are reimbursed by us. We estimate the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

License and Collaboration Agreements

Pursuant to the Sanofi License Agreement, we granted to Sanofi exclusive, worldwide licenses to certain of our patents, trademarks and know-how for the development and commercialization of Afrezza. The terms of the Sanofi License Agreement provide for consideration to us in the form of a non-refundable upfront payment, product sales, manufacturing, regulatory and sales milestone payments and profit and loss sharing. On January 4, 2016, we received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement, effective April 4, 2016.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has "stand-alone value" to the customer.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Under the terms of the Sanofi License Agreement, Sanofi Supply Agreement and the Sanofi Loan Facility, we determined that the arrangement contained significant deliverables including (i) licenses to develop and commercialize Afrezza and to use our trademarks, (ii) development activities, and (iii) manufacture and supply services for Afrezza. Due to the proprietary nature of the manufacturing services to be provided by us, we determined that all of the significant deliverables should be combined into a single unit of accounting. As of September 30, 2016, we determined that the remaining costs under the Sanofi License Agreement are reasonably estimable. Accordingly, the fixed or determinable fee requirement for revenue recognition was met and there are no future obligations to Sanofi. The amount of revenue recognized totaled $161.8 million, which consisted of an upfront payment of $150.0 million and two milestone payments of $25.0 million each, net of $64.8 million of net loss share with Sanofi, as well as $17.4 million in sales of Afrezza and $9.2 million related to a sale of raw insulin, both to Sanofi. These payments and sales were made pursuant to the contractual terms of the agreements with Sanofi.

Deferred Costs

As of December 31, 2015, deferred costs from collaboration of $13.5 million represented the costs of product manufactured and sold to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi. During the third quarter of 2016, the costs related to the Sanofi product sales were recognized as product costs – collaboration in the condensed consolidated statement of operations.

At September 30, 2016, deferred costs from commercial product sales represented the cost of product shipped to ICS and wholesale distributors, but not sold through by pharmacies to patients. Cost of goods sold related to commercial product sales for the three and nine months ended September 30, 2016 included $0.1 million of cost related to product sold through from pharmacies to patients.

Warrant

We account for our warrants as either equity or liabilities based upon the characteristics and provisions of each instrument and evaluation of sufficient authorized shares available to satisfy the obligations. Warrants classified as derivative liabilities are recorded on our condensed consolidated balance sheets at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or decreases in other income (expense) in the condensed consolidated statements of operations. We estimate the fair value of our derivative liabilities using third party valuation analysis that utilizes option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as expected volatility, expected life, yield, and risk-free interest rate. Warrants classified as equity are recorded within additional paid in capital at the issuance date and are not remeasured in subsequent periods, unless the underlying assumptions change to trigger liability accounting.

Recently Issued Accounting Standards

See “Recently Issued Accounting Standards” under Note 1 to the condensed consolidated financial statements included in this report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Due to the fixed interest rates of our debt, we currently do not have exposure to changes in our interest expense as a result of changes in interest rates. The interest rate on amounts borrowed under The Mann Group Loan Arrangement for the three and nine months ended September 30, 2016 was a fixed rate equal to 5.84%. As of September 30, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million. We also have debt related to the 2018 notes at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75%, debt related to the Tranche B notes at a fixed interest rate of 8.75%, and debt related to the Sanofi Loan Facility at a fixed rate of 8.5%.

Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds 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 September 30, 2016 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts.

Foreign Currency Exchange Risk

We incur and will continue to incur significant expenditures for insulin supply obligations under our supply agreement with Amphastar. Such obligations are denominated in euros. During the nine months ended September 30, 2016, we made supply purchases of insulin contemplated under our supply agreement with Amphastar. At the end of each reporting period, these liabilities, if any, are 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. We have not entered into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks, but may enter into foreign currency hedging transactions in the future. 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 were to have occurred on September 30, 2016 this change would have resulted in a foreign currency impact to our pre-tax losses of approximately $10.4 million.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of September 30, 2016. 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.

