

MANNKIND CORP  
Form 10-Q  
August 07, 2017  
[Table of Contents](#)

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

**Form 10-Q**

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

**For the quarterly period ended June 30, 2017**

**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)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>  <b>incorporation or organization)</b>  <b>25134 Rye Canyon Loop Suite 300</b>  <b>Valencia, California</b> <b>(Address of principal executive offices)</b>	<b>13-3607736</b> <b>(I.R.S. Employer</b>  <b>Identification No.)</b>   <b>91355</b> <b>(Zip Code)</b>  <b>(661) 775-5300</b>  <b>(Registrant's telephone number, including area code)</b>
--	---

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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act.

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

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

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

As of August 1, 2017, there were 104,682,717 shares of the registrant's common stock, \$0.01 par value per share, outstanding.



---

**Table of Contents**

**MANNKIND CORPORATION**

**Form 10-Q**

**For the Quarterly Period Ended June 30, 2017**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I: FINANCIAL INFORMATION</u></b>	<b>2</b>
<u>Item 1. Financial Statements (Unaudited)</u>	2
<u>Condensed Consolidated Balance Sheets: June 30, 2017 and December 31, 2016</u>	2
<u>Condensed Consolidated Statements of Operations: Three and six months ended June 30, 2017 and 2016</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss: Three and six months ended June 30, 2017 and 2016</u>	4
<u>Condensed Consolidated Statements of Cash Flows: Six months ended June 30, 2017 and 2016</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	36
<u>Item 4. Controls and Procedures</u>	36
<b><u>PART II: OTHER INFORMATION</u></b>	<b>37</b>
<u>Item 1. Legal Proceedings</u>	37
<u>Item 1A. Risk Factors</u>	37
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	59
<u>Item 3. Defaults Upon Senior Securities</u>	59
<u>Item 4. Mine Safety Disclosures</u>	59
<u>Item 5. Other Information</u>	60
<u>Item 6. Exhibits</u>	60
<b><u>SIGNATURES</u></b>	

Table of Contents**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)**

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 43,384	\$ 22,895
Accounts receivable, net	1,312	302
Receivable from Sanofi		30,557
Inventory	3,172	2,331
Asset held for sale		16,730
Deferred costs from commercial product sales	500	309
Prepaid expenses and other current assets	2,563	4,364
Total current assets	50,931	77,488
Property and equipment net	27,920	28,927
Other assets	523	648
Total assets	\$ 79,374	\$ 107,063
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 6,541	\$ 3,263
Accrued expenses and other current liabilities	9,076	7,937
Facility financing obligation	57,484	71,339
Deferred revenue net	2,592	3,419
Deferred payments from collaboration current	250	1,000
Recognized loss on purchase commitments current	9,926	5,093
Total current liabilities	85,869	92,051
Note payable to principal stockholder	79,666	49,521
Accrued interest note payable to principal stockholder		9,281
Senior convertible notes	27,649	27,635
Recognized loss on purchase commitments long term	99,001	95,942
Deferred payments from collaboration long term	625	
Warrant liability	605	7,381

Edgar Filing: MANNKIND CORP - Form 10-Q

Milestone rights liability and other liabilities	7,202	8,845
Total liabilities	300,617	290,656
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2017 and December 31, 2016		
Common stock, \$0.01 par value 140,000,000 shares authorized, 104,615,982 and 95,680,831 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	1,046	957
Additional paid-in capital	2,566,960	2,553,039
Accumulated other comprehensive loss	(21)	(24)
Accumulated deficit	(2,789,228)	(2,737,565)
Total stockholders' deficit	(221,243)	(183,593)
Total liabilities and stockholders' deficit	\$ 79,374	\$ 107,063

See notes to condensed consolidated financial statements.

**Table of Contents**

**MANNKIND CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Net revenue commercial product sales	\$ 1,548	\$	\$ 2,745	\$
Net revenue collaboration	63		125	
Revenue other	552		2,302	
Total revenues	2,163		5,172	
Expenses:				
Cost of goods sold	5,086	4,045	7,635	9,213
Research and development	3,123	4,310	6,251	9,440
Selling, general and administrative	18,566	11,110	33,956	18,460
Property and equipment impairment	111		111	
(Gain) loss on foreign currency translation	6,848	(341)	8,392	2,023
Total expenses	33,734	19,124	56,345	39,136
Loss from operations	(31,571)	(19,124)	(51,173)	(39,136)
Other income (expense):				
Change in fair value of warrant liability	147	(5,306)	6,776	(5,306)
Interest income	58	26	114	41
Interest expense on notes	(2,422)	(4,181)	(5,128)	(8,401)
Interest expense on note payable to principal stockholder	(721)	(721)	(1,435)	(1,443)
Loss on extinguishment of debt	(830)		(830)	
Other income		(653)	13	(586)
Total other expense	(3,768)	(10,835)	(490)	(15,695)
Loss before benefit for income taxes	(35,339)	(29,959)	(51,663)	(54,831)
Income tax benefit				
Net loss	\$ (35,339)	\$ (29,959)	\$ (51,663)	\$ (54,831)
Net loss per share basic and diluted	\$ (0.35)	\$ (0.33)	\$ (0.53)	\$ (0.62)
	99,864	91,061	97,816	88,416

Shares used to compute basic and diluted net loss per  
share

See notes to condensed consolidated financial statements.



**Table of Contents**

**MANNKIND CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(Unaudited)**

**(In thousands)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Net loss	\$ (35,339)	\$ (29,959)	\$ (51,663)	\$ (54,831)
Other comprehensive loss:				
Cumulative translation gain (loss)	3	(2)	3	(1)
Comprehensive loss	\$ (35,336)	\$ (29,961)	\$ (51,660)	\$ (54,832)

See notes to condensed consolidated financial statements.

**Table of Contents**

**MANNKIND CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(In thousands)

	<b>Six months ended June 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (51,663)	\$ (54,831)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion	1,787	2,058
Stock-based compensation expense	2,516	2,628
Loss on extinguishment of debt	830	
Gain on disposal of property and equipment	(24)	
Loss on foreign currency translation	8,392	2,023
Interest incurred through borrowings under Sanofi Loan Facility		2,604
Interest on note payable to principal stockholder	1,435	1,443
Warrant issuance cost		653
Change in fair value of warrant liability	(6,776)	5,306
Other, net	114	717
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,010)	23
Receivable from Sanofi	30,557	
Inventory	(841)	(2,866)
Deferred costs from commercial product sales	(191)	
Prepaid expenses and other current assets	1,800	2,595
Other assets	125	(238)
Accounts payable	3,357	(12,532)
Accrued expenses and other current liabilities	(483)	2,663
Deferred payments from collaboration	(125)	9,379
Deferred revenue net	(827)	
Recognized loss on purchase commitments	(500)	(3,892)
Net cash used in operating activities	(11,527)	(42,267)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment		(1,144)
Net proceeds from sale of asset held for sale	16,651	
Proceeds from sale of property and equipment	24	17
Net cash provided by (used in) investing activities	16,675	(1,127)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		

Proceeds from issuance of common stock		734	
Proceeds from direct placement		50,000	
Issuance cost associated with direct placement		(2,678)	
Borrowings on note payable to principal stockholder	19,429		
Principal payments on facility financing obligation	(4,000)		
Payment of employment taxes related to vested restricted stock units	(88)		(3)
Net cash provided by financing activities	15,341		48,053
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	20,489		4,659
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	22,895		59,074
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	\$ 43,384	\$	63,733
<b>SUPPLEMENTAL CASH FLOWS DISCLOSURES:</b>			
Interest paid in cash, net of amounts capitalized	\$ 4,141	\$	4,608
<b>NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>			
Repayment of facility financing obligation through issuance of common stock	\$ 11,000	\$	
Capitalization of interest on note payable to principal stockholder	\$ 10,716	\$	
Reclassification of deferred payments from collaboration to Sanofi Loan Facility and loss share obligation	\$	\$	5,003
Reclassification of deferred costs from loss on purchase commitment to deferred costs from collaboration	\$	\$	9,202

See notes to condensed consolidated financial statements.

**Table of Contents**

**MANNKIND CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Description of Business and Significant Accounting Policies**

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries ( MannKind, the Company, we or us ), have been prepared in accordance with generally accepted accounting principles in the United States of America ( GAAP ) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the SEC ). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 16, 2017 (the Annual Report ).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and six months ended June 30, 2017 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates or assumptions. Management considers many factors in selecting appropriate financial accounting policies, and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. The more significant estimates reflected in these accompanying condensed consolidated financial statements include revenue recognition, assessing long-lived assets and deferred product costs for impairment, accrued expenses, inventory recoverability, valuation of the facility financing obligation, loss on purchase commitments, warrant liability, milestone rights, stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. 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 approved product, Afrezza (insulin human [rDNA origin]) 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.

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-Aventis U.S. LLC ( Sanofi ), pursuant to which Sanofi was responsible for global commercial, regulatory and development activities for Afrezza.

On January 4, 2016, the Company received written notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. The effective date of termination was April 4, 2016, which was when the Company assumed responsibility for worldwide development and commercialization of Afrezza. 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 in late July 2016. The Company began recognizing commercial product sales revenue when MannKind-branded Afrezza was dispensed from pharmacies to patients in August 2016.

On November 9, 2016, the Company entered into a settlement agreement with Sanofi (the Settlement Agreement). Under the terms of the Settlement Agreement, the promissory note between the Company and Aventisub LLC (Aventisub), a Sanofi affiliate, was terminated with Aventisub agreeing to fully forgive the outstanding loan balance of \$72.0 million. Sanofi also purchased \$10.2 million of insulin from the Company in December 2016 under an existing insulin put option and made a cash payment of \$30.6 million to the Company in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without the Company being required to deliver any insulin for such payment. The Company was also relieved of its obligation to pay Sanofi \$0.5 million in previously uncharged costs pursuant to the Sanofi License Agreement. The Company and Sanofi also agreed to a general release of potential claims against each other.

**Table of Contents**

During their initial transition of the commercial responsibilities from Sanofi in the second half of 2016, the Company utilized a contract sales organization to promote Afrezza while the Company focused its internal resources on establishing a channel strategy, entering into distribution agreements and developing co-pay assistance programs, a voucher program, data agreements and payor relationships. In early 2017, the Company recruited its own sales force to promote Afrezza to endocrinologists and certain high-prescribing primary care physicians. In the future, the Company may seek to supplement its sales force through a co-promotion arrangement – an agreement with a third party that has an underutilized primary care sales force, which can be used to promote Afrezza to greater number of primary care physicians. The Company's current strategy for future commercialization of Afrezza outside of the United States, subject to receipt of the necessary foreign regulatory approvals, is to seek and establish partnerships in foreign jurisdictions where there are appropriate commercial opportunities.

The Company has never been profitable or generated positive cash flow from cumulative operations to date. Historically, the Company has 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 and 2017 as a result of non-recurring payments from Sanofi. As of June 30, 2017, the Company had an accumulated deficit of \$2.8 billion.

At June 30, 2017, the Company's capital resources consisted of cash and cash equivalents of \$43.4 million. The Company expects to continue to incur significant expenditures to support commercial manufacturing and sales and marketing of Afrezza and the development of product candidates in the Company's pipeline. 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") that resulted in the issuance of 9.75% Senior Convertible Notes due 2019 ("2019 notes") and the First Amendment to Facility Agreement and Registration Rights Agreement (the "First Amendment") that resulted in the issuance of an additional tranche of 8.75% Senior Convertible Notes due 2019 ("Tranche B notes") (see Note 6 – Borrowings) 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 ("The Mann Group") (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 June 29, 2017, the Company entered into an Exchange and Third Amendment to Facility Agreement (the "Third Amendment") with Deerfield which, among other things, amended such financial covenant to provide that, if certain conditions are met, then the obligation to maintain at least \$25.0 million in cash as of the end of each quarter will be reduced to \$10.0 million as of August 31, 2017, September 30, 2017, October 31, 2017 and December 31, 2017 (see Note 6 – Borrowings).

