MANNKIND CORP
Form 10-Q
May 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended March 31, 2016

Or

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

For the transition period from _____ to _____.

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of	***(I.R.S. Employer***
incorporation or organization)	***Identification No.)***
25134 Rye Canyon Loop Suite 300	
Valencia, California	**91355**
(Address of principal executive offices)	***(Zip Code)***

(661) 775-5300

(Registrant s telephone number, including area code)

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

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

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

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

As of May 2, 2016, there were 429,161,347 shares of the registrant s common stock, $0.01 par value per share, outstanding.

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MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended March 31, 2016

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PART 1: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share data)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,653	$ 59,074
Receivables from collaboration	144	23
Deferred product costs from collaboration	13,539	13,539
Prepaid expenses and other current assets	2,807	4,018
Total current assets	44,143	76,654
Property and equipment net	48,033	48,749
Other assets	1,096	1,009
Total	$ 93,272	$ 126,412
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 582	$ 15,599
Accrued expenses and other current liabilities	8,077	7,929
Facility financing obligation	75,010	74,582
Deferred product sales from collaboration	17,680	17,503
Deferred payments from collaboration	134,935	140,231
Purchase commitment liabilities current	12,927	12,475
Total current liabilities	249,211	268,319
Note payable to principal stockholder	49,521	49,521
Sanofi loan facility and loss share obligation	68,835	62,371
Senior convertible notes	27,618	27,613
Net purchase commitments	55,605	53,692
Other liabilities	15,946	15,225
Total liabilities	466,736	476,741
Commitments and contingencies		
Stockholders equity (deficit):		

Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at March 31, 2016 and December 31, 2015		
Common stock, $0.01 par value 550,000,000 shares authorized at March 31, 2016 and December 31, 2015; 429,138,685 and 428,670,943 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	4,290	4,287
Additional paid-in capital	2,510,367	2,508,633
Accumulated other comprehensive loss	(19)	(20)
Accumulated deficit	(2,888,102)	(2,863,229)
Total stockholders deficit	(373,464)	(350,329)
Total	$ 93,272	$ 126,412

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three months ended March 31,	
	2016	**2015**
Revenue	$	$
Operating expenses:		
Research and development	5,130	9,377
General and administrative	7,351	10,479
Product manufacturing	7,532	1,882
Total operating expenses	20,013	21,738
Loss from operations	(20,013)	(21,738)
Other income	67	1,413
Interest expense on note payable to principal stockholder	(721)	(714)
Interest expense on notes	(4,221)	(9,622)
Interest income	15	3
Loss before benefit for income taxes	(24,873)	(30,658)
Income tax benefit		
Net loss	$ (24,873)	$ (30,658)
Net loss per share basic and diluted	$ (0.06)	$ (0.08)
Shares used to compute basic and diluted net loss per share	428,858	398,916

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three months ended March 31,	
	2016	**2015**
Net loss	$ (24,873)	$ (30,658)
Other comprehensive loss:		
Cumulative translation gain (loss)	1	(7)
Other comprehensive gain (loss)	1	(7)
Comprehensive loss	$ (24,872)	$ (30,665)

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three months ended March 31,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (24,873)	$ (30,658)
Adjustments to reconcile net loss to net cash provided by (used) in operating activities:		
Depreciation and accretion	1,023	2,988
Stock-based compensation expense	1,273	2,003
Interest incurred through borrowings under Sanofi Loan Facility	1,168	33
Loss on foreign currency exchange	2,364	
Other, net	696	(7)
Changes in assets and liabilities:		
Inventory		(7,119)
Receivables from Collaboration	(121)	46,154
Prepaid expenses and other current assets	1,211	3,831
Deferred product costs from collaboration		(6,251)
Other assets	(86)	(872)
Accounts payable	(14,799)	(4,182)
Accrued expenses and other current liabilities	488	(10,660)
Deferred product sales from collaboration	177	7,050
Other liabilities	721	710
Net cash provided by (used in) operating activities	(30,758)	3,020
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,144)	(4,203)
Proceeds from sale of property and equipment	17	
Net cash used in investing activities	(1,127)	(4,203)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	467	6,168
Milestone payment		(4,220)
Payment of employment taxes related to vested restricted stock units	(3)	(762)
Net cash provided by financing activities	464	1,186
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ (31,421)	$ 3

CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	59,074	120,841
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 27,653	$ 120,844
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	2,713	4,749
Non-cash construction in progress and property and equipment	558	1,094

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (MannKind, the Company, we or us), have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2015 filed with the SEC on March 15, 2016 (the Annual Report).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three months ended March 31, 2016 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets and deferred product costs for impairment, accrued expenses, valuation of 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. Our 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.

Basis of Presentation The Company s primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, raising capital and commercial manufacturing. It is costly to develop therapeutic products and conduct clinical studies for these products. As of March 31, 2016, the Company had an accumulated deficit of $2.9 billion and has reported negative cash flow from operations since inception, other than for the nine months ended September 30, 2014, the year ended December 31, 2014, and for the three months ended March 31, 2015, as a result of receipt of the upfront payment and milestone payments from Sanofi-Aventis U.S. LLC (Sanofi).

At March 31, 2016, the Company s capital resources consisted of cash and cash equivalents of $27.7 million. The Company expects to continue to incur significant expenditures to support commercial manufacturing and sales and marketing of AFREZZA and the development of other product candidates. The facility agreement (the Facility Agreement) with Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design

International II, L.P. (collectively, Deerfield) and the First Amendment to Facility Agreement and Registration Rights Agreement (the First Amendment) that resulted in additional sales of an additional tranche of notes (the Tranche B notes) (see Note 12 Facility Agreement) requires the Company to maintain at least $25.0 million in cash and cash equivalents or available borrowings under the loan arrangement, dated as of October 2, 2007, between The Company and The Mann Group LLC (as amended, restated, or otherwise modified as of the date hereof, The Mann Group Loan Arrangement), as of the last day of each fiscal quarter. The Company will need to continue to incur expenses for the commercialization of AFREZZA and will need to raise additional capital to finance such activities. The Company cannot be certain that it will be able to raise additional capital on favorable terms, or at all, which raises 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.

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

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On January 4, 2016 the Company received notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Pursuant to a transition agreement between the Company and Sanofi, all rights to AFREZZA transferred back to the Company on April 4, 2016 to the Company. Accordingly, on April 5, 2016, the Company assumed responsibility for the worldwide development and commercialization of AFREZZA from Sanofi, in a transition designed to ensure that patients will not experience any interruption in their treatment. Under the terms of the transition agreement, Sanofi will continue to fulfill orders for AFREZZA until such time as Sanofi s inventory of usable product is depleted or until the Company provides Sanofi written notice requesting that Sanofi cease such activities, but in any event no later than October 1, 2016.

Under the Sanofi License Agreement, worldwide profits and losses, which are determined based on the difference between the net sales of AFREZZA and the costs and expenses incurred by the Company and Sanofi that are specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of AFREZZA, are shared 65% by Sanofi and 35% by the Company until Sanofi ceases to distribute AFREZZA. As a result of this loss share provision, and because the Company does not currently have the ability to estimate the amount of costs that would potentially be incurred related to the Sanofi License Agreement, the amount of up-front cash payment or milestone payments that could be recognized as revenue is not fixed or determinable. In connection with the Sanofi License Agreement, an affiliate of Sanofi provided the Company with a secured loan facility (the Sanofi Loan Facility) of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement.

Additional funding sources that are, or in certain circumstances may be, available to the Company, include approximately $30.1 million principal amount of available borrowings under The Mann Group Loan Arrangement. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under The Mann Group Loan Arrangement (see Note 4 Related-party arrangements). The Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company is seeking and will need to raise additional capital, whether through a sale of equity or debt securities, a strategic business collaboration with a pharmaceutical company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the development and commercialization of AFREZZA and other product candidates and to support its other ongoing activities. However, the Company cannot provide assurances that such additional capital will be available on acceptable terms or at all.

Fair Value of Financial Instruments The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, accounts payable and accrued liabilities approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to related party, senior convertible notes, and the Facility Agreement are discussed in Note 7 Fair Value of Financial Instruments.