As previously disclosed under Item 9A. "Controls and Procedures" in our Annual Report on Form 10-K for our fiscal year ended December 31, 2015, we concluded that our disclosure controls and procedures were not effective as of December 31, 2015 based on the material weakness identified. We did not maintain sufficient internal control over financial reporting due to the lack of operating effectiveness of our controls over the impairment testing that we performed in accordance with ASC 360-10, *Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories*, as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors, which management has determined constituted a material weakness. Further, during the three months ended June 30, 2016, we identified a material weakness in our internal control over significant non-routine transactions. Specifically, this deficiency in operation of internal controls resulted in an inadequate evaluation of the underlying accounting guidance for transactions entered into during the quarter and insufficient review of underlying analyses.

Based on management's assessment, including consideration of the control deficiencies discussed above and the timing of remedial actions noted below, management has concluded that our disclosure controls and procedures were not effective as of September 30, 2016.

Remediation Efforts to Address Identified Material Weaknesses

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and 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. During the three months ended September 30, 2016, remedial actions have been implemented to address the material weaknesses that were identified during the fiscal year ended December 31, 2015 and during the three months ended June 30, 2016. We have devoted significant effort and resources to the remediation of the material weaknesses and the improvement of our internal control over financial reporting. While we previously had processes in place over significant and non-routine transactions and the testing of impairment and disposal of long-lived assets and inventories, we enhanced these processes to better evaluate our research of the nuances of the complex accounting standards related to these accounting areas. We also engaged a third party accounting firm as a consultant to assist us in our financial reporting compliance, including the interpretation and application of new and complex accounting guidance.

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 2016 we implemented additional controls over revenue and cost of goods sold due to our new commercialization efforts directed towards Afrezza. We will continue to enhance these controls as the volume of transactions and further changes to the commercialization process occur.

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, several complaints were filed in the U.S. District Court for the Central District of California (the "District Court") against MannKind and certain of our officers and directors on behalf of certain purchasers of our common stock, which were consolidated into a single action. The amended complaint alleged that MannKind and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of MannKind's common stock. We and the named defendants brought a motion to dismiss the class action, which the District Court granted in August 2016 without leave to amend the complaint. The lead plaintiff has appealed the decision to the Ninth Circuit Court of Appeals. We will vigorously oppose the appeal.

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. We will vigorously defend against the claims advanced.

Subsequent to the filing of the federal securities class action against MannKind, two shareholder derivative complaints were filed in the Superior Court for the State of California, County of Los Angeles against certain of MannKind's directors and officers. The complaints allege breaches of fiduciary duties by the defendants and other violations of law. Among other allegations, the complaints allege that the defendants caused MannKind to make false and misleading statements or omissions of material fact regarding MannKind's business and the prospects for sales of Afrezza, thereby artificially inflating the price of MannKind's common stock. Following the dismissal of the federal securities class action, each derivative complaint was voluntarily dismissed by its plaintiff.

We are also 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

*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. We anticipate that our near term revenues will also, to a much lesser extent, depend on our ability to enter into licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us.

We assumed responsibility for worldwide commercialization of Afrezza in April 2016, prior to which time Sanofi was responsible for global commercial activities for Afrezza. We began distributing Afrezza in the United States in late July 2016, and intend to continue the commercialization of Afrezza in the United States through our own commercial organization. Successful commercialization of Afrezza is subject to many risks and there are many factors that could cause the commercialization of Afrezza to be unsuccessful, including a number of factors that are outside our control. 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, the availability of alternative treatments and lack of coverage or adequate reimbursement.

We have never, as an organization, launched or commercialized a product other than Afrezza, and there is no guarantee that we will be able to successfully do so with Afrezza. 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. While we have established a commercial team and have hired a U.S. sales force through a contract sales organization, we will need to maintain and continue to build 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. We have engaged a contract sales organization to conduct sales activities, but there are risks regarding whether a subcontractor will provide the level of effort and attention to Afrezza necessary for successful commercialization. In addition, Afrezza is a novel insulin therapy with a distinct 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.