On June 27, 2017, the Company borrowed the remaining \$30.1 million principal amount available under The Mann Group Loan Arrangement, of which \$19.4 million was received in cash and the remaining amount of \$10.7 million representing accrued and unpaid interest as of June 30, 2017 was capitalized into borrowed principal (see Note 5 – Related-Party Arrangements). As a result, no additional funds remain available for borrowing under The Mann Group Loan Arrangement. On March 1, 2017, following stockholder approval, the Company's board of directors approved a reverse stock split ratio of 1-for-5. On March 1, 2017, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment of the Company's Amended and Restated Certificate of Incorporation (the "Charter Amendment") to effect the 1-for-5 reverse stock split of the Company's outstanding common stock (the "Reverse Stock Split") and to reduce the authorized number of shares of the Company's common stock from 700,000,000 to 140,000,000 shares. The Company's common stock began trading on the NASDAQ Global Market on a split-adjusted basis when the market opened on March 3, 2017. As a result, all common stock share amounts included in these condensed consolidated financial statements have been retroactively reduced by a factor of five, and all common stock per share amounts have been increased by a factor of five, with the exception of the Company's common stock par value.

On April 18, 2017, the Company entered into an Exchange Agreement with Deerfield resulting in the cash repayment of \$4.0 million under the Tranche B notes and the conversion of \$1.0 million and \$5.0 million of the Tranche B notes and the 2019 notes, respectively, into shares of common stock. On June 29, 2017, the Company entered into the Third Amendment with Deerfield resulting in the conversion of \$5.0 million of the 2019 notes into shares of common stock and deferment of the payment of \$10.0 million of principal amount of the 2019 notes due July 18, 2017 to August 31, 2017, with an option for the Company to elect to further defer the payment of such principal amount from August 31, 2017 to October 31, 2017 upon the Company's delivery on August 31, 2017 of a written certification to Deerfield that certain conditions have been met (see Note 6 – Borrowings).

The Company will need to raise additional capital, whether through a sale of equity or debt securities, a strategic business collaboration with another 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 other product candidates and to support its other ongoing activities. The Company cannot provide assurances that such additional capital will be available on acceptable terms or at all. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Table of Contents**

**Reclassifications** Certain amounts from previous periods have been reclassified to conform to the 2017 presentation. Specifically, on the condensed consolidated statements of operations, product manufacturing has been renamed to costs of goods sold. In addition, the Company reclassified (gain) loss on foreign currency translation from the previously reported classification of product manufacturing to (gain) loss on foreign currency translation and also reclassified change in fair value of warrant liability from the previously reported classification of other income to change in fair value of warrant liability in the accompanying condensed consolidated statements of operations.

**Correction of an Immaterial Error** Subsequent to the issuance of the Company's financial statements for the year ended December 31, 2016 on Form 10-K and prior to the filing of financial statements for the first quarter of 2017 on Form 10-Q, the Company determined that the common stock par value as of December 31, 2016 should not have been adjusted for the impact of the reverse stock split on March 3, 2017 as described above. Management evaluated the materiality of the errors from a quantitative and qualitative perspective and concluded that this adjustment was not material to the Company's financial position as of March 31, 2017 or December 31, 2016 and that there was no impact to the results of operations for any periods presented. Since the revisions were not material, no amendments to previously filed reports were required. The Company has elected to revise the historical consolidated financial information presented herein to reflect the correction of this error for the prior period presented and to conform to the current year presentation.

(In thousands)	2016 as Previously Presented	Adjustments	2016 as Adjusted
Common stock	\$ 4,784	\$ (3,827)	\$ 957
Additional paid-in capital	\$ 2,549,212	\$ 3,827	\$ 2,553,039

**Revenue Recognition** 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 condensed consolidated balance sheets until such time that all criteria are met. To date, the Company has had revenue from commercial sales of Afrezza, collaborations, and from the sale of intellectual property and bulk insulin sales, which are described more fully below.

**Revenue Recognition Net Revenue Commercial Product Sales** Between July 1, 2016 and December 15, 2016, the Company sold Afrezza to Integrated Commercialization Solutions Direct (ICS) and title and risk of loss transferred to ICS upon shipment. After December 15, 2016, ICS became a third party logistics provider and stopped taking title and risk of loss upon shipment of Afrezza to ICS. The Company sells Afrezza in the United States to wholesale pharmaceutical distributors through ICS, and ultimately to retail pharmacies, which are collectively referred to as customers. The Company provides the right of return to its wholesale distributors and, through them, to its retail pharmacy customers for unopened product for a period beginning six months prior to and ending twelve months 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. Deferred revenue is presented net of deferred product sales discounts which are further described in *Gross-to-Net Adjustments* below. 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.

For the three and six months ended June 30, 2017, net revenue from commercial product sales consisted of \$1.5 million and \$2.7 million of net sales of Afrezza dispensed to patients, respectively. As of June 30, 2017 and December 31, 2016, the ending balances for net deferred revenue, were \$2.6 million and \$3.4 million, on its condensed consolidated balance sheets of which \$1.0 million and \$0.8 million are gross-to-net revenue adjustments, respectively. The difference, as compared with December 31, 2016, represented deferred revenue from bulk insulin sales of approximately \$1.7 million, which is described more fully under the heading *Revenue Recognition Revenue Other* below. For the three and six months ended June 30, 2017, shipments to three wholesale distributors represented 93% of total shipments.

## **Table of Contents**

*Gross-to-net Adjustments* Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, estimated rebates and chargebacks and patient discount and co-pay assistance 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 condensed consolidated statements of operations at the time product revenue is recognized. Gross-to-net adjustments were approximately \$1.1 million and \$1.5 million, which represents 41% and 36% of gross revenue from product sales for the three and six months ended June 30, 2017, respectively. Gross-to-net items that are unpaid at the end of each period are presented in accrued expense and other current liabilities.

*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 and deferred revenue by the prompt pay discount amount (at the time of shipment to the wholesale distributor). The Company recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

*Rebates and Chargebacks* The Company participates in federal and state government-managed Medicare and Medicaid programs and, as such, is required to provide rebates under these programs. The Company continues to pursue participation in certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating entities. Rebates provided through these other qualifying programs are included in the Medicaid and Medicare rebate accrual. Chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which currently consist primarily of Federal government entities purchasing off the Federal Supply Schedule, generally purchase the product at its contracted price, plus a mark-up from the wholesaler. The wholesaler, in-turn, charges back to the Company the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler by the customer.

The Company accounts for these rebates and chargebacks by establishing an accrual based on contractual discount rates, expected utilization under each contract and an estimate of the amount of inventory in the distribution channel that will become subject to such rebates and chargebacks based on historical payor data provided by a third-party vendor along with additional data including forecasted participation rates. From that data, as well as input received from the commercial team, an estimated participation rate for each program is determined and applied at the 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 may be paid can be up to 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 and chargebacks are recognized as a reduction of gross revenue in the period the related revenue is recognized.

*Other Rebates and Discounts* The Company has entered into agreements with certain third-party payors and with pharmacy benefit managers that act as an intermediary with certain third-party payors in the fulfillment of

prescriptions. Under these agreements, the Company has agreed to provide certain contracted discounts to ease access to reimbursement for Afrezza patients including, but not limited to, the removal of prior authorization or step edit requirements or modifying the reimbursement tier under the payor's formulary. The Company accounts for these charges by establishing an accrual based on the contracted discount rates and, with input received from management, estimated participation rates.

*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 gross revenue in the same period the related revenue is recognized.

*Deferred Costs from Commercial Product Sales* Deferred costs from commercial product sales represents the cost of product (including labor, overhead and shipping costs to the third party logistics provider) shipped to wholesale distributors, but not dispensed by retail pharmacies to patients. If the Company estimates that inventory that has been shipped to wholesale distributors will be returned for credit because there is a risk of product expiry, deferred costs of commercial product sales is reduced and cost of goods sold is increased for the cost of such inventory.

*Revenue Recognition Net Revenue Collaborations* The Company enters into collaborations under which the Company must perform certain obligations and receives periodic payments. The Company evaluates the collaborations under the multiple element revenue recognition accounting guidance. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered elements have 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

**Table of Contents**

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. The terms of and the accounting for the Company's collaborations are described more fully in Note 7 – Collaboration Arrangements.

*Revenue Recognition – Revenue – Other* consists of revenue from bulk insulin sales and the sale of intellectual property to Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ( Fosun ), which is accounted for under the multiple-deliverable revenue recognition guidance and more fully described in Note 8 – Sale of Intellectual Property. Revenue from bulk insulin sales are recognized after delivery and customer acceptance of the bulk insulin. When the accounting requirements for revenue recognition of bulk insulin sales are not met, the Company defers recognition of revenue until such time that all criteria are met. The ending balance in deferred revenue related to bulk insulin sales was approximately \$1.7 million as of December 31, 2016. There was no deferred revenue related to bulk insulin sales as of June 30, 2017.

*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 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.

*Accounts Receivable and Allowances* – Accounts receivable are recorded at the invoiced amount and are not interest bearing. The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. The Company makes ongoing assumptions relating to the collectability of its accounts receivable in its calculation of the allowance for doubtful accounts. If the Company estimates that inventory that has been shipped to wholesale distributors will be returned for credit because there is risk of product expiration, the Company reduces deferred revenue and increases the allowance for returns for such inventory. As of June 30, 2017, there was \$0.2 million in allowance for returns. As of December 31, 2016, there was no allowance for returns. As of June 30, 2017 and December 31, 2016, there was no allowance for doubtful accounts. As of June 30, 2017 and December 31, 2016, the Company has three wholesale distributors representing approximately 93% and 95% of gross accounts receivable, respectively.

*Inventories* – Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products based on management's judgment that future economic benefits are expected to be realized; otherwise, such costs are expensed as cost of goods sold. The Company periodically analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated net realizable value and writes down such inventories, as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or may become obsolete or are forecasted to become obsolete due to expiration, the Company will record a charge to write down such unmarketable inventory to its estimated net realizable value.

*Recognized Loss on Purchase Commitments* – The Company assesses whether losses on long term purchase commitments should be accrued. Losses that are expected to arise from firm, non-cancellable, commitments for the future purchases are recognized unless recoverable. When making the assessment, the Company also considers whether it is able to renegotiate with its vendors. The recognized loss on purchase commitments is reduced as inventory items are purchased. No new contracts were identified in 2017 or 2016 that required a new loss on purchase commitment accrual.

*Fair Value of Financial Instruments* – The carrying amounts reported in the accompanying condensed consolidated financial statements for cash, accounts receivable, accounts payable and accrued expenses and other current liabilities

(excluding the milestone rights liability) approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to principal stockholder (also referred to as The Mann Group Loan Arrangement), senior convertible notes, the facility financing obligation, the milestone rights liability and the warrant liability are disclosed in Note 9 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, subject to an estimated forfeiture rate. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Restricted stock units are valued based on the market price on the grant date. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

**Table of Contents**

**Warrants** The Company has issued warrants to purchase shares of its common stock. 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.

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

The computation of basic and diluted net loss per share for the three and six months ended June 30, 2017 and 2016 excludes the common stock equivalents of the following potentially dilutive securities because their inclusion would be anti-dilutive:

	<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>
Restricted stock units	1,193,100	910,751
Senior convertible notes	814,561	814,561
Warrants	9,740,597	9,740,597
Stock options	7,972,175	5,643,966
	<b>19,720,433</b>	<b>17,109,875</b>

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

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which requires an entity to recognize the amount of revenue when 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 additional ASU s which clarified certain aspects of the new guidance.

The Company will adopt the new guidance for the year beginning January 1, 2018. The Company has the option to either apply the new guidance retrospectively for all prior reporting periods presented (full retrospective) or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (modified retrospective). The Company currently anticipates it will apply the new guidance using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. The Company plans to continue analyzing the potential impacts of the application throughout 2017 and, depending on factors that may impact the results, could elect to apply the new guidance on a full retrospective basis.

Currently, for commercial sales of Afrezza, the Company has limited sales and returns history, and as such is unable to 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 earliest 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, a sell-through model, 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.

## **Table of Contents**

Upon adoption of the new guidance, the Company expects that it will move from its current sell-through model to a sell-to model for revenue related to commercial sales of Afrezza and will record revenue at the time title and risk of loss passes to its distributors (generally at shipment or delivery to the distributors) along with an estimate of potential returns as variable consideration. The Company also anticipates that its ability to estimate potential returns will improve with an additional six months of sales history that it will have obtained by January 1, 2018.