Deferred product costs from collaboration Deferred product costs represent the costs of product manufactured and shipped to Sanofi, not to exceed the amount of deferred product sales related to the collaboration, for which recognition of revenue has been deferred. Given that the costs of inventory delivered to a customer, but for which revenue may not yet be recognized, meet both the definition and characteristics of an asset and the Company believes that it is probable that the amount of future revenue will exceed the amount of deferred costs (i.e., the asset would be realizable through the recognition of probable future income), the Company has elected to account for the deferred costs related to the product sold to Sanofi as an asset and carry forward to future periods until the related revenue is recognized.

Recently Issued Accounting Standards From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date.

In May 2014, the FASB issued ASU 2014-09 related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard requires a company to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. We are assessing the potential impact of the new standards on our consolidated financial statements and have not yet selected a method of adoption.

In August 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an

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entity must provide certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-15 will have on its consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost. The amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company is evaluating the impact the adoption of ASU 2015-11 will have on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update is intended to improve the recognition and measurement of financial instruments. The ASU affects public and private companies, not-for-profit organizations, and employee benefit plans that hold financial assets or owe financial liabilities. The 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 2016-01 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The adoption of this standard is not expected to have a material impact on our financial position. The Company is evaluating the impact the adoption of ASU 2016-02 will have on its consolidated financial statements.

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

2. Property and equipment

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

	Estimated Useful Life (Years)	March 31, 2016	December 31, 2015
Land		$ 3,435	$ 3,435
Buildings	39-40	21,590	21,590

Building improvements	5-40	60,584	60,584
Machinery and equipment	3-15	67,761	68,434
Furniture, fixtures and office equipment	5-10	4,114	4,114
Computer equipment and software	3	9,519	9,519
Construction in progress		460	586
		167,463	168,262
Less accumulated depreciation and amortization		(119,430)	(119,513)
Property and equipment net		$ 48,033	$ 48,749

The December 31, 2015 balances have been reclassified to the current year presentation by allocating the impairment of $140.4 million to the individual asset groups.

Depreciation and amortization expense related to property and equipment for the three months ended March 31, 2016 and 2015 was $0.6 million and $2.3 million, respectively.

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3. Accrued expenses and other current liabilities

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

	March 31, 2016	December 31, 2015
Salary and related expenses	$ 5,685	$ 5,662
Accrued interest	199	615
Construction in progress		238
Other	2,193	1,414
Accrued expenses and other current liabilities	$ 8,077	$ 7,929

4. Related-party arrangements

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

As of March 31, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million, and the amount available for future borrowings was $30.1 million. Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized as additional borrowings at any time and would be classified as non-current upon mutual agreement of both parties. As of March 31, 2016, the Company had accrued $7.1 million of interest in other long term liabilities. The Mann Group can require the Company to prepay up to $200.0 million in advances that have been outstanding for at least 12 months (less approximately $105.0 million aggregate principal amount that has been cancelled in connection with two common stock purchase agreements). If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice (or the number of days to maturity of the note if less than 90 days) to prepay such advances. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under The Mann Group Loan Arrangement until the Company s payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group s option, and the interest rate will increase to the one-year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under The Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

During the three months ended March 31, 2016, there were no additional borrowings under or amendments to The Mann Group Loan Arrangement.

In May 2015, the Company entered into a sublease agreement with the Alfred Mann Foundation for Scientific Research (the Mann Foundation), a California not-for-profit corporation. The lease is for approximately 12,500 square feet of office space in Valencia, California and expires in April 2017. The office space contains the Company s principal executive offices. Lease payments to the Mann Foundation for the three months ended March 31, 2016 were $65,000 and there were no lease payments to the Mann Foundation for the three months ended March 31, 2015.

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 10 Commitments and contingencies).

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5. Senior convertible notes

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

	March 31, 2016	December 31, 2015
2018 notes		
Principal amount	$ 27,690	$ 27,690
Unamortized premium	603	660
Unaccreted debt issuance costs	(675)	(737)
Net carrying amount	$ 27,618	$ 27,613

Issuance of new 5.75% Convertible Senior Subordinated Exchange Notes due 2018 in exchange for 2015 notes

On July 28, 2015, the Company entered into a privately-negotiated exchange agreement (the Note Exchange Agreement) with a select holder of the Company s 5.75% Senior Convertible Notes due 2015 (the 2015 notes), pursuant to which the Company agreed to issue $27.7 million aggregate principal amount of new 5.75% Convertible Senior Subordinated Exchange Notes due 2018 (the 2018 notes) to such holder in exchange for the delivery to the Company of the same principal amount of 2015 notes. The 2018 notes were issued at the closing of the exchange on August 10, 2015. The Company analyzed this exchange under the provisions of ASC 470-50 and concluded that the exchange represents an extinguishment of the 2015 notes and a new issuance of 2018 notes and recorded such notes at fair value which resulted in a premium of $0.7 million.

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

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

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2018 notes will have the option to require the Company to repurchase all or any portion of that holder s 2018 notes. The

fundamental change repurchase price will be 100% of the principal amount of the 2018 notes to be repurchased plus accrued and unpaid interest, if any.

On or after the date that is one year following the original issue date of the 2018 notes, the Company will have the right to redeem for cash all or part of the 2018 notes if the last reported sale price of its common stock exceeds 130% of the conversion price then in effect for 20 or more trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date of the redemption notice. The redemption price will equal the sum of 100% of the principal amount of the 2018 notes to be redeemed, plus accrued and unpaid interest. Under the terms of the indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the indenture, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the term of the 2018 notes under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2018 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the term of the 2018 notes under existing commitments.

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

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

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Accretion of debt issuance expense in connection with the 2018 notes for the three months ended March 31, 2016 was $62,000. Amortization of 2018 notes premium for the three months ended March 31, 2016 was $57,000.

6. Collaboration arrangement

Sanofi License Agreement and Sanofi Supply Agreement

As disclosed in Note 1 under Basis of Presentation, the Company entered into a license and collaboration agreement with Sanofi which was terminated effective April 4, 2016. On April 5, 2016 the Company assumed responsibility for the worldwide development and commercialization of AFREZZA from Sanofi, in a transition designed to ensure that patients will not experience any interruption in their treatment. Under terms of the transition agreement, Sanofi will continue to fulfill orders for AFREZZA until such time as Sanofi s inventory of usable product is depleted or until the Company provides Sanofi written notice requesting that Sanofi cease such activities, but in any event no later than October 1, 2016. As previously disclosed, worldwide profits and losses incurred by the Company and Sanofi that are specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of AFREZZA, are shared 65% by Sanofi and 35% by the Company until Sanofi Ceases to distribute AFREZZA.

The Company analyzed the agreements entered into with Sanofi to determine whether the consideration, or a portion thereof, could be recognized as revenue. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. In addition, revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Under the terms of the Sanofi License Agreement, Sanofi Supply Agreement and the Sanofi Loan Facility the Company determined that the arrangement contained significant deliverables including (i) licenses to develop and commercialize AFREZZA and to use the Company s trademarks, (ii) development activities, and (iii) manufacture and supply services for AFREZZA. Due to the proprietary nature of the manufacturing services being provided by the Company, the Company determined that all of the significant deliverables should be combined into a single unit of accounting. The Company believes that the manufacturing services are proprietary due to the fact that since the late 1990 s, the Company has developed proprietary knowledge and patented equipment and tools that are used in the manufacturing process of AFREZZA. Due to the complexities of particle formulation and the specialized knowledge and equipment needed to handle the AFREZZA powder, neither Sanofi nor any third-party contract manufacturing organization currently possesses the capability of manufacturing AFREZZA.

In order for revenue to be recognized, the seller s price to the buyer must be fixed and determinable. Given that as of March 31, 2016 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 believes this requirement for revenue recognition has not been met. As such, the Company did not recognize any revenue pursuant to the Sanofi License Agreement or the Sanofi Supply Agreement for the three months ended March 31, 2016. The Company has recorded the $150.0 million up-front payment and $50.0 million from milestone payments as deferred payments from collaboration. In addition, as of March 31, 2016 the Company has recorded $17.7 million in AFREZZA product shipments to Sanofi recorded as deferred product sales from collaboration and recorded $13.5 million as deferred product costs from collaboration. Deferred product costs represent the costs of product manufactured and shipped to Sanofi, not to exceed the amount of deferred product sales,

for which recognition of revenue has been deferred. During the quarter ended March 31, 2016, the Company s portion of the loss sharing was $5.5 million, which resulted in the reclassification from current deferred payments from collaboration to Sanofi loan facility and loss share obligation to reflect amounts owed to Sanofi.