We are also responsible for negotiating and securing coverage and reimbursement for Afrezza. If we are unable to obtain coverage of, and adequate payment levels for Afrezza, physicians may limit how much or under what circumstances they will prescribe or administer Afrezza and patients may decline to purchase Afrezza, which would have an adverse effect on our ability to generate revenues.

We are also responsible for the NDA for Afrezza and its maintenance. Prior to the termination of the Sanofi License Agreement in April 2016, we had no experience with the maintenance of an NDA and 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.

Maintaining and further building the internal infrastructure to further develop and commercialize Afrezza will be costly and time-consuming, and we may not be successful in our efforts or successful in obtaining financing to support those efforts.

If we fail to successfully commercialize Afrezza in the United States, our business, financial condition and results of operations will be materially and adversely affected.

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

While Afrezza has been approved in the United States by the FDA for glycemic control in adult patients with diabetes, it has not been approved in any other jurisdiction. In order to market Afrezza outside of the United States, we must obtain regulatory approval in each applicable 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 NDA for Afrezza.

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 appropriate commercial opportunities. It may be difficult to find 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, on terms that we view to be less than attractive or to 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 not be able to advance these programs unless we are able to enter into collaborations with third parties to fund of 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 have never been profitable or generated positive cash flow from cumulative operations to date. Historically, we have reported negative cash flow from operations other than for the nine months ended September 30, 2014, for the year ended December 31, 2014, and for the three months ended March 31, 2015 as a result of our receipt of an upfront payment and milestone payments from Sanofi. As of September 30, 2016, we had an accumulated deficit of $2.8 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill 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 connection with our quarterly assessment of impairment indicators and inventory valuation for the quarter ended December 31, 2015, we identified an impairment of our long-lived assets which resulted in charges of $140.4 million in such quarter. In addition, we agreed to purchase certain annual minimum quantities of insulin for an aggregate total purchase price of approximately €120.1 million, of which €92.4 million is remaining at September 30, 2016. The annual minimum quantity for 2016 is €6.1 million, of which €6.1 million has been purchased as of September 30, 2016. 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. As of September 30, 2016, we had stockholders' deficit of $238.7 million. 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 will need to raise additional capital to fund our operations, and our inability to do so could raise substantial doubt about our ability to continue as a going concern.**

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, and to avoid defaulting under the covenant in our Facility Agreement with Deerfield, which requires us to maintain at least $25.0 million in cash and cash equivalents or available borrowings under The Mann Group Loan Arrangement as of the last day of each fiscal quarter. It may be difficult for us to raise additional funds on favorable terms, or at all. As of September 30, 2016, we had stockholders' deficit of $238.7 million, which may raise concerns about our solvency and affect our ability to raise additional capital. 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;
- the costs of developing and commercializing Afrezza on our own in the United States, including the costs of building our commercialization capabilities;
- the costs of finding regional collaboration partners for the development and commercialization of Afrezza in foreign jurisdictions;
- the demand by any or all of the holders of the 2018 notes, the 2019 notes, and the Tranche B notes to require us to repay or repurchase such debt securities if and when required;
- our ability to repay or refinance existing indebtedness, and the extent to which the 2018 notes or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;
- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facilities;
- our obligation to make milestone payments pursuant to the Milestone Rights issued to the Milestone Purchasers and pursuant to the Milestone Rights Purchase Agreement dated July 1, 2013 (the "Milestone Agreement");
- our success in establishing 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 on acceptable terms, or at all. Issuances of additional debt or equity securities or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or 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 also will need to 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 collaborations, 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 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 be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. 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, in which case we will be required to raise additional capital. There can be no assurances that we will be able to raise additional capital on favorable terms, or at all. If we are unable to raise adequate additional capital 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.