Additionally, the Company has historically entered into collaborative agreements with third-parties under which periodic payments have been received. Revenue recognition for certain payments received have been deferred until the price is fixed and determinable. Further, revenue for certain payments to be received in the future has been prohibited from recognition until received. The Company expects that some of these amounts will be considered variable consideration and may be able to be recognized earlier under the new guidance.

The financial impact upon the adoption will be dependent upon a number of factors, including the amount of revenue that has been deferred under the sell-through model for Afrezza, the amount of the revenue deferred under collaborative arrangements and the Company's estimate of variable consideration at the date of adoption. At this time, the Company has not completed its evaluation of the inputs, assumptions and methodologies that will be used to recognize revenue related to variable consideration under the new guidance.

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 update 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 condensed 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 operating leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The new standard will be effective on January 1, 2019. The Company is evaluating the impact the adoption of ASU No. 2016-02 will have on its condensed 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 will have on its condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. This ASU requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include cash and restricted cash equivalents. ASU 2016-08 is effective for fiscal years beginning after December 15, 2018, including interim periods within those periods, using a retrospective transition method to each period presented. The Company has evaluated the effect that this guidance will have on its condensed consolidated financial statements and related disclosures and has determined it will not result in a material impact.



In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The ASU clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company early adopted ASU 2017-01 on April 1, 2017 and has determined it will not result in a material impact on the Company's condensed consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. This ASU reduces both diversity in practice and cost and complexity when applying ASC 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company is evaluating the impact the adoption will have on its condensed consolidated financial statements.

**Table of Contents**

In July 2017, the FASB issued ASU No. 2017-11, *Earnings per Share (Topic 260) and Derivatives and Hedging (Topic 815): Accounting for Certain Financial Instruments with Down Round Provisions*. This ASU addresses the complexity and cost of accounting for certain financial instruments with down round features that require fair value measurement of the entire instrument or conversion option and requires entities that present earnings per share in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, including interim periods within those periods. The Company is evaluating the impact the adoption will have on its condensed consolidated financial statements.

**2. Inventory**

Inventory consists of the following (in thousands):

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
Raw materials	\$ 431	\$
Work-in-process	2,391	2,120
Finished goods	350	211
Total inventory	\$ 3,172	\$ 2,331

Work-in-process and finished goods as of June 30, 2017 and December 31, 2016 include conversion costs but not materials cost because the materials used in its production were previously written off. During the three and six months ended June 30, 2017, the Company recorded a write-down of inventory of approximately \$1.5 million for inventory that was forecasted to become obsolete due to expiration which is recorded in costs of goods sold in the accompanying condensed consolidated statements of operations.

**3. Property and Equipment**

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

	<b>Estimated Useful Life (Years)</b>	<b>June 30, 2017</b>	<b>December 31, 2016</b>
Land		\$ 875	\$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	34,957	34,957
Machinery and equipment	3-15	62,992	62,992
Furniture, fixtures and office equipment	5-10	3,556	3,556
Computer equipment and software	3	8,531	8,531
Construction in progress		91	202
		128,391	128,502
Less accumulated depreciation		(100,471)	(99,575)
Total property and equipment, net		\$ 27,920	\$ 28,927

Depreciation expense related to property and equipment for the three and six months ended June 30, 2017 and 2016 was as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Depreciation expense	\$ 450	\$ 589	\$ 896	\$ 1,179

Management evaluated certain equipment that was not yet in service and determined that since the equipment was not being used and there was no current estimated date for installation and therefore no future cash flows associated with the equipment, a write-down of construction in progress of approximately \$0.1 million was recorded during the three and six months ended June 30, 2017. The Company did not record any impairment charges for the three and six months ended June 30, 2016.

**Table of Contents**

On January 6, 2017, the Company and Rexford Industrial Realty, L.P. ( Rexford ) entered into an Agreement of Purchase and Sale and Joint Escrow Instructions (the Purchase Agreement ), pursuant to which the Company agreed to sell and Rexford agreed to purchase certain parcels of real estate owned by the Company in Valencia, California and certain related improvements, personal property, equipment, supplies and fixtures (collectively, the Property ) for \$17.3 million. The sale and purchase of the Property for \$17.3 million pursuant to the terms of the Purchase Agreement, as amended, was completed on February 17, 2017. Net proceeds were \$16.7 million after deducting broker's commission and other fees of approximately \$0.6 million paid by the Company. Net proceeds received approximated the carrying value of the asset held for sale.

**4. Accrued Expenses and Other Current Liabilities**

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

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
Salary and related expenses	\$ 3,729	\$ 3,814
Current portion of milestone rights liability	1,643	
Professional fees	968	875
Discounts and allowances for commercial product sales	1,036	754
Sales and marketing services	218	144
Restructuring	362	1,376
Accrued interest	624	619
Other	496	355
<b>Accrued expenses and other current liabilities</b>	<b>\$ 9,076</b>	<b>\$ 7,937</b>

**5. Related-Party Arrangements**

In October 2007, the Company entered into The Mann Group Loan Arrangement, which 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.

On June 27, 2017, the Company entered into an agreement with The Mann Group, pursuant to which the parties agreed to, among other things, (i) capitalize \$10.7 million of accrued and unpaid interest as of June 30, 2017, resulting in such amount being classified as outstanding principal under The Mann Group Loan Arrangement; (ii) advance to the Company approximately \$19.4 million of cash, the remaining amount available for borrowing by the Company under The Mann Group Loan Arrangement after the foregoing capitalization of accrued and unpaid interest; and (iii) defer all interest payable on the outstanding principal until July 1, 2018, unless such payments are otherwise permitted under the subordination agreement with Deerfield, and subject to further deferral pursuant to the terms of the subordination agreement with Deerfield which terms are more fully disclosed below.

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. 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. In addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under The Mann Group Loan Arrangement until the Company's payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group's option, and the interest rate will increase to the one-year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under The Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

**Table of Contents**

As of June 30, 2017 and December 31, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was \$79.7 million and \$49.5 million, respectively. As of June 30, 2017, there was no accrued or unpaid interest as a result of all unpaid accrued interest being capitalized pursuant to the June 27, 2017 agreement with The Mann Group. As of December 31, 2016, the Company had accrued and unpaid interest related to the above note of \$9.3 million. Interest expense on the Company's note payable to the Company's principal stockholder for the three and six months ended June 30, 2017 and 2016 were as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Interest expense on note payable to principal stockholder	\$ 721	\$ 721	\$ 1,435	\$ 1,443

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 was for approximately 12,500 square feet of office space in Valencia, California, which expired in April 2017 and has been renewed on a month-to-month basis at a rate of \$20,000 per month, which is expected to expire on August 31, 2017 when the Company moves into its new corporate headquarters (see Note 11). The office space contains the Company's principal executive offices. Lease payments to the Mann Foundation for the three and six months ended June 30, 2017 and 2016 were as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Lease payments	\$ 60	\$ 67	\$ 122	\$ 133

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. Borrowings**

Borrowings consist of the following (in thousands):

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
<b>Facility Financing Obligation (2019 Notes)</b>		
Principal amount	\$ 60,000	\$ 75,000
Unamortized debt discount	(2,516)	(3,661)
Net carrying amount	\$ 57,484	\$ 71,339
<b>Senior Convertible Notes (2018 Notes)</b>		
Principal amount	\$ 27,690	\$ 27,690
Unamortized premium	306	426
Unaccreted debt issuance costs	(347)	(481)

Net carrying amount	\$	27,649	\$	27,635
---------------------	----	--------	----	--------

<b>Note payable to principal stockholder net carrying amount</b>	\$	79,666	\$	49,521
--	----	--------	----	--------

*Facility Financing Obligation (2019 Notes)* On April 18, 2017, the Company entered into an Exchange Agreement with Deerfield pursuant to which the Company agreed to, among other things, (i) repay \$4.0 million principal amount under the Tranche B notes; (ii) exchange \$1.0 million principal amount under the Tranche B notes for 869,565 shares of the Company's common stock (the "Tranche B Exchange Shares"); and (iii) exchange \$5 million principal amount under the 2019 notes for 4,347,826 shares of the Company's common stock (together with the Tranche B Exchange Shares, the "April Exchange Shares"). The exchange price for the Exchange Shares was \$1.15 per share.

**Table of Contents**

The Company evaluated the transaction and determined that since the principal amount being repaid and exchanged under the Tranche B notes and the principal amount being exchanged under the 2019 notes represents the principal amount that would have otherwise become due and payable in May and July of 2017 under the Tranche B Notes and 2019 notes, respectively, the extinguishment of the May and July 2017 payments was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction by recording a loss on extinguishment of debt of \$0.3 million for the three and six months ended June 30, 2017 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The net carrying value of the related debt includes the acceleration of the debt discount and issuance costs amounting to approximately \$8,000 as a result of the transaction. The reacquisition price was calculated using the \$4.0 million cash repayment and the fair value of the April Exchange Shares on April 18, 2017. The fair value of the April Exchange Shares was determined to be \$1.22 per share representing the closing trading price of the Company's common stock on The NASDAQ Global Market on April 18, 2017.

On June 29, 2017, the Company entered into the Third Amendment with Deerfield, pursuant to which the Company agreed to, among other things, (i) exchange \$5.0 million principal amount under the 2019 notes for 3,584,230 shares of the Company's common stock (the June Exchange Shares) at an exchange price of \$1.395 per share and (ii) amend the Facility Agreement with Deerfield, to (A) defer the payment of \$10.0 million in principal amount of the 2019 notes from the original July 18, 2017 due date to August 31, 2017, with an option for the Company to elect to further defer the payment of such principal amount from August 31, 2017 to October 31, 2017 upon the Company's delivery on August 31, 2017 of a written certification to Deerfield that certain conditions have been met, including that no event of default under the Facility Agreement has occurred, Michael Castagna remains the Company's Chief Executive Officer, the Company has received the advance from The Mann Group (see Note 5 Related-Party Arrangements), the Company has at least \$10 million in cash and cash equivalents on hand, no material adverse effect on the Company has occurred, the engagement letter between the Company and Greenhill & Co., Inc. (Greenhill) has remained in full force and effect and Greenhill has remained actively engaged in exploring capital structure and financial alternatives on behalf of the Company in accordance with such engagement letter (collectively, the Extension Conditions), and (B) amend the Company's financial covenant under the Facility Agreement to provide that, if the Extension Conditions remain satisfied, the obligation under the Facility Agreement to maintain at least \$25 million in cash (including available borrowings under The Mann Group Loan Arrangement) as of the end of each quarter will be reduced to \$10 million as of August 31, 2017, September 30, 2017, October 31, 2017 and December 31, 2017.

The Company evaluated the transaction and determined that since the principal amount being repaid and exchanged under the 2019 notes represents the principal amount that would have otherwise become due and payable under the 2019 notes, the \$5.0 million prepayment was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction by recording a loss on extinguishment of debt of \$0.5 million for the three and six months ended June 30, 2017 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The net carrying value of the related debt includes the acceleration of the debt discount and issuance costs amounting to approximately \$0.3 million as a result of the transaction. The reacquisition price was calculated using the fair value of the June Exchange Shares on June 29, 2017. The fair value of the Exchange Shares was determined to be \$1.45 per share representing the closing trading price of the Company's common stock on The NASDAQ Global Market on June 29, 2017.

As of June 30, 2017, there was \$45.0 million principal amount of 2019 notes and \$15.0 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%. Interest is paid quarterly in arrears on the last day of each March, June, September and December. The Facility Financing Obligation principal repayment schedule is comprised of annual payments which began on July 1, 2016 and end on December 9, 2019. As of June 30, 2017, future payments for the years ending December 31, 2017, 2018, and 2019 are \$10.0 million, \$20.0 million and \$30.0 million, respectively.