Sanofi Loan Facility

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

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The obligations of the Company under the Sanofi Loan Facility are guaranteed by the Company s wholly-owned subsidiary, MannKind LLC, and are secured by a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which the Company purchases or has purchased such insulin, and a second priority security interest in the Company s assets that secure the Company s obligations under the Facility Agreement, as amended. In addition, the Company granted to Sanofi, as additional security for the obligations under the Sanofi Loan Facility, a first priority mortgage on the Company s facility in Valencia, California, which has a carrying value of $17.7 million as of March 31, 2016.

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

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

The Company s total cumulative portion of the loss sharing, including interest, was $68.8 million, of which $63.5 million was borrowed under the Sanofi Loan Facility as of March 31, 2016. Subsequent to March 31, 2016, the Company borrowed $5.3 million under the Sanofi Loan Facility to finance the portion of the Company s loss for the quarter ended March 31, 2016. The total amount owed to Sanofi is $68.8 million, which includes $2.8 million in paid-in-kind interest capitalized as principal.

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

7. Fair Value of Financial Instruments

The Company applies various valuation approaches in determining the fair value of its financial assets and liabilities within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Significant inputs to the valuation model are unobservable.

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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 and 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 March 31, 2016 and December 31, 2015, the Company held $27.7 million and $59.1 million, respectively, of cash and cash equivalents, consisting primarily of money market funds of $26.0 million and $55.8 million, respectively, and the remaining in non-interest bearing checking accounts. 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).

Related-Party Arrangement

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

2018 notes, facility financing obligation and Sanofi Loan Facility

The following is a summary of the carrying values and estimated fair values of the 2018 notes, the facility financing obligation (i.e., the 2019 notes and Tranche B notes), and the Sanofi Loan Facility (in millions):

	March 31, 2016		December 31, 2015	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2018 notes	$ 27.6	$ 21.8	$ 27.6	$ 21.3
Facility financing obligation	$ 75.0	$ 79.4	$ 74.6	$ 78.4
Sanofi Loan Facility	$ 63.5	$ 48.2	$ 44.5	$ 36.5

2018 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 (21%), 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 12 Facility Agreement, in connection with the Facility Agreement, the Company issued 2019 notes and subsequently issued Tranche B notes (the Facility Financing Obligation). 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 March 31, 2016 the market discount rate was recalculated at 12.0% for the 2019 notes and 11% for the Tranche B notes, which reflected decline in the market price of benchmark U.S. Treasury securities as compared to prior measurement date (Level 3 in the fair value hierarchy).

In addition to the 2019 notes and Tranche B notes, the Company also issued certain rights to receive payments of up to $90.0 million upon occurrence of specified strategic and sales milestones (the Milestone Rights). These rights are not reflected in the facility financing obligation. The estimated fair value of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (14.5%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of March 31, 2016, the carrying value of the Milestone Rights is $8.9 million, classified as a long-term liability in other liabilities and the fair value is estimated at $17.7 million.

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Sanofi Loan Facility

As discussed in Note 6 the Sanofi Loan Facility, consists of a senior secured revolving promissory note and a guaranty and security agreement with an affiliate of Sanofi which provides the Company with a secured loan facility of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement. The estimated fair value was determined using a discounted cash flow model in which time outstanding and discount rate were primary variables. This method considered the key elements of the contractual terms of the Sanofi Loan Facility, market-based estimated cost of capital, and time value of money, namely the amount of time to settlement and the estimated discount rate (11%) appropriate for the liability (Level 3 in the fair value hierarchy). As of March 31, 2016 the carrying value of the Sanofi Loan Facility is $63.5 million and the fair value is estimated at $48.2 million.

8. Accounting for stock-based compensation

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three months ended March 31, 2016 and 2015 was as follows (in thousands):

	Three months ended March 31,	
	2016	2015
Stock-based compensation	$ 1,273	$ 2,003

During the three months ended March 31, 2016, the Company issued stock awards to employees with a four-year vesting schedule. The grant date fair value of the 2,364,200 restricted stock units and 4,920,267 stock options issued was $2,175,064 and $2,988,418, respectively, with a grant date fair value per share of $0.92 and $0.61, respectively.

As of March 31, 2016, there was $5.7 million and $7.4 million of unrecognized compensation cost related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 3.0 years.

9. Net loss per common share

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 excluding the 9,000,000 shares loaned to Bank of America under a share lending arrangement for the period ended March 31, 2015. In the third quarter of 2015, the 9,000,000 shares loaned to Bank of America were returned and therefore do not impact the first quarter of 2016. Prior to the return of those shares, the borrowed shares were not considered outstanding for the purpose of computing and reporting basic or diluted loss per share because the share borrower had to return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof).

Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying condensed consolidated statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, are not included in the diluted net loss per share calculation and excluded the 9,000,000 shares of the Company s common stock loaned under the share lending arrangement.

On February 8, 2016, all unexercised warrants related to the February 2012 public offering expired. The only remaining warrants outstanding relate to those issued to the Company s placement agent in exchange for services related to the Company s offering on November 9, 2015 for selected investment funds in Israel.

Potentially dilutive securities outstanding are summarized as follows (in shares):

	March 31,	
	2016	**2015**
Exercise of common stock options	24,102,471	21,615,264
Vesting of restricted stock units	3,946,007	2,647,020
Exercise of common stock warrants	159,303	6,200,721
Conversion of senior convertible notes into common stock	4,072,809	14,708,590
	32,280,590	45,171,595

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10. 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 March 31, 2016, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company and no accrual has been recorded. The Company maintains liability insurance coverage to protect the Company s assets from losses arising out of or involving activities associated with ongoing and normal business operations. In accordance with ASC 450 *Contingencies*, 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 Sanofies election to terminate the Sanofi License Agreement and the subsequent decline in the Company s stock price, several complaints were filed in the U.S. District Court for the Central District of California (the District Court) against the Company and certain of its officers and directors on behalf of certain purchasers of its common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been pled as putative shareholder class actions. In general, the complaints allege that the Company and certain of its officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages and other relief. On April 29, 2016, two putative shareholders filed a Joint Stipulation with the District Court seeking an order consolidating the actions for all purposes, appointing them co-lead plaintiffs, and approving their selection of lead counsel. The Company will vigorously defend against the claims advanced.

Following the public announcement of Sanofies election to terminate the Sanofi License Agreement and the subsequent decline in the Company s stock price, two motions were submitted to the district court at Tel Aviv (Economic Department) for the certification of a class action against the Company and certain of its officers and directors. In general, the complaints allege that the Company and certain of its officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. The Company will vigorously defend against the claims advanced.

On March 10, 2016, a shareholder derivative complaint, captioned *Hoang Dao v. Matthew Pfeffer, et al*., Case No. BC613361, was filed in the Superior Court for the State of California, County of Los Angeles against certain of the Company s directors and officers. The complaint alleges breaches of fiduciary duties by the defendants and other violations of law. Among other allegations, the complaint alleges that the defendants caused the Company to make false and misleading statements or omissions of material fact regarding the Company s business and the prospects for

sales of Afrezza, thereby artificially inflating the price of the Company s common stock. The plaintiff is seeking unspecified monetary damages and other relief, including reforms to the Company s corporate governance and internal procedures. The Company has not yet been served with the complaint and summons in this matter.

Contingencies In connection with the Facility Agreement, on July 1, 2013 the Company also entered into a Milestone Rights Purchase Agreement (the Milestone Agreement) with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, the Milestone Purchasers), pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product in the United States and the achievement of specified net sales figures (see Note 12 Facility Agreement).