*We have a substantial amount of debt pursuant to the 2018 notes, 2019 notes, Tranche B notes, The Mann Group Loan Arrangement and the Sanofi Loan Facility, and we may be unable to make required payments of interest and principal as they become due.**

As of September 30, 2016, we had $222.5 million principal amount of outstanding debt, consisting of:

- $27.7 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;
- $55.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and each $25.0 million of which is due and payable in July and December 2019;
- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, the balance of which is due and payable in December 2019;
- $49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement, bearing interest at 5.84% and maturing and due on January 5, 2020; and
- $70.3 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

We may borrow an additional $30.1 million under The Mann Group Loan Arrangement. The available borrowings may be used to capitalize accrued interest into principal upon mutual agreement of the parties, as accrued interest becomes due and payable under The Mann Group Loan Arrangement. As of September 30, 2016 the accrued and unpaid interest under The Mann Group Loan Arrangement was $8.6 million.

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 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective 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 2018 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum, paid-in-kind on a quarterly basis (2.06% per quarter compounded). Loans under The Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum, due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group mutually agree. 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 2018 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or the loans under The Mann Group Loan Arrangement or the Sanofi Loan Facility 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.

*The agreements governing our indebtedness contain covenants that we may not be able to meet and place restrictions on our operating and financial flexibility.**

Our obligations under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes, and the Milestone Agreement are secured by substantially all of our assets, including our intellectual property, accounts receivables, equipment, general intangibles, inventory (excluding the insulin inventory) and investment property, and all of the proceeds and products of the foregoing. Our obligations under the Facility Agreement and the Milestone Agreement are also secured by a certain mortgage on our facility in Danbury, Connecticut. Our obligations under the Sanofi Loan Facility are secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which we purchase or have purchased such insulin, and a second priority security interest in our assets that secure our obligations under the Facility Agreement.

The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the 2019 notes or the Tranche B notes; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents, including amounts available to us under The Mann Group Loan Arrangement, falling below $25.0 million as of the last day of any fiscal quarter. If we fail to timely pay accrued interest under The Mann Group Loan Arrangement when required, we will be in default under The Mann Group Loan Arrangement. During any such time as an event of default is continuing under The Mann Group Loan Arrangement, The Mann Group will not be obligated to make additional borrowings available to us. If an event of default is continuing under The Mann Group Loan Arrangement as of the last day of a fiscal quarter, we may be in breach of the financial covenant under the Facility Agreement that requires us to maintain cash and cash equivalents (including available borrowings under The Mann Group Loan Arrangement) of at least $25.0 million if our other cash and cash equivalents on hand do not equal or exceed $25.0 million. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the 2019 notes and Tranche B notes may declare all or any portion of the 2019 notes and Tranche B notes to be immediately due and payable. The Milestone Agreement includes customary representations and warranties and covenants by us, including restrictions on transfers of intellectual property related to Afrezza. The milestones are subject to acceleration in the event we transfer our intellectual property related to Afrezza in violation of the terms of the Milestone Agreement.

Similarly, the Sanofi Loan Facility includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens and make certain changes to our organizational documents. Events of default under the Sanofi Loan Facility include: our failure to make timely payments due under the Sanofi Loan Facility; inaccuracies in our representations and warranties to the lender; our failure to comply with any of our covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into

in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, the lender may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including our failure to timely make payments due under the Sanofi Loan Facility; our failure to comply with the negative covenants under the Sanofi Loan Facility limiting our ability to incur additional indebtedness or grant certain liens; our insolvency or the occurrence of certain bankruptcy-related events; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect) occur and are continuing, the lender may accelerate all of our repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor.

There can be no assurance that we will be able to comply with the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the 2019 notes or Tranche B notes or the lender under the Sanofi Loan Facility would demand repayment of the outstanding balance of the 2019 notes, the Tranche B notes or the loans under the Sanofi Loan Facility as applicable or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders and the holders of our other securities. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations. If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

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.

A number of established pharmaceutical companies have or are developing technologies for the treatment of unmet medical needs.