In connection with the Facility Agreement, on July 1, 2013, the Company entered into a Milestone Rights Purchase Agreement (the "Milestone Agreement") with Deerfield and Horizon Santé FLML SÁRL (collectively, the "Milestone Purchasers"), which requires the Company to make contingent payments to the Milestone Purchasers, totaling up to \$90.0 million, upon the Company achieving specified commercialization milestones (the "Milestone Rights"). As of June 30, 2017 and December 31, 2016, the remaining milestone rights liability balance was \$8.9 million. The Company currently estimates that it will reach the next milestone in the second quarter of 2018. Accordingly, \$1.6 million in value related to the next milestone payment was recorded in accrued expenses and other current liabilities as of June 30, 2017, resulting in \$7.2 million and \$8.9 million being recorded in milestone rights liability and other liabilities, which is non-current, in the accompanying condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016, respectively.

**Table of Contents**

Accretion of debt issuance cost and debt discount in connection with the Facility Agreement during the three and six months ended June 30, 2017 and 2016, which includes the acceleration of the debt discount and issuance costs related to the transactions disclosed above, are as follows (in thousands):

		<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
		<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Accretion expense	debt issuance cost	\$ 24	\$ 9	\$ 32	\$ 17
Accretion expense	debt discount	\$ 686	\$ 433	\$ 1,133	\$ 852

The Facility Agreement includes customary representations, warranties and covenants, including a restriction on the incurrence of additional indebtedness, and a financial covenant which requires the Company's cash and cash equivalents, which include available borrowings on the note payable to a principal stockholder, on the last day of each fiscal quarter to not be less than \$25.0 million, or pursuant to the Third Amendment, \$10.0 million as of the last day of each month through October 31, 2017 and as of December 31, 2017 if certain conditions are met. As discussed in Note 1 Description of Business and Summary of Significant Accounting Policies, the Company will need to raise additional capital to support its current operating plans. 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 sheets as of June 30, 2017 and December 31, 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.

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

**Security Agreement** In connection with the Facility Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the "Security Agreement") with Deerfield and Horizon Santé FLML SÁRL (collectively, the "Purchasers"), pursuant to which the Company and MannKind LLC each granted the Purchasers a security interest in substantially all of their respective assets, including respective intellectual property, accounts, receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Security Agreement includes customary covenants by the Company and MannKind LLC, remedies of the Purchasers and representations and warranties by the Company and MannKind LLC. The security interests granted by the Company and MannKind LLC will terminate upon repayment of the 2019 notes and Tranche B notes, if applicable, in full. The Company's obligations under the Facility Agreement and the Milestone Agreement are also secured by the Company's facilities in Danbury, Connecticut, which has a carrying value of \$27.9 million.

**Embedded Derivatives** The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. In 2014, the Company analyzed the Tranche B notes and identified embedded derivatives which required separate accounting. However, all of the embedded derivatives were determined to have a *de minimis* value as of June 30, 2017 and December 31, 2016.

*Issuance of new 5.75% Convertible Senior Subordinated Exchange Notes Due 2018 in Exchange for 2015 Notes* The 5.75% Convertible Senior Subordinated Exchange Notes Due 2018 (the 2018 notes ) are the Company s general, unsecured, senior obligations, except that the 2018 notes were subordinated to the Sanofi loan facility prior to the extinguishment of the facility on November 9, 2016. 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. Accrued interest related to these notes is recorded in accrued expenses and other current liabilities on the accompanying condensed consolidated balance sheets.

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 29 shares per \$1,000 principal amount of 2018 notes, which is equal to a conversion price of approximately \$34.00 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, 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. 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.

**Table of Contents**

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 2019 notes and the Tranche B notes issued to Deerfield pursuant to the 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 and accretion of debt issuance costs related to the 2018 notes for the three and six months ended June 30, 2017 and 2016 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Amortization of debt premium	\$ 61	\$ 58	\$ 120	\$ 115
Accretion expense debt issuance cost	\$ 68	\$ 63	\$ 134	\$ 126

**7. Collaboration Arrangements**

*Receptor Collaboration and License Agreement* On January 20, 2016, the Company entered into a Collaboration and License Agreement (the "CLA") with Receptor Life Sciences, Inc. ("Receptor") pursuant to which the Company performed initial formulation studies on compounds identified by Receptor and Receptor obtained the option to acquire an exclusive license to develop, manufacture and commercialize certain products that use the Company's technology to deliver the compounds via oral inhalation.

The Company received \$0.4 million in nonrefundable payments in 2016 prior to Receptor exercising the option. On December 30, 2016, following successful completion of the studies, Receptor exercised its option and paid the Company a \$1.0 million nonrefundable option exercise and license fee. Under the CLA, the Company may receive the following additional payments:

Nonrefundable milestone payments upon the completion of certain technology transfer activities and the achievement of specified sales targets;

Royalties upon Receptor's and its sublicensees' sale of the product; and

Milestones upon total worldwide sales reaching certain agreed upon levels.

The Company evaluated the accounting for the payments received in 2016 under the multiple element accounting guidance and determined that the \$0.4 million in payments received prior to Receptor exercising its option are separable from the other elements of the agreement and represented payments to offset costs incurred. Therefore, those payments reduced the Company's research and development expense in 2016. The \$1.0 million license fee received in 2016 does not have standalone value from the follow-on transfer of technology. Therefore, the license fee was recorded in deferred payments from collaboration as of December 31, 2016 and will be recognized in net revenue collaboration over four years. Recognized revenue related to this license agreement amounted to \$0.1 million for the three and six months ended June 30, 2017. See Note 1 Description of Business and Summary of Significant Accounting Policies for additional information on the Company's accounting for multiple element arrangements.

## **Table of Contents**

On March 15, 2017, the Company entered into a Manufacturing and Supply Agreement with Receptor pursuant to which the Company will provide certain raw materials to Receptor. On March 16, 2017, the Company agreed to provide certain additional research and formulation consulting services to Receptor.

*Sanofi License Agreement and Sanofi Supply Agreement* On August 11, 2014, the Company executed the Sanofi License Agreement, pursuant to which Sanofi was responsible for global commercial, regulatory and development activities for Afrezza. 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").

During the term of the Sanofi License Agreement, worldwide profits and losses 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. These profits and losses were shared 65% by Sanofi and 35% by the Company. On January 4, 2016, the Company received a 90-day notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. The effective date of termination was April 4, 2016. On April 5, 2016, 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.

The Company analyzed the agreements entered into with Sanofi at their inception and determined that prior to December 31, 2015, 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 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, Sanofi provided information to the Company to enable it to reasonably estimate the remaining costs under the Sanofi License Agreement and the Sanofi Supply Agreement. Accordingly, the fixed or determinable fee requirement for revenue recognition was met and there were no future obligations to Sanofi. Therefore, the Company recognized \$172.0 million of net revenue from collaboration for the year ended December 31, 2016. The revenue recognized includes the upfront payment of \$150.0 million and the two milestone payments of \$25.0 million each, net of \$64.9 million of net loss share with Sanofi, as well as \$17.5 million in sales of Afrezza and \$19.4 million from sales of bulk insulin, both to Sanofi. These payments and sales were made pursuant to the contractual terms of the agreements with Sanofi.

*Sanofi Loan Facility* On September 23, 2014, the Company entered into a senior secured revolving promissory note and a guaranty and security agreement (collectively, the "Sanofi Loan Facility") with an affiliate of Sanofi, which provided 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.

Advances under the Sanofi Loan Facility bore interest at a rate of 8.5% per annum and were payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. The Company was 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.

The Company's total portion of the loss sharing was \$57.7 million for the year ended December 31, 2015, of which \$44.5 million was borrowed under the Sanofi Loan Facility as of December 31, 2015. Subsequent to December 31, 2015, the Company borrowed \$17.9 million under the Sanofi Loan Facility to finance the portion of the Company's loss for the quarters ended December 31, 2015 and March 31, 2016. The total amount owed to Sanofi at September 30, 2016 was \$71.2 million, which included \$5.8 million of paid-in-kind interest.

On November 9, 2016, the Company entered into a settlement agreement with Sanofi (the "Settlement Agreement"). Under the terms of the Settlement Agreement, the promissory note between the Company and Aventisub LLC, a Sanofi affiliate, was terminated, with Aventisub agreeing to forgive the full outstanding loan balance of \$72.0 million. Sanofi also agreed to purchase \$10.2 million of insulin from the Company in December 2016 under an existing insulin put option as well as make a cash payment of \$30.6 million to the Company in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without the Company being required to deliver any insulin for such payment. The Company was also relieved of its obligation to pay Sanofi \$0.5 million in previously uncharged costs pursuant to the Sanofi License Agreement. The Company and Sanofi also agreed to a general release of potential claims against each other.

## **Table of Contents**

The settlement was accounted for in the year ended December 31, 2016, except for a \$30.6 million cash payment received under the insulin put option agreement which reduced the receivable from Sanofi between December 31, 2016 and June 30, 2017.

## **8. Sale of Intellectual Property**

On April 12, 2017 the Company entered into an agreement (the "Agreement") to sell certain oncology assets and patents to Fosun. Fosun is required to pay the Company a one-time nonrefundable payment of \$0.6 million (which was received net of taxes in June of 2017), royalties on net sales of products by Fosun and its affiliates and other consideration based on revenues from any licensees. The Company determined that the sale of the assets did not constitute a business and accordingly accounted for the transaction as a sale of assets. The Company evaluated the accounting for the payments received in 2017 under the multiple element accounting guidance and recorded the \$0.6 million in payments received in revenue other in the accompanying condensed consolidated financial statements for the three and six months ended June 30, 2017 as the deliverables under the Agreement were substantially delivered as of June 30, 2017. See Note 1 Description of Business and Summary of Significant Accounting Policies for additional information on the Company's accounting for multiple element arrangements. The Company also evaluated the accounting for royalties and other consideration in the Agreement. Since the amount of product that Fosun will ultimately be able to sell upon successfully utilizing this technology is uncertain, no royalty revenue will be recognized until such time when Fosun or its affiliates sell product to a third party and royalties are due to MannKind.

## **9. 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 that 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 June 30, 2017 and December 31, 2016, the Company held cash equivalents of \$42.1 million and \$20.5 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 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.

**Table of Contents**

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

	Carrying Value	As of June 30, 2017			Total
		Level 1	Level 2	Level 3	
Financial liabilities:					
Senior convertible notes	\$ 27.6	\$	\$	\$ 24.2	\$ 24.2
Facility financing obligation	57.5			60.0	60.0
Milestone rights	8.9			18.2	18.2
Warrant liability (at recurring fair value)	0.6			0.6	0.6
Total financial liabilities	\$ 94.6	\$	\$	\$ 103.0	\$ 103.0

	Carrying Value	As of December 31, 2016			Total
		Level 1	Level 2	Level 3	
Financial liabilities:					
Senior convertible notes	\$ 27.6	\$	\$	\$ 22.9	\$ 22.9
Facility financing obligation	71.3			74.5	74.5
Milestone rights	8.9			18.4	18.4
Warrant liability (at recurring fair value)	7.4			7.4	7.4
Total financial liabilities	\$ 115.2	\$	\$	\$ 123.2	\$ 123.2

On May 12, 2016 we issued certain warrants with a fair value of \$12.8 million. As of June 30, 2017 and December 31, 2016, the fair value of the warrant liability was \$0.6 million and \$7.4 million, respectively. The fair value of the warrants liability as of June 30, 2017 was estimated using a Monte Carlo valuation pricing model with the following underlying assumptions: (a) a risk-free interest rate of 1.4%; (b) an assumed dividend yield of zero percent; (c) an expected term of 0.9 years; and (d) an expected volatility of 112%. The following table provides a roll forward of the fair value of the warrant liability which is the only Level 3 financial instrument that is carried at fair value (in millions):

Balance at beginning of period December 31, 2016	\$ 7.4
Additions	
Changes in fair value	(6.8)
Payments	
Fair value, end of period June 30, 2017	\$ 0.6

*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 (100%) 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 6 Borrowings, 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 June 30, 2017, the market discount rate was recalculated at 12% for the principal for the facility financing obligation. Under the terms of the Facility Agreement, the Company is restricted from distributing any of its assets or declaring and distributing a dividend to its stockholders.