Commitments On July 31, 2014, the Company entered into a supply agreement (the Insulin Supply Agreement) with Amphastar France Pharmaceuticals S.A.S., a French corporation (Amphastar), pursuant to which Amphastar manufactures for and supplies to the Company certain quantities of recombinant human insulin for use in AFREZZA. Under the terms of the Insulin Supply Agreement, Amphastar is responsible for manufacturing the insulin in accordance with the Company s specifications and agreed-upon quality standards. The Company has agreed to purchase annual minimum quantities of insulin for calendar years 2015 through 2019 under the Insulin Supply Agreement of an aggregate total of approximately 120.1 million, of which 98.5 million is remaining at March 31, 2016. The Company has contracted for the purchase of 28.8 million in 2016 and the remaining annual minimum quantities will be 23.3 million for the years ending December 31, 2017 through 2019. The Company may request to

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purchase additional quantities of insulin over such annual minimum quantities and will incur a cancellation fee of approximately $5.2 million if not purchased (see Note 2 Summary of Significant accounting policies). Based on our purchase commitments outstanding in foreign currency at March 31. 2016, the Company incurred a loss on foreign currency exchange of $2.4 million for the quarter ended.

Unless earlier terminated, the term of the Insulin Supply Agreement expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months written notice given prior to the end of the initial term or any additional two year term. The Company and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, the Company may terminate the Insulin Supply Agreement upon two years prior written notice to Amphastar without cause or upon 30 days prior written notice to Amphastar if a controlling regulatory authority withdraws approval for AFREZZA, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require the Company to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

Under the terms of the Sanofi Supply Agreement, in the event that Sanofi terminates the Sanofi License Agreement for various reasons (including the reasons cited in its notice of termination to the Company), then upon written notice from the Company within 30 days following the termination date, Sanofi is obligated to purchase up to $50 million of the Company s insulin inventory as a percentage of each lot received or receivable by the Company (the Insulin Put). On April 14, 2016, the Company provided Sanofi with written notice that it was exercising the Insulin Put. The Company and Sanofi are currently discussing the schedule of purchases and deliveries pursuant to the Insulin Put.

11. Income taxes

As required by ASC 740 Income Taxes (ASC 740), 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.

ASC 740-10-25 *Income Taxes Recognition* clarifies the accounting and disclosure for uncertainty in tax positions, as defined. This guidance seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to this guidance. Tax years since 1993 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

Accounting Standard Update 2015-17, *Balance Sheet Classification of Deferred Taxes* requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. For public business entities, the amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. As permitted by the standard, we adopted the new presentation and the adoption did not have an impact on our consolidated financial statements and disclosures.

12. Facility Agreement

As of March 31, 2016, there were $60.0 million principal amount of 2019 notes and $20.0 million principal amount of Tranche B notes outstanding. The 2019 notes accrue interest at annual rate of 9.75% and the Tranche B notes accrue interest at an annual rate of 8.75%. The Facility Agreement principal repayment schedule is comprised of annual

payments beginning on July 1, 2016 and ending December 9, 2019. The repayment dates correspond to the dates on which the 2019 notes or Tranche B notes, as applicable, were issued.

In conjunction with the Facility Agreement, the Company entered into a Milestone Rights Agreement with Deerfield which requires the Company to make contingent payments to Deerfield, totaling up to $90.0 million, upon the Company achieving specified commercialization milestones. The Milestone Rights were initially recorded as a short-term liability equal to $3.2 million included in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet and a long-term liability equal to $13.1 million included in other liabilities. As of March 31, 2016, the remaining liability balance of $8.9 million is classified as long-term liability in other liabilities.

Accretion of debt issuance cost and debt discount in connection with the Facility financing agreement during the three months ended March 31, 2016 and 2015 are as follows (in thousands):

	Three months ended March 31, 2016	Three months ended March 31, 2015
Accretion expense- debt issuance cost	$ 9	$ 9
Accretion expense- debt discount	$ 419	$ 364

The Facility Agreement contains a financial covenant that requires the Company s cash and cash equivalents, which include available borrowings under the Loan Arrangement, on the last day of each fiscal quarter to not be less than $25.0 million. The Company will need to raise additional capital to support its current operating plans. Due to the uncertainties related to maintaining

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sufficient resources to comply with the aforementioned covenant, the 2019 notes have been classified as current liabilities in the accompanying balance sheet as of March 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.

13. Subsequent Events

On April 26, 2016, MannKind Corporation (the Company) entered into an At Market Issuance Sales Agreement (the Sales Agreement) with FBR Capital Markets & Co. (FBR), pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50.0 million from time to time through FBR as its sales agent. The Company is not obligated to make any sales of common stock under the Sales Agreement.

The issuance and sale of the common stock by the Company under the Sales Agreement, if any, is subject to the continuing effectiveness of the Company s registration statement on Form S-3 (File No. 333-210792), filed with the Securities and Exchange Commission on April 18, 2016 (the Registration Statement). The Registration Statement became effective on April 27, 2016.

FBR may sell the common stock by any method that is deemed to be an at the market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on or through The NASDAQ Global Market or to or through a market maker. FBR may also sell the common stock in negotiated transactions, subject to our approval. Subject to the terms and conditions of the Sales Agreement, FBR will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the common stock from time to time, based upon the Company s instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose).

Unless earlier terminated as provided below, the Sales Agreement will automatically terminate upon the earlier of (1) the sale of all common stock subject to the Sales Agreement and (2) April 26, 2019. The Sales Agreement may be terminated by the Company or FBR at any time upon 10 days notice to the other party, or by FBR at any time in certain circumstances, including the occurrence of a material adverse change in the Company.

The Company will pay FBR an aggregate commission rate equal to up to 3.0% of the gross proceeds of the sales price per share for common stock sold through FBR under the Sales Agreement. The Company has also provided FBR with customary indemnification rights and expense reimbursements for up to $25,000 of expenses.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements in this report that are not strictly historical in nature are forward-looking statements within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as anticipate, believe, could, estimate, expect, goal, intend, may, plan, potential, predict, project, should, will, would, and similar expressions intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this quarterly report on Form 10-Q. The preceding interim condensed consolidated financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and related notes for the year ended December 31, 2015 and Management s Discussion and Analysis of Financial Condition and Results of Operations contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

OVERVIEW

We are a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes. 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.

As of March 31, 2016, we had an accumulated deficit of $2.9 billion and a stockholders deficit of $373.5 million. We have funded our operations primarily through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement, borrowings under The Mann Group Loan Arrangement, receipt of upfront and milestone payments under the Sanofi License Agreement and borrowings under the Sanofi Loan Facility to fund our portion of the loss share. As discussed below in Liquidity and Capital Resources , if we are unable to obtain additional funding, there will be substantial doubt about our ability to continue as a going concern.

During 2015 and the first quarter of 2016, all sales and marketing activities related to AFREZZA were conducted by Sanofi pursuant to the Sanofi License Agreement, and we were responsible for manufacturing AFREZZA to supply Sanofi s demand for the product pursuant to the Sanofi Supply Agreement.

On January 4, 2016 we received notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Pursuant to a transition agreement with Sanofi, all rights to AFREZZA transferred back to us on April 4, 2016 (the Termination Date), after which we assumed responsibility for the worldwide development and commercialization of AFREZZA. The transition is designed to ensure that patients will not experience any interruption in their treatment. Under terms of the transition agreement, Sanofi will continue to fulfill orders for AFREZZA until such time as Sanofi s inventory of usable product is depleted or until we provide Sanofi with written notice requesting that Sanofi cease such activities, but in any event no later than October 1, 2016.

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

RESEARCH AND DEVELOPMENT EXPENSES

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

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

GENERAL AND ADMINISTRATIVE EXPENSES

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

PRODUCT MANUFACTURING EXPENSES

Product manufacturing expenses represent under-absorbed labor and overhead, foreign currency exchange impact, and inventory write-offs, which are expensed in the period in which they are incurred rather than as a portion of the inventory cost.

CRITICAL ACCOUNTING POLICIES

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

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU 2014-09 related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard requires a company to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. We are assessing the potential impact of the new standards on our consolidated financial statements and have not yet selected a method of adoption.

In August 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. We are evaluating the impact the adoption of ASU 2014-15 will have on our consolidated financial statements. In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330, Inventory,

currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost. The amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We are evaluating the impact the adoption of ASU 2015-11 will have on our consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update is intended to improve the recognition and measurement of financial instruments. The ASU affects public and private companies, not-for-profit organizations, and employee benefit plans that hold financial assets or owe financial liabilities. The update is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are evaluating the impact the adoption of ASU 2016-01 will have on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. The adoption of this standard is not expected to have a material impact on our financial position. We are evaluating the impact the adoption of ASU 2016-02 will have on our consolidated financial statements.