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 will depend not only on our ability to develop our product candidates but to improve them and 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. For example, with the approval of Afrezza, the FDA has required a five-year, randomized, controlled trial in 8,000 – 10,000 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. 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, or if we fail to 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 approved source of insulin for Afrezza is manufactured by Amphastar and the only source of our proprietary inert excipient, FDKP (fumaryl diketopiperazine), which is the primary component of our Technosphere technology platform, is manufactured by Lonza Group Ltd. (Lonza). 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 current good manufacturing practices ("cGMPs") for drug products, and the production of the Afrezza inhaler and related cartridges in accordance with quality system regulation ("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 or Lonza ceases to manufacture or is otherwise unable to deliver insulin for Afrezza or FDKP, respectively, 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 blisters containing cartridges 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 educate physicians about the benefits and advantages of Afrezza or our other products and to provide adequate support for them, 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 pricing and reimbursement 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 governments and 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 has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services 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 governmental 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, particularly the countries of the European Union, 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 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 ("PPACA") became law in the United States. PPACA substantially changes 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;
- 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 Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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;
- new 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 new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The medical device excise tax has been suspended by the Consolidated Appropriations Act of 2016 (the "CAA") through December 31, 2017. Absent further Congressional action, the excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund PPACA programs. Further, there have been judicial and Congressional challenges to other aspects of PPACA, and we expect there will be additional challenges and amendments to PPACA in the future.

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 Bipartisan Budget Act of 2015, will stay in effect through 2025 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. 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.

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 offering 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 civil False Claims Act, and civil monetary penalty 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 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, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the 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; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; 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.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, 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 civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, 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 of $10,000 per day for each day the submission is late beyond the due date. 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 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 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 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.

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. In connection with the audit of our financial statements for the year ended December 31, 2015, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we identified related to management review controls and our impairment testing that we performed in accordance with ASC 360-10, *Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories*, as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors. Further, during the three months ended June 30, 2016, we identified a material weakness in our internal control over significant non-routine transactions. Specifically, this deficiency in operation of internal controls resulted in an inadequate evaluation of the underlying accounting guidance for transactions entered into during the quarter and insufficient review of underlying analyses. As a result of these material weaknesses, we and our independent registered public accounting firm evaluated our internal control over financial reporting as ineffective.

We are taking steps to remediate the material weaknesses in our internal control over financial reporting, including designing additional training programs for relevant personnel and developing specific review procedures regarding management review controls. However, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all. If we are unable to successfully remediate our material weaknesses, or if we identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and 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.

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 class action 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, several complaints were filed in the U.S. District Court for the Central District of California (the "District Court") against MannKind and certain of our officers and directors on behalf of certain purchasers of our common stock, which were consolidated into a single action. The amended complaint alleged that MannKind and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of MannKind's common stock. We and the other defendants brought a motion to dismiss the class action that was pending against MannKind and two of our executives, which the District Court granted without leave to amend the complaint. The lead plaintiff has appealed the decision to the Ninth Circuit Court of Appeals. Although we will vigorously oppose the appeal, there can be no assurance that we will be successful.

We and certain of our directors and executive officers have also been named in similar lawsuits filed in Israel. We intend to vigorously defend against these claims. 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. 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. During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of $1.6 million. It has conducted at its expense all work and 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.

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.

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.

*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, as part of the approval of Afrezza, the FDA required that we complete a clinical trial to evaluate the potential risk of pulmonary malignancy with Afrezza. 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’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. **

At present, there are a number of clinical studies being conducted by other pharmaceutical companies involving insulin delivery systems. 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.