*Milestone Rights Liability* In addition to the Facility Financing Obligation, the Company also issued 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 (14%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of June 30, 2017, the carrying value of the milestone rights liability was \$8.9 million and the fair value was estimated at \$18.2 million. The fair value measurement of the liability is sensitive to the discount rate and the timing and probability of making milestone payments. If the achievement of each of the milestones which

**Table of Contents**

require payments were to be six months later than in the current forecast, the fair value of the liability would decrease by 7%. If the probabilities of meeting the milestones were to decrease by 5% or 10%, the fair value of the liability would decrease by 14% and 26%, respectively. Over the long term, these inputs are interrelated because if the Company's performance improves, the timing of meeting the milestones would likely be earlier, the probability of making payments on the milestones would likely be higher and the discount rate would likely decrease, all of which would increase the fair value of the liability. The inverse is also true.

**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; (d) an expected volatility based upon the Company's historical volatility over the remaining contractual term of the warrants; and (e) 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).

**Embedded Derivatives** The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. The Company analyzed the Tranche B notes and identified embedded derivatives, which required separate accounting. However, all of the embedded derivatives were determined to have a *de minimis* value at June 30, 2017 and December 31, 2016.

## **10. Stock-Based Compensation Expense**

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 implemented the standard on January 1, 2017 and the standard did not have a material impact on the Company's financial statements as:

The Company, as of December 31, 2016, had not recognized \$11.6 million of excess tax benefits related to windfalls. As a result of adoption, it will now recognize these benefits as deferred tax assets. However, after assessment for realizability, the Company has also recorded a full valuation allowance against the deferred tax assets. This resulted in a zero cumulative effect adjustment to accumulated deficit as a result of the adoption. All shortfalls related to non-qualified options and restricted stock units are now recorded as an income tax expense for the period, offset by a full valuation allowance.

Due to the full valuation allowance for the Company's deferred tax assets, the excess income tax benefits have never been recorded in additional paid-in-capital. The Company does not contemplate any impact going forward as any amounts to be recorded in the condensed consolidated statements of operations would be fully offset by the valuation allowance nor result in a related classification in cash flows for operating activities.

The Company will continue to recognize forfeitures through estimates consistent with our past practices as opposed to when they occur.

The Company already classifies cash paid to taxing authorities arising from the withholding of shares from employees in cash flows from financing activities.

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2017 and 2016 was as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Stock-based compensation	\$ 1,250	\$ 1,355	\$ 2,516	\$ 2,628

During the six months ended June 30, 2017, the Company issued 544,105 restricted units to certain employees which vest over a four-year period. The grant date fair value of the restricted stock units was \$0.6 million with a weighted average grant date fair value per share of \$1.10.

**Table of Contents**

During the six months ended June 30, 2017, the Company granted certain employees stock options to purchase an aggregate of 2,150,537 shares of common stock at a weighted average exercise price of \$1.31 per share of which 1,508,159 of these awards vest in four equal tranches upon the achievement of certain product sales targets. The remaining 642,378 options vest over a four year period. The grant date fair value of these awards is \$2.0 million with a weighted average grant date fair value of \$0.93 per share, as determined using a Black-Scholes option pricing model.

As of June 30, 2017, there was \$4.2 million, \$4.4 million and \$3.9 million of unrecognized compensation expense related to restricted stock units, options with performance conditions and options that vest over the vesting period. The Company evaluates stock awards with performance conditions as the probability that the performance conditions will be met and uses that information to estimate the date at which those performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

On a periodic basis and as of June 30, 2017, the Company reviewed the probability of achieving the performance conditions for each of the four vesting tranches of the performance-based stock options that were granted during 2017 and in prior years and determined that it was probable that the Company would achieve the first vesting tranche in December 2017. Therefore, the Company recorded compensation expense related to performance-based stock options of \$0.4 million and \$0.7 million during the three and six months ended June 30, 2017, respectively. The Company further determined that no compensation costs would be recognized for the second, third and fourth vesting tranches as the probability of achieving those performance conditions has not been determined.

**11. Commitments and Contingencies**

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

*Litigation* The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of June 30, 2017, 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, 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 its officers and directors. In general, the complaints alleged that MannKind and certain of its officers and directors violated Israeli and U.S. securities laws

by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court has been asked to determine whether Israeli or U.S. law is applicable before the case can be certified as a class action but has not yet ruled on this issue. The Company will vigorously defend against the claims advanced.

*Contingencies* In connection with the Facility Agreement, on July 1, 2013, the Company also entered into a the Milestone Agreement with the Milestone Purchasers, pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to \$90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an Afrezza product in the United States and the achievement of specified net sales figures (see Note 6 Borrowings).

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

**Table of Contents**

On November 9, 2016, the supply agreement with Amphastar was amended to extend the term over which the Company is required to purchase insulin, without reducing the total amount of insulin to be purchased. Under the amendment, annual minimum quantities of insulin to be purchased for calendar years 2017 through 2023 total an aggregate purchase price of \$93.0 million at June 30, 2017. The Insulin Supply Agreement specifies that Amphastar will be deemed to have satisfied its obligations with respect to quantity, if the actual quantity supplied is within plus or minus ten percent (+/- 10%) of the quantity set forth in the applicable purchase order. In addition, the aggregate cancellation fees that the Company would incur in the event that certain insulin quantities are not purchased was lowered from \$5.3 million for the period October 1, 2016 through 2018 to \$3.4 million over the same period. The Company has not yet purchased any insulin under the amended agreement in 2017. The annual purchase requirements under the contract are as follows:

2017	2.7 million
2018	8.9 million
2019	11.6 million
2020	15.5 million
2021	15.5 million
2022	19.4 million
2023	19.4 million

Unless earlier terminated, the term of the Insulin Supply Agreement with Amphastar expires on December 31, 2023 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.

At June 30, 2017, the Company has other firm commitments with suppliers for an aggregate of \$0.9 million.

*Office Lease* On May 5, 2017, the Company executed an office lease with Russell Ranch Road II LLC to lease office space for the Company's corporate headquarters in Westlake Village, California. The office lease commences on the earlier of (i) the date the Company commences business from the leased space or (ii) the later of the date of substantial completion of the build-out by the landlord or August 1, 2017. The lease requires monthly payments of \$40,951, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord. The lease expires 65 months from the commencement date and provides the Company with a five year renewal option. Future minimum lease payments are as follows:

2017	\$ 41,000
2018	457,000
2019	512,000
2020	528,000
2021	544,000



Thereafter	560,000
	<b>\$ 2,642,000</b>

## 12. Income Taxes

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded, in accordance with the applicable accounting standards, that net deferred tax assets should be fully reserved.

The Company has assessed its position with regards to uncertainty in tax positions and believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to this guidance. Tax years since 2012 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

**Table of Contents**

The Company adopted ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* in the first quarter of 2017. The adoption had no net impact on its income tax expense for the quarter and net deferred tax assets as of the date of adoption (See Note 10 – Stock-Based Compensation Expense).

**13. Restructuring Charges**

As of June 30, 2017 and December 31, 2016, the Company had a remaining restructuring accrual balance of \$0.4 million and \$1.4 million, respectively, which is recorded in accrued expenses and other current liabilities in the condensed consolidated balance sheets. The Company expects to substantially pay out the remainder of this obligation by end of first quarter of 2018.

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

Description	2016 Restructuring	2015 Restructuring	Total
Accrual January 1, 2017	\$ 209	\$ 1,167	\$ 1,376
Costs paid or settled	(209)	(805)	(1,014)
Accrual June 30, 2017	\$ 362	\$ 362	\$ 362

On May 25, 2017, the board of directors (the Board) replaced Matthew J. Pfeffer as Chief Executive Officer and Chief Financial Officer of the Company. Pursuant to a severance agreement in effect on that date, Mr. Pfeffer's estimated current value of payments and benefits upon termination totaled approximately \$1.2 million. At the time of the Board action, Mr. Pfeffer was expected to remain employed by the Company in an advisory capacity until July 31, 2017, before transitioning to severance. Subsequently, the Company and Mr. Pfeffer began negotiating a new agreement that would, if and when finalized, supersede the existing severance agreement. Given that the new agreement would override any prior severance agreements and amounts previously due to Mr. Pfeffer and contains special termination benefits that are contingent upon certain factors that cannot be reasonably estimated, the Company recorded no severance accrual for Mr. Pfeffer during the second quarter of 2017. Current salary and benefits continue to be accrued as earned.

**Table of Contents****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, 2016 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. Our only approved product, Afrezza, is a rapid-acting inhaled insulin that was approved by the FDA on June 27, 2014 to improve glycemic control in adult patients with diabetes. Afrezza became available by prescription in United States retail pharmacies in February 2015. According to the Centers for Disease Control and Prevention, 30.3 million people in the United States had diabetes in 2015. 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.

Afrezza is a rapid-acting inhaled insulin used to control high blood sugar in adults with type 1 and type 2 diabetes. The product consists of a dry powder formulation of human insulin delivered from a small 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.

On August 11, 2014, we executed the Sanofi License Agreement, pursuant to which Sanofi was responsible for global commercial, regulatory and development activities for Afrezza.

On January 4, 2016, we received written notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. The effective date of termination was April 4, 2016, which was when we assumed responsibility for worldwide development and commercialization of Afrezza. Under the 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 in late July 2016. We began recognizing commercial product sales revenue when MannKind-branded Afrezza was dispensed from pharmacies to patients in August 2016.

During the initial transition of the commercial responsibilities from Sanofi, we utilized a contract sales organization to promote Afrezza while we focused our internal resources on establishing a channel strategy, entering into distribution agreements and developing co-pay assistance programs, a voucher program, data agreements and payor relationships. In early 2017, we recruited our own sales force to promote Afrezza to endocrinologists and certain high-prescribing primary care physicians. In the future, we may seek to supplement our sales force through a co-promotion

arrangement an agreement with a third party that has an underutilized primary care sales force, which can be used to promote Afrezza to greater number of primary care physicians.

Our current strategy for 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.

We also believe our Technosphere formulations of active pharmaceutical ingredients have the potential to demonstrate clinical advantages over existing therapeutic options in a variety of therapeutic areas. In addition to our collaboration with Receptor (See Note 7, Collaboration Agreements of the Notes to the Condensed Consolidated Financial Statements in this report), we are actively exploring other opportunities to out-license our proprietary Technosphere formulation and device technologies. We continue the development of certain products related to our Technosphere formulations and will continue to do so if we are able to obtain the required funding.

---

**Table of Contents**

As of June 30, 2017, we had an accumulated deficit of \$2.8 billion and a stockholders' deficit of \$221.2 million. We had a net loss of approximately \$35.3 million and \$51.7 million for the three and six months ended June 30, 2017, respectively. We have historically funded our operations primarily through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement with Deerfield, borrowings under The Mann Group Loan Arrangement, which we can no longer borrow under as we have used all amounts available for borrowing, and the Sanofi License Agreement, which was terminated in 2016. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding, there will be substantial doubt about our ability to continue as a going concern. As of June 30, 2017, we had cash and cash equivalents of \$43.4 million, which, together with our debt obligations, including a \$10.0 million principal repayment that is scheduled to become due on August 31, 2017 (subject to a possible extension to October 31, 2017), raises substantial doubt about our solvency and ability to continue as a going concern. We estimate that our net operating cash flow for the second half of 2017 will be approximately \$18 to \$24 million per quarter assuming that we continue as a going concern during this period. However, we cannot provide assurance that our plans will not change or that changed circumstances will not result in net operating cash flow that are greater than we currently estimate.

Our business is subject to significant risks, including but not limited to our need to raise additional capital to fund our operations, our ability to successfully commercialize Afrezza and manufacture sufficient quantities of Afrezza and the risks inherent in our ongoing clinical trials and the regulatory approval process for our product candidates. Additional significant risks also include the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

**CRITICAL ACCOUNTING POLICIES**

Our critical accounting policies can be found in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K for the year ended December 31, 2016 and there have been no material changes.