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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 Update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We are evaluating the impact the adoption of ASU 2016-09 will have on our consolidated financial statements.

RESULTS OF OPERATIONS

Three months ended March 31, 2016 and 2015

Revenue

During the three months ended March 31, 2016 and 2015 we did not recognize any revenue. Due to the termination of the Sanofi License Agreement and based on our current operating plan, we expect to recognize, likely within 2016, $17.7 million as product sales from collaboration, $13.5 million as product costs from collaboration and income from collaboration related to upfront and milestone payments in excess of $100 million, which amounts are deferred as of March 31, 2016 due to the revenue recognition criteria not being met as of such date.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the three months ended March 31, 2016 and 2015 (dollars in thousands):

	Three months ended March 31,			
	2016	2015	$ Change	% Change
Clinical	$ 2,465	$ 3,826	$ (1,361)	(36%)
Manufacturing process development	1,519	3,405	(1,886)	(55%)
Research	642	1,403	(761)	(54%)
Research and development tax credit	(90)	(88)	(2)	2%
Stock-based compensation expense	594	831	(237)	(29%)
Research and development expenses	$ 5,130	$ 9,377	$ (4,247)	(45%)

The decrease in research and development expenses of $4.2 million for the three months ended March 31, 2016 compared to the three months ended March 31, 2015 was primarily due to a decrease of $1.9 million in manufacturing process development expenses and a $1.4 million decrease in clinical expenses as a result of the reduction in force and the closure of our Paramus, New Jersey facility in 2015. Research costs also decreased by $0.8 million compared to the same quarter of prior year due to lower research and development activities in the first quarter of 2016 and an up-front payment from Receptor Life Sciences in accordance with the license and collaboration agreement. Stock-based compensation declined by $0.2 million in 2016 compared to 2015 due to reduction in personnel in 2015.

We anticipate that our overall research and development expenses will decrease in 2016 compared to 2015 as a result of the restructuring in 2015 and due to the focus on the commercialization of AFREZZA for the remainder of 2016.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the three months ended March 31, 2016 and 2015 (dollars in thousands):

	Three months ended March 31,			
	2016	**2015**	**$ Change**	**% Change**
Salaries and employee related expenses	$ 2,193	$ 3,484	$ (1,291)	(37%)
Professional fees and other general expenses	4,479	5,823	(1,344)	(23%)
Stock-based compensation expense	679	1,172	(493)	(42%)
General and administrative expenses	$ 7,351	$ 10,479	$ (3,128)	(30%)

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The decrease in general and administrative expenses of $3.1 million for the three months ended March 31, 2016 compared to the three months ended March 31 2015 was primarily due to a $1.3 million decrease in salaries and personnel related expenses due to the reduction in force and closure of our Paramus, New Jersey facility in 2015 and a $1.3 million reduction in professional fees primarily due to a $1.0 million decrease in strategic planning activities performed in the first quarter of 2016 as compared to the first quarter of 2016. Stock compensation decreased by $0.5 million due to our decrease in personnel in 2015, which impacted the first quarter of 2016.

We expect general and administrative expenses to remain relatively flat in 2016 as compared to 2015 from the effects of the reduction in force and the closure of our Paramus, New Jersey facility in 2015. However, we expect sales and marketing expenses will increase in 2016 as we commercialize Afrezza.

Product Manufacturing

Product manufacturing expenses, which cannot be capitalized, were $7.5 million for the three months ended March 31, 2016 compared to the $1.9 million for the three months ended March 31, 2015, associated with AFREZZA product sales. The $5.6 million increase in product manufacturing expenses is due to $3.2 million in under-absorbed labor and overhead resulting from a lack of manufacturing in the first quarter of 2016 when compared to the increase in manufacturing in the first quarter of 2015 and a loss on foreign currency exchange of $2.4 million. Product manufacturing expenses represent under absorbed labor and overhead, which are expensed in the period in which they are incurred rather than as a portion of the inventory cost.

Although the Sanofi License Agreement terminated in the second quarter of 2016, we expect our 2016 production of AFREZZA to be relatively consistent with production levels in 2015, primarily as a result of existing customer demand. With the exception of the inventory write-off, we expect product manufacturing expenses to remain relatively flat in 2016 compared to 2015.

Other Income (Expense)

Other income decreased by $1.3 million for the three months ended March 31, 2016 compared to the three months ended March 31, 2015. The decrease for the three months ended March 31, 2016 is due to a non-recurring transaction of $1.4 million resulting from the relief of an accrual for potential expenses associated with the sale of intellectual property related to oncology in 2014, which was subsequently resolved without payment in the first quarter of 2015, offset by other income of $0.1 million for the three months ended March 31, 2016.

Interest Income and Expense

Interest expense decreased by $5.4 million for the three months ended March 31, 2016 compared to the three months ended March 31, 2015. The decrease was primarily driven by a non-recurring 2015 milestone payment of $5.8 million resulting from the achievement and re-measurement of the second milestone under the Milestone Agreement in the first quarter of 2015 and a decrease of $1.7 million in interest resulting from the settlement of the 2015 notes in the third quarter of 2015. The decrease was offset by an increase of $1.1 million interest expense associated with the Sanofi Loan Facility, $0.4 million interest expense related to the 2018 notes, and $0.3 million interest expense related to deferred payments to a supplier in 2016 and a decrease of $0.3 million in capitalized interest in 2016.

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, borrowings under the Facility Agreement with Deerfield,

receipt of upfront, milestone payments under the Sanofi License Agreement, and borrowings under the Sanofi Loan Facility.

As of March 31, 2016, we had $220.7 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;

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- $60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $5.0 million of which is due and payable in July 2016, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and $25.0 million of which is due and payable in July and December 2019;

- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, and $5.0 million of which is due and payable in December 2019;

- $49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at 5.84% and maturing and due on January 5, 2020; and

- $63.5 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

As of March 31, 2016, the amount available for future borrowings under The Mann Group Loan Arrangement was $30.1 million. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable. As of March 31, 2016, the accrued and unpaid interest under The Mann Group Loan Arrangement was $7.1 million.

As of March 31, 2016, all profits and losses from AFREZZA product sales by Sanofi or its affiliates after the Termination Date, if any, will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement through no later than October 1, 2016. Our total share of the net losses are $68.8 million, classified as Sanofi loan facility and loss share obligation, of which $63.5 million has been borrowed under the Sanofi Loan Facility. Subsequent to March 31, 2016, we borrowed an additional $5.3 million under the Sanofi Loan Facility to finance our share of the net losses for the first quarter of 2016, which was reclassified from current deferred payments from collaboration to Sanofi loan facility and loss share obligation, for a total of $68.8 million, which includes $2.8 million in paid-in-kind interest capitalized as additional principal. We will be required to make mandatory prepayments on any outstanding loans under the Sanofi Loan Facility from our share of any profits under the Sanofi License Agreement. Additionally, if we sell our Valencia facility, which we no longer use as our corporate headquarters, we will be required to prepay the loans under the Sanofi Loan Facility from the net cash proceeds of the sale within five business days of receipt.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2018 notes, 2019 notes, Tranche B notes, The Mann Group Loan Arrangement or Sanofi Loan Facility when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2018 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum, paid-in kind on a quarterly basis (2.06% per quarter

compounded). Loans under The Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum, due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group mutually agree. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2018 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or borrowings under The Mann Group Loan Arrangement or the Sanofi Loan Facility when required, we will be in default under the applicable instrument for such indebtedness, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

In connection with the execution of the Facility Agreement, on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures. We do not expect to pay any milestone payments in the next 12 months.

The Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires our cash and cash equivalents, which includes available borrowings under The Mann Group Loan Arrangement, on the last day of each fiscal quarter to not be less than $25.0 million. In the event of default under the Facility Agreement, the holders of the 2019 notes and Tranche B notes may declare all or any portion of the 2019 notes and Tranche B notes to be immediately due and payable. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain

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future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations.