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for Afrezza inhalation powder have terms extending into 2020, 2026, 2028, 2029, and 2030. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 and 2032, and we have method of treatment claims that extend into 2026 and 2029. 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.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of 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, enacted on September 16, 2011, the United States moved to a first inventor to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The full effects of these changes are currently unclear as the United States Patent and Trademark Office, or USPTO, must still implement various regulations, the courts have only begun to interpret these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. 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, patent law continues to evolve. Several further changes to patent law are before Congress. The United States Supreme Court has exhibited an increased interest in patent law and several of its recent decisions have tended to narrow the scope of patentable subject matter related to medical products and methods. These and recent decisions of lower courts and guidelines issued by the USPTO call into question the patentability of biological inventions that had previously been considered patentable. While none of this has had an immediately apparent impact on our core technology and patents, the full and ultimate effect of these developments is not yet known. 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 own a number of domestic and foreign patents and patent applications relating to Afrezza, we have identified certain third-party 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, warrant exercises, and the vesting of restricted stock unit awards; the purchase of shares of common stock under our employee stock purchase program; and the issuance of shares upon exchange or conversion of the 2018 notes or any other convertible debt we may issue. 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.

*As a result of the death of Alfred E. Mann, our founder and former largest stockholder, the stock that he previously controlled is currently controlled by a trust, and we cannot assure you of the manner in which the trustees will manage the holdings.**

At November 1, 2016, the estate of Alfred E. Mann beneficially owned approximately 27.7% of our outstanding shares of capital stock, including shares held in the Alfred E. Mann Living Trust, The Mann Group LLC and Mann Medical Research Organization (“MMRO”) (collectively, the “Mann Affiliated Entities”).

Mr. Mann passed away on February 25, 2016. All of the shares beneficially owned by Mr. Mann in his individual capacity, the Alfred E. Mann Living Trust, The Mann Group LLC and MMRO (a non-profit organization) are controlled by the Alfred E. Mann Living Trust. The trustees of the Alfred E. Mann Living Trust are Mr. Mann’s wife and two other trustees. The trustees have the power to sell the shares or deal with them as an owner. Relatives, other individuals and charities may receive bequests of shares under the trust. The residuary beneficiary of the trust is the Alfred E. Mann Family Foundation, a charitable organization under section 501(c)(3) of the Internal Revenue Code that is a private foundation under section 509 of the Code. The same three trustees control the Alfred E. Mann Family Foundation. The Alfred E. Mann Family Foundation will have the power to sell the shares or deal with them as an owner.

We have been informed by the trustees for the Mann Affiliated Entities that the trustees may seek to dispose of some or all of the shares beneficially owned by the Mann Affiliated Entities, pursuant to distributions to trust beneficiaries, one or more trading plans under Rule 10b5-1 of the Exchange Act or otherwise. Although at this time we are not aware of any definitive decision by the trustees relating to the holding or disposition of the shares held by the Mann Affiliated Entities, any sales or other disposition of our common stock by the Mann Affiliated Entities, or the perception that such sales may occur, including the entry into any such trading plans, could have a material adverse effect on the trading price of our common stock and could make it more difficult for us to raise capital through the sale of our common stock or securities convertible into or exercisable for our common stock, which could have a material adverse effect on our business and financial condition.

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

Since January 1, 2013, our closing stock price as reported on The NASDAQ Global Market has ranged from $0.42 to $10.96. The trading price of our common stock 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:

- the progress of our recent commercial launch of Afrezza in the United States and other events or circumstances that we or others estimate will impact the future commercial success of Afrezza;
- 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 successful commercialize 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;
- legislative developments;
- 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;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- 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. On September 14, 2016, we received notice from the Listing Qualifications Department of the NASDAQ Stock Market indicating that, for the previous 30 consecutive business days, the bid price for our common stock closed below the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market. The notification letter stated that we would be afforded 180 calendar days, or until March 13, 2017, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days. We intend to actively monitor the bid price for our common stock between now and March 13, 2017, and will consider all available options to resolve the deficiency and regain compliance with the minimum bid price requirement. However, we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with NASDAQ's listing requirements.

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, the exchange or conversion of our 2018 notes into common stock or the exercise of our warrants for common stock could negatively affect the market price of our common stock and other securities. **

As of November 1, 2016, we had 478,376,869 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. 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 2018 notes or upon the exercise of outstanding warrants, could adversely affect the market price of our common stock and other securities. In addition, the existence of these notes and warrants 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 Facility Agreement, 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.