**Table of Contents****RESULTS OF OPERATIONS****Three and six months ended June 30, 2017 and 2016****Revenues**

The following table provides a comparison of the revenue categories for the three months ended June 30, 2017 and 2016 (dollars in thousands):

	Three Months Ended June 30,			
	2017	2016	\$ Change	% Change
Revenues:				
Net revenue - commercial product sales:				
Gross revenue from product sales	\$ 2,625	\$	\$ 2,625	%
Gross-to-Net Adjustments:				
Wholesaler distribution fees, prompt pay discounts and other rebates and discounts	(645)		(645)	%
Patient discount and co-pay assistance programs	(207)		(207)	%
Rebates and chargebacks	(225)		(225)	%
Net revenue - commercial product sales	1,548		1,548	%
Net revenue - collaboration	63		63	%
Revenue - other	552		552	%
Total revenues	\$ 2,163	\$	\$ 2,163	%

During the three months ended June 30, 2017, we recognized net revenue from commercial product sales of \$1.5 million, representing net sales of Afrezza dispensed to patients. Estimated gross-to-net adjustments of \$1.1 million were approximately 41% of gross revenue from product sales for the three months ended June 30, 2017. During the three months ended June 30, 2016, we did not recognize any revenues from commercial product sales.

During the three months ended June 30, 2017, we recognized net revenue from collaboration of \$0.1 million, representing a portion of the licensing fee received in the fourth quarter of 2016, whereas during the three months ended June 30, 2016 we did not recognize any revenues from collaboration.

During the three months ended June 30, 2017, we recognized \$0.6 million of other revenues related to a sale of intellectual property whereas during the three months ended June 30, 2016 we did not recognize any other revenues.

The following table provides a comparison of the revenue categories for the six months ended June 30, 2017 and 2016 (dollars in thousands):

	Six Months Ended June 30,			
	2017	2016	\$ Change	% Change
Revenues:				

Edgar Filing: MANNKIND CORP - Form 10-Q

Net revenue - commercial product sales:

Gross revenue from product sales	\$ 4,268	\$	\$ 4,268	%
----------------------------------	----------	----	----------	---

Gross-to-Net Adjustments:

Wholesaler distribution fees, prompt pay discounts and other rebates and discounts	(843)		(843)	%
--	-------	--	-------	---

Patient discount and co-pay assistance programs	(331)		(331)	%
---	-------	--	-------	---

Rebates and chargebacks	(349)		(349)	%
-------------------------	-------	--	-------	---

Net revenue - commercial product sales	2,745		2,745	%
--	-------	--	-------	---

Net revenue - collaboration	125		125	%
-----------------------------	-----	--	-----	---

Revenue - other	2,302		2,302	%
-----------------	-------	--	-------	---

Total revenues	\$ 5,172	\$	\$ 5,172	%
----------------	----------	----	----------	---

During the six months ended June 30, 2017, we recognized net revenue from commercial product sales of \$2.7 million, representing net sales of Afrezza dispensed to patients. Estimated gross-to-net adjustments of \$1.5 million were approximately 36% of gross revenue from product sales for the six months ended June 30, 2017. During the six months ended June 30, 2016, we did not recognize any revenues from commercial product sales.

**Table of Contents**

During the six months ended June 30, 2017, we recognized net revenue from collaboration of \$0.1 million, representing a portion of the licensing fee received in the fourth quarter of 2016, whereas during the six months ended June 30, 2016 we did not recognize any revenues from collaboration.

During the six months ended June 30, 2017, we recognized \$2.3 million of other revenues primarily related to a sale of bulk insulin to a third party of \$1.7 million and a \$0.6 million sale of intellectual property, whereas during the six months ended June 30, 2016 we did not recognize any other revenues.

**Expenses**

Total expenses are primarily comprised of costs of goods sold, research and development expenses, selling expenses, and general and administrative expenses. Each is described in more detail below:

**Costs 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 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**

Our research and development expenses consist 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, laboratory supplies and materials, facility costs, costs for outsourced services and depreciation of equipment.

**Selling Expenses**

Our selling expenses are driven by salaries, benefits and stock-based compensation for sales and marketing personnel and for certain third party costs.

**General and Administrative Expenses**

Our general and administrative expenses are driven by salaries, benefits and stock-based compensation for administrative, finance, human resources, legal and information systems support personnel and for certain third party costs.

The following table provides a comparison of the expense categories for the three months ended June 30, 2017 and 2016 (dollars in thousands):

	Three Months Ended June 30,			
	2017	2016	\$ Change	% Change
Expenses:				
Cost of goods sold	\$ 5,086	\$ 4,045	\$ 1,041	26%
Research and development	3,123	4,310	(1,187)	(28%)
Selling	11,646	4,009	7,637	190%



Edgar Filing: MANNKIND CORP - Form 10-Q

General and administrative	6,920	7,101	(181)	(3%)
Property and equipment impairment	111		111	100%
(Gain) loss on foreign currency translation	6,848	(341)	7,189	(2108%)
Total expenses	\$ 33,734	\$ 19,124	\$ 14,610	76%

The increase in cost of goods sold of \$1.0 million for the three months ended June 30, 2017 compared to the same period in the prior year is primarily due to a write-down of inventory of approximately \$1.5 million for expiring and obsolescent inventory and by \$0.4 million of cost of goods sold attributed to the manufacturing of Afrezza dispensed to patients, offset by a \$0.9 million decrease in under-absorbed labor and overhead due to the reduction in work force in the fourth quarter of 2016.

**Table of Contents**

The decrease in research and development expense of \$1.2 million for the three months ended June 30, 2017 compared to the same period in the prior year is primarily due to decreases in compensation expense of \$1.3 million and non-cash stock-based compensation expense of \$0.2 million, each as a result of reductions in staff. Partially offsetting the decreases was an increase due to clinical trials of \$0.3 million.

The increase in selling expenses of \$7.6 million for the three months ended June 30, 2017 compared to the same period in the prior year is primarily due to increases of \$4.3 million for compensation expense associated with the sales force that we brought in-house in the first quarter of 2017, \$2.4 million for cost of external services and commercial support, \$1.5 million for promotional expenses, \$1.0 million for travel and related sales force expenses and \$0.4 million of other expenses. Partially offsetting the increase was a decrease in consultant spending of \$1.7 million as a result of the transition of some of the sales force in-house.

The increase in general and administrative expenses of \$0.2 million for the three months ended June 30, 2017 compared to the same period in the prior year was primarily due to increased spending of approximately \$0.4 million in supporting regulatory activities, \$0.3 million in supporting compliance activities, and \$0.2 million in human resources services. These increases were offset with a decrease of \$0.3 million in legal spending as a result of the Sanofi settlement that was reached in 2016 and a \$0.4 million reduction in patent spending.

Loss on foreign currency translation of \$6.8 million for the three months ended June 30, 2017 compared to a gain on foreign currency translation of \$0.3 million for the same period in the prior year was due to the currency translation of the U.S. dollar to euro exchange rate associated with the purchase commitments from Amphastar.

The following table provides a comparison of the expense categories for the six months ended June 30, 2017 and 2016 (dollars in thousands):

	Six Months Ended June 30,			
	2017	2016	\$ Change	% Change
Expenses:				
Cost of goods sold	\$ 7,635	\$ 9,213	\$ (1,578)	(17%)
Research and development	\$ 6,251	9,440	(3,189)	(34%)
Selling	19,371	4,017	15,354	382%
General and administrative	14,585	14,443	142	1%
Property and equipment impairment	111		111	100%
Loss on foreign currency translation	8,392	2,023	6,369	315%
Total expenses	\$ 56,345	\$ 39,136	\$ 17,209	44%

The decrease in cost of goods sold of \$1.6 million for the six months ended June 30, 2017 compared to the same period in the prior year is primarily due to a \$3.3 million decrease in under-absorbed labor and overhead resulting from the reduction in work force in the fourth quarter of 2016 and no manufacturing of Afrezza in the first quarter of 2016. A decrease of \$0.3 million is deferred cost related to defer revenue. These decreases were offset by a write-down of inventory of approximately \$1.5 million for expiring and obsolescent inventory and \$0.7 million of cost of goods sold attributed to the manufacturing of Afrezza dispensed to patients.

The decrease in research and development expense of \$3.2 million for the six months ended June 30, 2017 compared to the same period in the prior year is primarily due to decreases in compensation expense of \$3.2 million and non-cash stock-based compensation expense of \$0.3 million, each as a result of reductions in staff. Partially offsetting the decreases was an increase due to clinical trials of \$0.4 million.

The increase in selling expenses of \$15.4 million for the six months ended June 30, 2017 compared to the same period in the prior year is primarily due to increases of \$8.3 million for compensation expense associated with the sales force that we brought in-house in the first quarter of 2017, \$4.7 million for cost of external services and commercial support, \$1.9 million for travel and related sales force expenses, \$0.6 million of other expenses, \$0.4 million for product samples related expense, and \$0.2 million for promotional expenses. Partially offsetting the increase was a decrease in consultant spending of \$1.0 million as a result of the transition of some of the sales force in-house.

The increase in general and administrative expenses of \$0.1 million for the six months ended June 30, 2017 compared to the same period in the prior year was primarily due to increased spending of \$0.6 million in supporting regulatory activities, and \$0.2 million increased spending in information systems supporting salesforce personnel. These increases offset with a decrease of \$0.7 million in legal spending as a result of the Sanofi settlement that was reached in 2016.

**Table of Contents**

Loss on foreign currency translation of \$8.4 million for the six months ended June 30, 2017 compared to \$2.0 million for the same period in the prior year was due to the currency translation impacting the U.S. dollar to euro exchange rate associated with the recognized loss on purchase commitments related to Amphastar.

**Other Income (Expense)**

The following table provides a comparison of the other income (expense) categories for the three months ended June 30, 2017 and 2016 (dollars in thousands):

	Three Months Ended June 30,			
	2017	2016	\$Change	% Change
Change in fair value of warrant liability	\$ 147	\$ (5,306)	\$ 5,453	(103%)
Interest income	58	26	32	123%
Interest expense on notes	(2,422)	(4,181)	1,759	(42%)
Interest expense on note payable to principal stockholder	(721)	(721)		%
Loss on extinguishment of debt	(830)		(830)	100%
Other income		(653)	653	(100%)
<b>Total other income (expense)</b>	<b>\$ (3,768)</b>	<b>\$ (10,835)</b>	<b>\$ 7,067</b>	<b>(65%)</b>

During the three months ended June 30, 2017, we recorded a \$0.1 million change in the fair value of the warrant liability compared to \$5.3 million for the same period in the prior year primarily due to the change in our stock price.

The decrease of \$1.7 million in the interest expense on notes for the three months ended June 30, 2017 compared to the same period in the prior year was primarily related to the Sanofi debt that was forgiven in the fourth quarter of 2016.

The increase in the loss on extinguishment of debt of \$0.8 million compared to the same period in the prior year was related to the Deerfield exchange transactions that were completed in April and June of 2017.

The following table provides a comparison of the other income (expense) categories for the six months ended June 30, 2017 and 2016 (dollars in thousands):

	Six Months Ended June 30,			
	2017	2016	\$ Change	% Change
Change in fair value of warrant liability	\$ 6,776	\$ (5,306)	\$ 12,082	(228%)
Interest income	114	41	73	178%
Interest expense on notes	(5,128)	(8,401)	3,273	(39%)
Interest expense on note payable to principal stockholder	(1,435)	(1,443)	8	(1%)
Loss on extinguishment of debt	(830)		(830)	100%
Other income	13	(586)	599	(102%)

Total other income (expense)	\$ (490)	\$ (15,695)	\$ 15,205	(97%)
------------------------------	----------	-------------	-----------	-------

During the six months ended June 30, 2017, we recorded a \$6.8 million change in the fair value of the warrant liability compared to \$5.3 million for the same period in the prior year primarily due to the change in our stock price.

The decrease of \$3.3 million in the interest expense on notes for the six months ended June 30, 2017 compared to the same period in the prior year was primarily related to the Sanofi debt that was forgiven in the fourth quarter of 2016.

The increase in the loss on extinguishment of debt of \$0.8 million compared to the same period in the prior year was related to the Deerfield exchange transactions entered into in April and June 2017.

## LIQUIDITY AND CAPITAL RESOURCES

To date, we have funded our operations through the sale of equity securities and convertible debt securities, borrowings under The Mann Group Loan Arrangement, which we can no longer borrow under as we have used all amounts available for borrowing, borrowings under the Facility Agreement with Deerfield, receipt of upfront, milestone payments under the Sanofi License Agreement, and borrowings under the Sanofi Loan Facility which terminated in 2016.