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

On July 31, 2014, we entered into the Insulin Supply Agreement, pursuant to which we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019, for an aggregate total purchase price of approximately 120.1 million, of which 98.5 million is remaining at March 31, 2016. We have contracted for the purchase of 28.8 million in 2016 and the remaining annual minimum quantities will be 23.3 million for the years ended December 31, 2017 through 2019. Unless earlier terminated, the term of the Insulin Supply Agreement expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months written notice, given prior to the end of the initial term or any additional two year term. We and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, we may terminate the Insulin Supply Agreement upon two years prior written notice to Amphastar without cause or upon 30 days prior written notice to Amphastar if a controlling regulatory authority withdraws approval for AFREZZA, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require us to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination. Under the terms of the Sanofi Supply Agreement, in the event that Sanofi terminates the Sanofi License Agreement for various reasons (including the reasons cited in its notice of termination to the Company), then upon written notice from the Company within 30 days following the termination date, Sanofi is obligated to purchase up to $50 million of the Company s insulin inventory as a percentage of each lot received or receivable by the Company (the Insulin Put). On April 14, 2016, the Company provided Sanofi with written notice that it was exercising the Insulin Put. The Company and Sanofi are currently discussing the schedule of purchases and deliveries pursuant to the Insulin Put.

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

During the three months ended March 31, 2016, we used $30.8 million of cash for our operating activities as a result of our net loss of $24.9 million, adjusted by non-cash charges of $6.5 million and a net decrease in assets and liabilities of $12.4 million. The non-cash charges included $2.3 million of depreciation and accretion and stock-based compensation, a $2.4 million loss on foreign currency exchange, $1.2 million in interest accrued through borrowings under Sanofi Loan Facility, and $0.7 million of impairment charges. The change in net assets and liabilities was predominately due to the net decrease in accounts payable of $15.0 million offset by a decrease in prepaids and other current assets at March 31, 2016 compared to December 31, 2015.

During the three months ended March 31, 2015 cash provided by operations was $3.0 million as a result of our net loss of $30.7 million, adjusted by non-cash charges of $5.0 million and a net increase in assets and liabilities of $28.7 million. The non-cash charges included $5.0 million of depreciation and accretion and stock-based compensation. The change in net assets and liabilities was predominately due to a $50.0 million decrease in milestone receivable from Sanofi, earned as of December 31, 2014 and received in the first quarter 2015, offset by $5.8 million in interest expense associated with the achievement and payment of the second milestone to Deerfield for product launch on February 3, 2015 and decreases in accrued expenses primarily due to the $4.9 million inventory payment to Amphastar and a $2.9 million interest payment related to the 2015 notes.

We used $1.1 million of cash for investing activities during the three months ended March 31, 2016, compared to $4.2 million of cash for investing activities during the three months ended March 31, 2015. The $3.1 million decrease was due to a decrease in purchase of machinery and equipment in 2016 compared to 2015.

Our financing activities provided $0.5 million of cash for the three months ended March 31, 2016 from exercises of stock options, compared to $1.2 million for the three months ended March 31, 2015 from $6.2 million in warrant exercises and $4.2 million in stock option exercises, offset by a $4.2 million outflow associated with the achievement and payment of the second milestone to Deerfield for product launch on February 3, 2015 and a $0.8 million payment for employment taxes related to vested restricted stock units.

As of March 31, 2016, we had $27.7 million in cash and cash equivalents. We expect to expend our capital resources for the manufacturing, sales and marketing of AFREZZA subsequent to the termination with Sanofi and to develop our other product candidates. We also intend to use our capital resources for general corporate purposes.

If we enter into strategic business collaborations with respect to our other product candidates, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There

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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, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

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

Off-Balance Sheet Arrangements

As of March 31, 2016, we did not have any off-balance sheet arrangements.

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 months ended March 31, 2015 was a fixed rate equal to 5.84%. As of March 31, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million. We also have debt related to the 2018 notes at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75%, 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 March 31, 2016 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts.

Foreign Currency Exchange Risk

We incur and will continue to incur significant expenditures for insulin supply obligations under our supply agreement with Amphastar. Such obligations are denominated in euros. 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. During the three months ended March 31, 2016, we did not purchase any inventory and for the year ended December 31, 2016 we are required to purchase the minimum quarterly supply

purchases of insulin contemplated under our supply agreement with Amphastar. If a change in the U.S. dollar to euro exchange rate equal to 10% of the U.S. dollar to euro exchange rate on March 31, 2016 were to have occurred on March 31, 2016, this change would have resulted in a foreign currency impact to our pre-tax losses of approximately $11.2 million.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of March 31, 2016. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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As previously disclosed under Item 9A. Controls and Procedures in our Annual Report on Form 10-K for our fiscal year ended December 31, 2015, we concluded that our disclosure controls and procedures were not effective as of December 31, 2015 based on the material weakness identified. We did not maintain sufficient internal control over financial reporting due to the lack of operating effectiveness of our controls over the impairment testing that we performed in accordance with ASC 360-10, *Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories,* as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors, which management has determined constituted a material weakness.

Remediation generally requires making changes to how controls are designed and then adhering to those changes for a sufficient period of time such that the effectiveness of those changes is demonstrated with an appropriate amount of consistency. Although progress has been made through March 31, 2016 to remediate the material weakness discussed above, these enhanced controls have not yet been fully implemented or operating for a sufficient period of time to conclude they are operating effectively and we continue to improve our internal control processes, therefore the material weakness continues to exist.

Based on management s assessment, including consideration of the control deficiencies discussed above, management has concluded that the Company s disclosure controls and procedures were not effective as of March 31, 2016.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline of the price of our common stock, several complaints were filed in the U.S. District Court for the Central District of California against us and certain of our officers and directors on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been pled as putative shareholder class actions. In general, the complaints allege that we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking monetary damages and other relief. We expect the complaints to be transferred to a single court and consolidated for all purposes, following which the court would be expected to appoint a lead plaintiff and lead counsel and to order the lead plaintiff to file a consolidated complaint. We will vigorously defend against the claims advanced.

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline of the price of our common stock, two motions were submitted to the District Court at Tel Aviv (Economic Department) for the certification of a class action against us and certain of our officers and directors. In general, the complaints allege that we and certain of our officers and directors violated Israeli and US securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the

price of our common stock. The plaintiffs are seeking monetary damages. 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 with an asterisk (*) next to the title contain changes to the description of the risk factors previously disclosed in Item 1A to our 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 depend heavily on the successful commercialization of our only approved product, AFREZZA.**

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 ability to generate revenues will depend on the successful commercialization of AFREZZA and our ability to enter into licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us.

On February 3, 2015, AFREZZA became available by prescription in United States retail pharmacies. We must receive the necessary approvals from foreign regulatory agencies before AFREZZA can be marketed outside of the United States. Even with such regulatory approval, we ultimately may be unable to gain market acceptance of AFREZZA for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and lack of coverage or adequate reimbursement.

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On April 5, 2016, we assumed responsibility for the worldwide development and commercialization of AFREZZA from Sanofi and expect to begin distributing AFREZZA in the third quarter of 2016. Until that time, Sanofi will continue to distribute AFREZZA from its existing inventory of product, and all profits and losses from AFREZZA product sales by Sanofi or its affiliates will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement. We intend to continue the development and commercialization of AFREZZA in the United States on our own and to seek regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions where there are appropriate commercial opportunities. If we fail to commercialize AFREZZA successfully, our business, financial condition and results of operations will be materially and adversely affected.

*We may not be able to successfully develop and commercialize AFREZZA on our own in the United States or find regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions. The commercialization and development of AFREZZA will require substantial capital that we may not be able to obtain.**

Following the termination of the Sanofi License Agreement, we have assumed responsibility for commercializing and developing AFREZZA in the United States. We have no experience with commercializing AFREZZA and may not have sufficient resources to undertake and maintain such activities on our own. In order to commercialize AFREZZA in the United States, we will need to continue to build our commercialization capabilities, including sales and marketing capabilities, through hiring our own personnel or subcontracting to a commercial sales organization, or a combination of these. The market for skilled commercial personnel is highly competitive, and we may not be able to find and hire all of the personnel we need on a timely basis. We may engage in sales and marketing activities by subcontracting with a skilled commercial sales organization, though there are risks regarding whether a subcontractor will provide the level of effort and attention to AFREZZA necessary for successful commercialization. We are also responsible for negotiating and securing coverage and reimbursement for AFREZZA. If we are unable to obtain coverage of, and adequate payment levels for AFREZZA, physicians may limit how much or under what circumstances they will prescribe or administer AFREZZA and patients may decline to purchase AFREZZA, which would have an adverse effect on our ability to generate revenues. Building the internal infrastructure to further develop and commercialize AFREZZA will be costly and time-consuming, and may be distracting to management, and we may not be successful in our efforts or successful in obtaining financing to support those efforts.