*We have a limited number of unreserved shares available for future issuance, which may impair our ability to conduct future financing and other transactions.**

Our amended and restated certificate of incorporation currently authorizes us to issue up to 700,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of November 1, 2016, we had a total of 221,623,131 shares of common stock that were authorized but unissued, and we have currently reserved a significant number of these shares for future issuance pursuant to outstanding equity awards, outstanding warrants, our equity plans and our 2018 notes. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our amended and restated certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

If we are unable to enter into new arrangements to issue shares of our common stock or securities convertible or exercisable into shares of our common stock, our ability to complete equity-based financings or other transactions that involve the potential issuance of our common stock or securities convertible or exercisable into our common stock, will be limited. In lieu of issuing common stock or securities convertible into our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which may require us to grant security interests in our assets and property and/or impose covenants upon us that restrict our business. If we are unable to issue additional shares of common stock or securities convertible or exercisable into our common stock, our ability to enter into strategic transactions such as acquisitions of companies or technologies, may also be limited. If we propose to amend our amended and restated certificate of incorporation to increase our authorized shares of common stock, such a proposal would require the approval by the holders of a majority of our outstanding shares of common stock, and we cannot assure you that such a proposal would be adopted. If we are unable to complete financing, strategic or other transactions due to our inability to issue additional shares of common stock or securities convertible or exercisable into our common stock, our financial condition and business prospects may be materially harmed.

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), originally filed with the SEC on August 9, 2016).
3.2	Amended and Restated Bylaws (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on November 19, 2007).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of common stock certificate (incorporated by reference to MannKind's Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 18, 2013).
4.3	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind's current report on Form 8-K (File No. 000-50865), originally 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 MannKind's Annual Report on Form 10-K (File No. 000-50865), originally 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).

Exhibit Number	Description of Document
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 MannKind's Current Report on Form 8-K (File No. 000-50865), originally 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 MannKind's Current Report on Form 8-K (File No. 000-50865), originally 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 MannKind's Current Report on Form 8-K (File No. 000-50865), originally 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 MannKind's Annual Report on Form 10-K (File No. 000-50865), originally 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	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind Corporation and Aventisub LLC (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 29, 2014).
4.12	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind Corporation, MannKind LLC and Aventisub LLC (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.13	Indenture, by and between MannKind and U.S. Bank (as successor trustee to Wells Fargo, N.A., dated August 10, 2015 (incorporated by reference to Exhibit 4.18 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.14	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2018 (included in Exhibit 4.18 as Exhibit A thereto) (incorporated by reference to Exhibit 4.19 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.15	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).
4.16	Form of Series A Common Stock Purchase Warrant (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 May 10, 2016).
4.17	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
31	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and 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.

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SIGNATURE

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

Dated: November 9, 2016

MANNKIND CORPORATION

By: /s/ MATTHEW J. PFEFFER
Matthew J. Pfeffer
Chief Executive Officer and Chief Financial Officer
(*on behalf of the registrant and as the registrant's Principal Financial Officer)*

Exhibit 31

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

I, Matthew J. Pfeffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2016 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my conclusion 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. I have disclosed, based on my 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.

Date: November 9, 2016

/s/ MATTHEW J. PFEFFER

Matthew J. Pfeffer
Chief Executive Officer and Chief Financial Officer

Exhibit 32

CERTIFICATION OF
CHIEF EXECUTIVE OFFICER AND 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)

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended September 30, 2016, as filed with the Securities and Exchange Commission on or about the date hereof to which this certification is attached as Exhibit 32 (the "Report") and pursuant to the requirement set forth in Rule 13a-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), Matthew J. Pfeffer, Chief Executive Officer and 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.

Date: November 9, 2016

In Witness Whereof, the undersigned has set his hand hereto as of the 9th day of November 2016.

/s/ Matthew J. Pfeffer
Matthew J. Pfeffer
Chief Executive Officer and Chief Financial Officer

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