---

**Table of Contents**

As of June 30, 2017, we had \$167.4 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;

\$45.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, \$10.0 million of which is due and payable in August 2017 (with an option for us to elect to further defer the payment of such principal amount from August 31, 2017 to October 31, 2017 if we meet certain conditions described in the Third Amendment), \$15.0 million of which is due and payable in each of July 2018 and July 2019, and \$5.0 million of which is due and payable in December 2019;

\$15.0 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 2018 and 2019, and \$5.0 million of which is due and payable in December 2019; and

\$79.7 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at a fixed rate of 5.84% per annum and maturing on January 5, 2020.

On June 27, 2017, we entered into an agreement with The Mann Group, pursuant to which the parties agreed to, among other things, (i) capitalize \$10.7 million of accrued and unpaid interest as of June 30, 2017 under The Mann Group Loan Arrangement, resulting in such amount being classified as outstanding principal under The Mann Group Loan Arrangement, (ii) advance to us approximately \$19.4 million, the remaining amount available for borrowing by us under The Mann Group Loan Arrangement after the foregoing capitalization of accrued and unpaid interest, and (iii) defer all interest payable on the outstanding principal under The Mann Group Loan Arrangement until July 1, 2018, unless such payments are otherwise permitted under the subordination agreement with Deerfield, and subject to further deferral under the subordination agreement with Deerfield until our payment obligations to Deerfield have been satisfied in full. There are no additional funds available to borrow under The Mann Group Loan Arrangement. As of June 30, 2017, there was no accrued and unpaid interest under The Mann Group Loan Arrangement.

On April 18, 2017, we entered into an Exchange Agreement with Deerfield resulting in the cash repayment of \$4.0 million under the Tranche B notes and the conversion of \$1.0 million and \$5.0 million of the Tranche B notes and the 2019 notes, respectively, to common shares. On June 29, 2017, we entered into the Third Amendment resulting in the conversion of \$5.0 million of the 2019 notes to common shares and deferment of \$10.0 million of principal amount of the 2019 notes due July 18, 2017 to August 31, 2017 with an option to further defer the payment of such principal amount from August 31, 2017 to October 31, 2017 if certain conditions are met.

Outstanding debt is more fully described in Note 5 Related Party Arrangements, Note 6- Borrowings, Note 9 Fair Value of Financial Instruments and Note 11 Commitments and Contingencies.

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 or The Mann Group Loan Arrangement when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 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. Outstanding 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, except that The Mann Group has agreed to defer interest payments until July 1, 2018 unless otherwise permitted by the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full. 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, and Tranche B notes or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or borrowings under The Mann Group Loan Arrangement, we will be in default under the applicable instrument for such indebtedness, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the 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. In addition, 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, or pursuant to the Third Amendment, \$10.0 million as of the last day of each month through October 31, 2017 and as of December 31, 2017 if certain conditions are met. See Note 11 Commitments and Contingencies and Note 6 Borrowings for further information related to the Facility Agreement.

**Table of Contents**

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

Pursuant to the Sanofi License Agreement, we received an initial upfront payment of \$150.0 million and milestone payments totaling \$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. In addition, on November 9, 2016, in connection with the Settlement Agreement, we and Aventisub LLC, an affiliate of Sanofi, agreed to terminate the Sanofi Loan Facility. In connection with such termination, Aventisub LLC agreed to forgive the full outstanding loan balance on the Sanofi Loan Facility of \$72.0 million owed by us and agreed to release its security interests encumbering our assets. Sanofi also agreed to make a cash payment of \$30.6 million to us, which was received in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without being required to deliver any insulin for such payment. See Note 7 Collaboration Arrangements for further information related to the Sanofi agreements.

Cash used in operating activities, which consists of net loss adjusted for the various non-cash items, changes in working capital and changes in other balance sheet accounts, totaled \$11.5 million for the six months ended June 30, 2017. Cash used in operating activities totaled \$42.3 million for the six months ended June 30, 2016.

During the six months ended June 30, 2017, we used \$11.5 million of cash for our operating activities as a result of our net loss of \$51.7 million, offset by a net decrease in operating assets and liabilities of \$31.9 million and non-cash charges of \$8.3 million. The decrease in operating assets and liabilities was primarily as a result of the receipt of \$30.6 million from Sanofi pursuant to the insulin put option in January 2017, increases in accounts payable of \$3.4 million and decreases in prepaid expenses and other assets of \$1.9 million, offset by decreases in deferred revenue of \$0.8 million, purchase commitment liabilities of \$0.5 million and accrued expenses and other current liabilities of \$0.5 million and increases accounts receivable of \$1.0 million, inventory of \$0.8 million, and deferred costs from commercial product sales of \$0.2 million. The non-cash charges included \$6.8 million from changes in the fair value of the warrant liability, offset by \$8.4 million loss on foreign currency exchange, \$2.5 million of stock-based compensation, \$1.8 million of depreciation, amortization and accretion, \$1.4 million of interest accrued through notes payable to principal stockholder and \$0.8 million of loss on extinguishment of debt.

During the six months ended June 30, 2016, we used \$42.3 million of cash for our operating activities as a result of our net loss of \$54.8 million, offset by non-cash charges of \$17.4 million and a net decrease in operating assets and liabilities of \$4.8 million. The non-cash charges included \$4.7 million of depreciation and accretion and stock-based compensation, \$2.0 million loss on foreign currency exchange, \$2.6 million of interest accrued through borrowings under Sanofi Loan Facility, \$5.3 million from changes in the fair value of the warrant liability, \$0.7 million from warrant issuance costs, \$1.4 million interest accrued through notes payable to principal stockholder and \$0.7 million of impairment charges. The net decrease in operating assets and liabilities was due to decreases in accounts payable of \$12.5 million and \$3.9 million in purchase commitments liability, and an increase of \$2.9 million in inventory, offset by an increase of \$9.2 million in deferred payments from collaboration, \$2.6 million in prepaid expenses and other current assets, and \$2.7 million increase in accrued expenses and other liabilities.

Cash provided from investing activities was \$16.7 million for the six months ended June 30, 2017 compared to cash used in investing activities of \$1.1 million for the six months ended June 30, 2016. The difference was primarily related to net proceeds received during the six months ended June 30, 2017 for the sale of certain parcels of real estate owned by us in Valencia, California and certain related improvements, personal property, equipment, supplies and fixtures for \$16.7 million.



Cash provided from financing activities was \$15.3 million for the six months ended June 30, 2017 primarily related to \$19.4 million received from borrowings on the note payable to principal stockholder offset by a principal payment of \$4.0 million on the facility financing obligation. Cash provided by financing activities of \$48.1 million for the six months ended June 30, 2016 was primarily related to \$47.4 in net proceeds received from the sale of stock and warrants during the six months ended June 30, 2016.

As of June 30, 2017, we had \$43.4 million in cash and cash equivalents, which, together with our debt obligations, including a \$10.0 million principal repayment that is scheduled to become due on August 31, 2017 (subject to a possible extension to October 31, 2017), raises substantial doubt about our solvency and ability to continue as a going concern. We expect to expend our capital resources for the manufacturing, sales and marketing of Afrezza and to develop our product candidates. We also intend to use our capital resources for general corporate purposes. We estimate that our net operating cash flow for the second half of 2017 will be approximately \$18 to \$24 million per quarter assuming that we continue as a going concern during this period. However, we cannot provide assurance that our plans will not change or that changed circumstances will not result in net operating cash flow that are greater than we currently estimate.

## **Table of Contents**

If we enter into strategic business collaborations with respect to our product candidates or Afrezza for commercialization outside of the United States, we may, as part of the transaction, 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 will be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

## **Off-Balance Sheet Arrangements**

As of June 30, 2017, we did not have any off-balance sheet arrangements.

## **Contractual Obligations**

As of June 30, 2017, there were no material changes outside of the ordinary course of business in our contractual obligations from those disclosed within Management's Discussion and Analysis of Financial Condition and Results of Operations, as contained in the Annual Report, except for the following:

### *Note Payable To Principal Stockholder*

On June 27, 2017, we entered into an agreement with The Mann Group, pursuant to which the parties agreed to, among other things, (i) capitalize \$10.7 million of accrued and unpaid interest as of June 30, 2017 under The Mann Group Loan Arrangement, resulting in such amount being classified as outstanding principal under The Mann Group Loan Arrangement, (ii) advance to us approximately \$19.4 million, the remaining amount available for borrowing by us under The Mann Group Loan Arrangement after the foregoing capitalization of accrued and unpaid interest, and (iii) defer all interest payable on the outstanding principal under The Mann Group Loan Arrangement until July 1, 2018, unless such payments are otherwise permitted under the subordination agreement with Deerfield, and subject to further deferral under the subordination agreement with Deerfield until our payment obligations to Deerfield have been satisfied in full. The outstanding principal amount, including the additional amounts borrowed under the June 2017 agreement, and all accrued interest thereon will continue to be due on January 5, 2020.

### *Facility Financing Obligation*

On April 18, 2017, we entered into an Exchange Agreement with Deerfield resulting in the cash repayment of \$4.0 million under the Tranche B notes and the conversion of \$1.0 million and \$5.0 million of the Tranche B notes and the

2019 notes, respectively, to common shares. The principal amount being repaid and exchanged under the Tranche B notes and the principal amount being exchanged under the 2019 notes represents the principal amount that would have otherwise become due and payable in May 2017 and July 2017 under the Tranche B notes and the 2019 notes, respectively. On June 29, 2017, we entered into the Third Amendment resulting in the conversion of \$5.0 million of the 2019 notes to common shares and deferment of \$10.0 million of principal amount of the 2019 notes due July 18, 2017 to August 31, 2017.

**Table of Contents**

*Operating Lease Obligations*

On May 5, 2017, we executed an office lease with Russell Ranch Road II LLC to lease office space for our corporate headquarters in Westlake Village, California. The office lease commences on the earlier of (i) the date we commence business from the leased space or (ii) the later of the date of substantial completion of the build-out by the landlord or August 1, 2017. The lease requires monthly payments of \$40,951, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord. The lease expires 65 months from the commencement date and provides us with a five year renewal option.

Our contractual obligations are more fully described in Note 5 Related Party Arrangements, Note 6 Borrowings, Note 9 Fair Value of Financial Instruments and Note 11 Commitments and Contingencies.

---

**Table of Contents**

**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 six months ended June 30, 2017 was a fixed rate equal to 5.84%. As of June 30, 2017, the total principal amount outstanding under The Mann Group Loan Arrangement was \$79.7 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% and debt related to the Tranche B notes at a fixed interest rate of 8.75%.

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 June 30, 2017 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio.

**Foreign Currency Exchange Risk**

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. 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 June 30, 2017, this change would have resulted in a foreign currency impact to our pre-tax losses of approximately \$10.6 million.

**ITEM 4. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of June 30, 2017. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, we have concluded, as of such date, that our disclosure controls and procedures were effective.

**Changes in Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) of the Exchange Act. An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, two motions were submitted to the district court at Tel Aviv, Economic Department for the certification of a class action against MannKind and certain of our officers and directors. In general, the complaints alleged that MannKind and certain of our officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court has been asked to determine whether Israeli or U.S. law is applicable before the case can be certified as a class action but has not yet ruled on this issue. We will vigorously defend against the claims advanced.

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**

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

This report includes disclosures stating that our existing cash resources and our accumulated stockholders' deficit 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 financial covenant in the Facility Agreement, 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. On June 29, 2017, we entered into the Third Amendment with Deerfield, which, among other things, amended such financial covenant to provide that, if certain conditions under the 2017 Facility Agreement Amendment remain satisfied, then the obligation to maintain at least \$25.0 million in cash as of the end of each quarter will be reduced to \$10.0 million as of the last day of each month through October 31, 2017 and as of December 31, 2017. It

may be difficult for us to raise additional funds on favorable terms, or at all. As of June 30, 2017, we had cash and cash equivalents of \$43.4 million and a stockholders' deficit of \$221.2 million, which, together with our debt obligations, including a \$10.0 principal repayment that is scheduled to become due in August 2017 (subject to a possible extension to October 2017) raises substantial doubt about our solvency and ability to continue as a going concern. Net operating cash flow for the second half of 2017 will be approximately \$18 to \$24 million per quarter. 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;



**Table of Contents**

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 under 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 in the future 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 continue to be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to total loss of investment to our stockholders and other security holders. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, holders of our common stock or other securities may lose the entire value of their investment.