As a result of the termination of the Sanofi License Agreement, we are also responsible for the NDA for AFREZZA and its maintenance. We have 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 ongoing or still 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.

We also intend to seek regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions where there are appropriate commercial opportunities. It may be difficult to find a new collaboration partner that is willing to devote the time and resources necessary to successfully commercialize AFREZZA. Collaborations with third parties may require us to relinquish material rights, including revenue from commercialization, on terms that are less attractive than our previous collaboration with Sanofi or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, especially in the current market, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of AFREZZA 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.

Our ability to successfully continue the development and commercialization of AFREZZA is also dependent upon the successful transition of AFREZZA to us from Sanofi. We and Sanofi are required to use diligent efforts to facilitate the smooth and orderly transition of relevant obligations and rights to us with respect to development and commercialization activities related to AFREZZA. During the transition period, we will be dependent on Sanofi to perform certain activities related to AFREZZA, which subjects us to a number of risks, including:

Sanofi may not perform as expected and we are not be able to control the amount and timing of resources that Sanofi devotes to the transition;

there may be disputes between us and Sanofi that may result in the delay of the achievement of regulatory and commercial objectives, or costly litigation or arbitration that diverts our management s attention and resources;

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the manner in which Sanofi effects the transition could adversely impact the development of or sales of AFREZZA and failure to comply with applicable regulatory guidelines could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;

business combinations or significant changes in Sanofi s business strategy or failure to apply financial and other resources to the transition may also adversely affect Sanofi s ability to perform its obligations; and

Sanofi may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

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

We have sought to develop our other product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all. Further research and development on these programs will require significant financial resources. Given our limited financial resources and our focus on development and commercialization of AFREZZA, we will not be able to advance these programs unless we are able to enter into collaborations with third parties to fund of these programs or to obtain funding to enable us to continue these programs.

A significant portion of the research that we have conducted involves new technologies, including our Technosphere platform technology. Even if our research programs identify product candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to develop and commercialize our other product candidates, or if we are significantly delayed in doing so, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.

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

We have never been profitable or generated positive cash flow from cumulative operations to date. Historically, we have reported negative cash flow from operations other than for the nine months ended September 30, 2014, for the year ended December 31, 2014, and for the three months ended March 31, 2015 as a result of our receipt of an upfront payment and milestone payments from Sanofi. As of March 31, 2016, we had an accumulated deficit of $2.9 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to continue the commercialization of AFREZZA. In connection with our quarterly assessment of impairment indicators and inventory valuation for the quarter ended December 31, 2015, we identified an impairment of our long-lived assets which resulted in charges of $140.4 million in such quarter. In addition, we have agreed to purchase annual minimum quantities of insulin for calendar years 2015 through 2019 under the Insulin Supply Agreement with Amphastar in the aggregate of approximately 120.1 million, of which 98.5 million is remaining at March 31, 2016. We are obligated to purchase 28.8 million in 2016 and the remaining

annual minimum quantities will be 23.3 million for the years ending December 31, 2017 through 2019. We may not have the necessary capital resources on hand in order to service this contractual commitment.

Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders equity. As of March 31, 2016, we had stockholders deficit of $373.5 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends heavily upon successfully commercializing AFREZZA, and we cannot be sure when, if ever, we will generate positive cash flow from operations or become profitable.

*We will need to raise additional capital to fund our operations, and our inability to do so could raise substantial doubt about our ability to continue as a going concern.**

We will need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities including the commercialization of AFREZZA and the development of other product candidates and to avoid defaulting under the covenant in the Facility Agreement with Deerfield, which requires us to maintain at least $25.0 million in cash and cash equivalents or available borrowings under The Mann Group Loan Arrangement

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as of the last day of each fiscal quarter. It may be difficult for us to raise additional funds on favorable terms, or at all. As of March 31, 2016, we had stockholders deficit of $373.5 million, which may raise concerns about our solvency and affect our ability to raise additional capital. The extent of our additional funding requirements will depend on a number of factors, including:

- the degree to which AFREZZA is commercially successful;
- the degree to which we are able to generate revenue from our Technosphere drug delivery platform;
- the costs of developing and commercializing AFREZZA on our own in the United States, including the costs of building our commercialization capabilities;
- the costs of finding regional collaboration partners for the development and commercialization of AFREZZA in foreign jurisdictions;
- the demand by any or all of the holders of the 2018 notes, the 2019 notes, and the Tranche B notes to require us to repay or repurchase such debt securities if and when required;
- our ability to repay or refinance existing indebtedness, and the extent to which the 2018 notes or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;
- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facilities;
- our obligation to make milestone payments pursuant to the Milestone Rights issued to the Milestone Purchasers and pursuant to the Milestone Rights Purchase Agreement dated July 1, 2013 (the Milestone Agreement);
- our obligation to bear our share of net losses, if any, if Sanofi makes any product sales under the Sanofi License Agreement after the Termination Date;
- our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;

actions taken by the FDA and other regulatory authorities affecting AFREZZA and our product candidates and competitive products;

the emergence of competing technologies and products and other market developments;

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;

the level of our legal and litigation expenses; and

the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

We have raised capital in the past through the sale of equity and debt securities and we may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities including asset-based borrowings. There can be no assurances, however, that we will be able to raise additional capital on acceptable terms, or at all. Issuances of additional debt or equity securities or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and will dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also will need to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. As of the date hereof, we have not obtained a solvency opinion or

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otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, holders of our common stock or other securities may lose the entire value of their investment.

We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we will be required to raise additional capital. There can be no assurances that we will be able to raise additional capital on favorable terms, or at all. If we are unable to raise adequate additional capital we will be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

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

As of March 31, 2016, we had $220.7 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;
- $60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $5.0 million of which is due and payable in July 2016, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and $25.0 million of which is due and payable in July and December 2019;
- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, the balance of which is due and payable in December 2019;
- $49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement, bearing interest at 5.84% and maturing and due on January 5, 2020; and
- $63.5 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

We may borrow an additional $30.1 million under The Mann Group Loan Arrangement. The available borrowings may be used to capitalize accrued interest into principal upon mutual agreement of the parties, as accrued interest becomes due and payable under The Mann Group Loan Arrangement. As of March 31, 2016 the accrued and unpaid interest under The Mann Group Loan Arrangement was $7.1 million.

All profits and losses from AFREZZA product sales by Sanofi or its affiliates, if any, will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement, and we may borrow up to an aggregate of $175.0 million pursuant to the Sanofi Loan Facility to fund our share of net losses from AFREZZA product sales by Sanofi or its affiliates. Our total share of the net losses are $68.8 million as of March 31, 2016, classified as Sanofi loan facility and loss share obligation, and such amount has been borrowed under the Sanofi Loan Facility as of March 31, 2016.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2018 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum, paid-in-kind on a quarterly basis (2.06% per quarter compounded). Loans under The Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum, due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group mutually agree. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2018 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or the loans under The Mann Group Loan Arrangement Sanofi Loan Facility when required, we will be in default under the instrument for such debt securities or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

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

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

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

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

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

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

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If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical studies and the submission of regulatory filings. From time to time, we publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of the achievement of these milestones can vary dramatically from our estimates, in many cases for reasons beyond our control, depending on numerous factors, including:

- the rate of progress, costs and results of our clinical studies and preclinical research and development activities;
- our ability to identify and enroll patients who meet clinical study eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent to which our clinical studies compete for clinical sites and eligible subjects with clinical studies sponsored by other companies; and
- actions by regulators.

In addition, if we do not obtain sufficient additional funds through sales of securities, strategic collaborations or the license or sale of certain of our assets on a timely basis, we may be required to reduce expenses by delaying, reducing or curtailing our development of product candidates. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development goals in the timeframes we expect (or within the timeframes expected by analysts or investors), our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities may decline.