We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. There can be no assurances that we will be able to raise additional capital in sufficient amounts or on favorable terms, or at all. If we are unable to raise adequate additional capital when required or in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment for our stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. In addition, if we default under the Facility Agreement, our senior secured lender, Deerfield, could foreclose on substantially all of our assets.

---

**Table of Contents**

***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, relative pricing compared with alternative products, 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. During our initial transition of the commercial responsibilities from Sanofi, we utilized a contract sales organization to promote Afrezza while we focused our internal resources on establishing a channel strategy, entering into distribution agreements and developing co-pay assistance programs, a voucher program, data agreements and payor relationships. In early 2017, we recruited our own sales force, which included some of the sales representatives that previously were employed by the 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 or retain them for a sufficient period. 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.

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

We are responsible for the NDA for Afrezza and its maintenance. 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 is 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.

***We expect that our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.***

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include the factors that will affect our funding requirements described above under "Risk Factors." We will need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.

## **Table of Contents**

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

***If we do not obtain regulatory approval of Afrezza in foreign jurisdictions, we will not be able to market Afrezza in 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, we have not yet sought approval 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, agree to unfavorable terms or assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, especially in the current market, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of Afrezza in foreign jurisdictions and could have a material and adverse impact on our business, financial condition and results of operations and the market price of our common stock and other securities could decline.

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

We have sought to develop our product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, most of 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 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 non-recurring payments from Sanofi. As of June 30, 2017, 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 and inventory, which resulted in charges of \$140.4 million and \$36.1 million, respectively, in such quarter. In addition, under the amended Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin for calendar years 2017 through 2023 for an aggregate total remaining purchase price of 93.0 million at June 30, 2017. We may not have the necessary capital resources on hand in order to service this contractual commitment.

---

**Table of Contents**

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 June 30, 2017, we had stockholders' deficit of \$221.2 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 have a substantial amount of debt pursuant to the 2018 notes, 2019 notes, Tranche B notes and The Mann Group Loan Arrangement, and we may be unable to make required payments of interest and principal as they become due.\****

As of June 30, 2017, we had \$167.4 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;

\$45.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, \$10.0 million of which is due and payable in August 2017 (with an option for us to elect to further defer the payment of such principal amount from August 31, 2017 to October 31, 2017 if we meet certain conditions described in the Third Amendment), \$15.0 million of which is due and payable in each of July 2018 and July 2019, and \$5.0 million of which is due and payable in December 2019;

\$15.0 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 2018 and 2019, and \$5.0 million of which is due and payable in December 2019; and

\$79.7 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at a fixed rate of 5.84% per annum due on January 5, 2020.

On June 27, 2017, we entered into an agreement with The Mann Group, pursuant to which the parties agreed to, among other things, (i) capitalize \$10.7 million of accrued and unpaid interest as of June 30, 2017 under The Mann Group Loan Arrangement, resulting in such amount being classified as outstanding principal under The Mann Group Loan Arrangement, (ii) advance to us approximately \$19.4 million, the remaining amount available for borrowing by us under The Mann Group Loan Arrangement after the foregoing capitalization of accrued and unpaid interest, and (iii) defer all interest payable on the outstanding principal under The Mann Group Loan Arrangement until July 1, 2018, unless such payments are otherwise permitted under the subordination agreement with Deerfield, and subject to further deferral pursuant to the terms of the subordination agreement with until our payment obligations to Deerfield have been satisfied in full. There are no additional funds available to borrow under The Mann Group Loan Arrangement. As of June 30, 2017, there was no accrued and unpaid interest under The Mann Group Loan Arrangement.

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. Outstanding 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, except that The Mann Group has agreed to defer interest payments until July 1, 2018 unless otherwise permitted by the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full. 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, or Tranche B notes, 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 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.



**Table of Contents*****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. 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, or pursuant to the 2017 Facility Agreement Amendment, \$10.0 million as of the last day of each month through October 31, 2017 and as of December 31, 2017 if certain conditions are met. 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. 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.

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 would demand repayment of the outstanding balance of the 2019 notes or the Tranche B notes 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 may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes, 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.

## **Table of Contents**

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. For example, in January 2017, Novo Nordisk announced that Fiasp®, a faster formulation of insulin aspart, was approved in Europe and Canada. It is currently undergoing regulatory review in the United States. 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.

**Table of Contents**

***If our suppliers fail to deliver materials and services needed for the production of Afrezza in a timely and sufficient manner or fail to comply with applicable regulations, and if we fail to timely identify and qualify alternative suppliers, our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities could decline.***

For the commercial manufacture of Afrezza, we need access to sufficient, reliable and affordable supplies of insulin, our Afrezza inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar. We must rely on our suppliers, including Amphastar, to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with the FDA's cGMP for drug products, and the production of the Afrezza inhaler and related cartridges in accordance with QSRs. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of Afrezza may be delayed. Likewise, if Amphastar ceases to manufacture or is otherwise unable to deliver insulin for Afrezza, we will need to locate an alternative source of supply and the production of Afrezza may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

***If we fail as an effective manufacturing organization or fail to engage third-party manufacturers with this capability, we may be unable to support commercialization of this product.***

We use our Danbury, Connecticut facility to formulate Afrezza inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We utilize a contract packager to assemble the final kits of foil-pouched 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.

---

**Table of Contents**

***If third-party payors do not cover Afrezza or any of our product candidates for which we receive regulatory approval, Afrezza or such product candidates might not be prescribed, used or purchased, which would adversely affect our revenues.***

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there 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, 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;



**Table of Contents**

a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of certain drug-device combination products, which was suspended for calendar years 2016 and 2017;

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. As a result there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May 2017. More recently, the Senate Republicans have released and then updated a draft bill known as the Better Care Reconciliation Act of 2017. Each of these Congressional proposals would repeal and replace certain aspects of the PPACA if ultimately enacted. The Senate Republicans have also contemplated legislation to repeal the PPACA without companion legislation to replace it. The prospects for enactment of these legislative initiatives remain uncertain. Further, Congress also could consider other legislation to replace elements of the PPACA. We continue to evaluate the potential effect of the possible repeal and replacement of the PPACA may have on our business.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and, following passage of the 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. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among

## **Table of Contents**

other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations, including those pertaining to fraud and abuse and patients' rights are and will be applicable to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others:

the federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws, including without limitation the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;

HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying, concealing, or covering

up a material fact in connection with the delivery of or payment for health care benefits;

HIPAA, as amended by HITECH, and their respective implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

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.

**Table of Contents**

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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.***

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price ( AMP ) and best price ( BP ) for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty 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.

---

**Table of Contents**

***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 our Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. A material weakness in our internal controls has been identified in the past, and we cannot assure you that we or our independent

registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

***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.



## **Table of Contents**

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

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, two motions were submitted to the District Court at Tel Aviv, Economic Department for the certification of a class action against MannKind and certain of our officers and directors. The complaints alleged 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 MannKind's common stock. The plaintiffs are seeking monetary damages. In November 2016, the court in Israel dismissed one of the actions without prejudice. In the remaining action, the district court has been asked to determine whether Israeli or U.S. law is applicable before the case can be certified as a class action but has not yet ruled on the issue. 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.

---

**Table of Contents**

***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 hackers. 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.

---

**Table of Contents**

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

## **Table of Contents**

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.***



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.

## Table of Contents

### **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, 2029, 2030 and 2031. As and when these different patents expire, Afrezza could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

An issued patent is presumed valid unless it is declared otherwise by a court of competent jurisdiction. However, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions, or post grant proceedings, including, oppositions, re-examinations or other review in the United States. In some instances we may seek re-examination or reissuance of our own patents. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

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. 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.

**Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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.

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

Between January 1, 2014 and June 30, 2017, our closing stock price as reported on The NASDAQ Global Market has ranged from \$0.71 to \$54.80, adjusted for the reverse stock split that occurred during this period; in unadjusted terms, the range over this period was \$0.14 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:

our ability to obtain marketing approval for Afrezza outside of the United States and to find collaboration partners for the commercialization of Afrezza in foreign jurisdictions;

our future estimates of Afrezza sales, prescriptions or other operating metrics;

our ability to successfully commercialize 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.

---

**Table of Contents**

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, on March 1, 2017, our board of directors and stockholders approved the Charter Amendment to effect the Reverse Stock Split. On March 3, 2017, our common stock began trading on The NASDAQ Global Market on a split-adjusted basis at a ratio of 1 share for 5. On March 16, 2017, we received a letter from the Nasdaq Stock Market indicating that we had regained compliance with the \$1.00 minimum closing bid price requirement. Since effecting the Reverse Stock Split, the market price per share of our common stock has closed below \$1.00 on multiple occasions. There can be no assurance that the market price per share of our common stock will remain in excess of the \$1.00 minimum closing bid price requirement in the future.

***If other biotechnology and biopharmaceutical companies or the securities markets in general encounter problems, the market price of our common stock and other securities could be adversely affected.***

Public companies in general, including companies listed on The NASDAQ Global Market, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock and other securities to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

***The future sale of our common stock, 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 August 1, 2017, we had 104,682,717 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock and other securities may decline. Likewise the issuance of additional shares of our common stock upon the exchange or conversion of some or all of our 2018 notes, 2019 notes, Tranche B 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

---

**Table of Contents**

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, as amended on March 1, 2017 to effect the Reverse Stock Split, currently authorizes us to issue up to 140,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of August 1, 2017, we had a total of 104,682,717 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.

**Table of Contents****ITEM 5. OTHER INFORMATION**

As previously disclosed in our Quarterly Report on Form 10-Q (filed on May 10, 2015), on May 5, 2017, we executed an office lease with Russell Ranch Road II LLC to lease approximately 64,300 square feet of office space located at 30930 Russell Ranch Road, Suite 301, Westlake Village, CA 91362 for our corporate headquarters. The office lease commences on the earlier of (i) the date the Company commences business from the leased space or (ii) the later of the date of substantial completion of the build-out by the landlord or August 1, 2017. The lease requires monthly payments of \$40,951, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord. The lease expires 65 months from the commencement date and provides us with a five year renewal option.

**ITEM 6. EXHIBITS****Exhibit**

<b>Number</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
3.2	Certificate of Amendment of Amended and Restated Certificate of incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 2, 2017).
3.3	Amended and Restated Bylaws (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).
4.3	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind's current report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.4	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.5	Form of Tranche B Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.8 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50856), filed with the SEC on May 12, 2014).
4.6	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.7	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).

Edgar Filing: MANNKIND CORP - Form 10-Q

- 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), 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), filed with the SEC on March 3, 2014).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
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	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).
4.12	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).
4.13	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).
4.14	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).
4.15	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).
4.16	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
10.1*	Form of Change of Control Agreement (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 7, 2017).
10.2	Exchange Agreement, dated April 18, 2017, by and among MannKind Corporation, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 19, 2017).
10.3	Office Lease, dated May 5 2017, by and between MannKind and Russell Ranch Road II LLC.
10.4	Agreement, dated June 27, 2017, by and between MannKind and The Mann Group 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 June 29, 2017).
10.5	Exchange and Third Amendment to Facility Agreement, dated June 29, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on June 29, 2017).
10.6*	Offer Letter Agreement, dated July 12, 2017, by and between MannKind and Steven Binder (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 17, 2017).
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.



Edgar Filing: MANNKIND CORP - Form 10-Q

- 31.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of the Chief Executive Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
- 32.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
- 101 Interactive Data Files pursuant to Rule 405 of Regulation S-T.

\* Indicates management contract or compensatory plan

**Table of Contents**

**SIGNATURE**

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

Dated: August 7, 2017

MANNKIND CORPORATION

By: /s/ MICHAEL CASTAGNA  
Michael Castagna  
Chief Executive Officer

(on behalf of the registrant and as the registrant's  
Principal Executive Officer)

By: /s/ STEVEN BINDER  
Steven Binder  
Chief Financial Officer

(on behalf of the registrant and as the registrant's  
Principal Financial and Accounting Officer)