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

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

The rapid rate of scientific discoveries and technological changes could result in AFREZZA or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology or AFREZZA less competitive, uneconomical or obsolete. Our future success will depend not only on our ability to develop our product candidates but to improve them and keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

We also expect to face competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in various areas of unmet medical need. These institutions are becoming increasingly aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

*Continued testing of AFREZZA or our product candidates may not yield successful results, and even if it does, we may still be unable to commercialize our product candidates.**

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical studies or in much larger populations may not be consistent with the earlier clinical results. For example, with the approval of AFREZZA, the FDA has required a five-year, randomized, controlled trial in 8,000 10,000 patients with type 2 diabetes, the primary objective of which is to compare the incidence of pulmonary malignancy observed with AFREZZA to that observed in a standard of care control group. If long-term use of a drug results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our or any future marketing partner s ability to market and sell the drug, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical studies, which may be time-consuming and expensive and may not produce favorable results.

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Our research and development programs are designed to test the safety and efficacy of our product candidates through extensive nonclinical and clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or impact commercialization of any of our product candidates, including the following:

- safety and efficacy results obtained in our nonclinical and early clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing a product candidate or alter the marketing of an approved product;

- the analysis of data collected from clinical studies of our product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;

- after reviewing clinical data, we or any collaborators may abandon projects that we previously believed were promising; and

- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use once approved.

As a result of any of these events, we, any collaborator, the FDA, or any other regulatory authorities, may suspend or terminate clinical studies or marketing of the drug at any time. Any suspension or termination of our clinical studies or marketing activities may harm our business, financial condition and results of operations and the market price of our common stock and other securities may decline.

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

For the commercial manufacture of AFREZZA, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for AFREZZA is manufactured by Amphastar and the only source of our proprietary inert excipient, FDKP (fumaryl diketopiperazine), which is the primary component of our Technosphere technology platform, is manufactured by Lonza. 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 cGMPs 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 or Lonza ceases to manufacture or is otherwise unable to deliver insulin for AFREZZA or FDKP, respectively, we will need to locate an alternative source of supply and the production of AFREZZA may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business,

financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

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

We use our Danbury, Connecticut facility to formulate AFREZZA inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We utilize a contract packager to assemble the final kits of foil-pouched blisters containing cartridges along with inhalers and the package insert. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to obtain sufficient quantities for the commercialization of AFREZZA at the costs that we currently anticipate. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of the product or any raw material on a timely basis, and at commercially reasonable prices, sustainable compliance and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for AFREZZA and we would lose potential revenues.

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*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 get approved may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals

to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of AFREZZA or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future marketing partner for AFREZZA, and companies that are prospective collaborators for our product candidates, our ability to commercialize AFREZZA and our product candidates under development may be adversely affected.

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of coverage and adequate reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for AFREZZA and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the

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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;

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

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

- a licensure framework for follow-on biological products;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare

Part D;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

new requirements to report annually to the Centers for Medicare & Medicaid Services (CMS) certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payments or transfers of value made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year;

a new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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

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

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

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

- federal civil and criminal false claims laws, including without limitation the civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal

healthcare programs that are false or fraudulent and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;

HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by HITECH and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that AFREZZA or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may be subject to similar foreign laws

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and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If 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 our other 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. However, 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 be able to obtain sufficient coverage at an acceptable cost, if at all. If losses from such claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities may decline.

If we lose any key employees or scientific advisors, our operations and our ability to execute our business strategy could be materially harmed.

We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all. In addition, in order to commercialize AFREZZA successfully, we may be required to expand our work force, particularly in the areas of manufacturing and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel on acceptable terms, if at all.

The loss of the services of any principal member of our management and scientific staff could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are at will and we currently do not have employment agreements with any of the principal members of our management or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

We have relationships with scientific advisors at academic and other institutions to conduct research or assist us in formulating our research, development or clinical strategy. These scientific advisors are not our employees and may have commitments to, and other obligations with, other entities that may limit their availability to us. We have limited control over the activities of these scientific advisors and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our programs could

harm our business. In addition, these advisors are not prohibited from, and may have arrangements with, other companies to assist those companies in developing technologies that may compete with AFREZZA or our product candidates.

*If our internal controls over financial reporting are not considered effective, our business, financial condition and market price of our common stock and other securities could be adversely affected. **

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, our internal controls over financial reporting.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated

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goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. In connection with the audit of our financial statements for the year ended December 31, 2015, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we identified related to impairment testing that we performed in accordance with ASC 360-10, *Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories*, as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors. As a result of this material weakness, we and our independent registered public accounting firm evaluated our internal control over financial reporting as ineffective.

We are taking steps to remediate the material weakness in our internal control over financial reporting, including designing additional training programs for relevant personnel and developing specific review procedures regarding the review of the impairment of assets. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all. If we are unable to successfully remediate our material weakness, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. These activities may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we undertake will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If we undertake any internal restructuring activities and fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

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

Several complaints were filed in the U.S. District Court for the Central District of California against us and certain of our officers and directors on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been pled as putative shareholder class actions. In general, the complaints allege that we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of our common stock. We and certain of our directors and executive officers have also been named in similar lawsuits filed in Israel. We intend to vigorously defend against these claims. If we are not successful in our defense, we could be forced to make significant payments to or other settlements with our stockholders and their

lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management s attention and resources, which could have a material adverse effect on our business, operating results and financial condition.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

We expect that at least for the foreseeable future, our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of AFREZZA. This facility and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in other countries. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, volcanic eruptions, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. We might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs or cause interruptions in our commercialization of AFREZZA.

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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.

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

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product candidates for commercial sale. The data collected from our clinical studies may not be sufficient to support regulatory approval of our product candidates. Even if we believe the data collected from our clinical studies are sufficient, regulatory agencies have substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

Questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by regulatory agencies in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined or forced to remove a product from the market, subject to criminal prosecution, or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval.

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies. For example, the FDA required the following post-marketing studies for AFREZZA that remain to be completed:

- a clinical trial to evaluate pharmacokinetics, safety and efficacy in pediatric patients; and
- a clinical trial to evaluate the potential risk of pulmonary malignancy with AFREZZA (as well as cardiovascular risk and the long-term effect of AFREZZA on pulmonary function).

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 AFFREZZA and any approved drug product to extensive and ongoing regulatory requirements concerning the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;

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refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;

product seizure or detention, or refusal to permit the import or export of our product candidates; and

injunctions or the imposition of civil or criminal penalties.

The FDA s and other regulatory authorities policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

*Our suppliers are subject to FDA inspection.**

We depend on suppliers for insulin and other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements and is subject to inspection by the FDA. Although we conduct our own inspections and review and/or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

If we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier s ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and commercialization of AFREZZA.

Reports of side effects or safety concerns in related technology fields or in other companies clinical studies could delay or prevent us from obtaining regulatory approval for our product candidates or negatively impact public perception of AFREZZA or any other products we may develop.

At present, there are a number of clinical studies being conducted by other pharmaceutical companies involving insulin delivery systems. If other pharmaceutical companies announce that they observed frequent adverse events in their studies involving insulin therapies, we may be subject to class warnings in the label for AFREZZA. In addition, the public perception of AFREZZA might be adversely affected, which could harm our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline, even if the concern relates to another company s products or product candidates.

There are also a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical studies could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline.

RISKS RELATED TO INTELLECTUAL PROPERTY

*If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably.**

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets and confidentiality agreements. We own a number of domestic and international patents, have a number of domestic and international patent applications pending and have licenses to additional patents. We cannot assure you that our patents and licenses will successfully preclude others from using our technologies, and we could incur substantial costs in seeking enforcement of our proprietary rights against infringement. Even if issued, the patents may not give us an advantage over competitors with alternative technologies.

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for AFREZZA inhalation powder have terms extending into 2020, 2026, 2028, 2029, and 2030. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 and 2032, and we have method of treatment claims that extend into 2026 and 2029. As and when these different patents expire, AFREZZA could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

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Moreover, 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 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, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first 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 effects of these changes are currently unclear as the United States Patent and Trademark Office, or USPTO, must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, patent law continues to evolve. Several further changes to patent law are before Congress. The United States Supreme Court has exhibited an increased interest in patent law and several of its recent decisions have tended to narrow the scope of patentable subject matter related to medical products and methods. For example, in March 2014 the USPTO, in response to Supreme Court decisions, issued new examination guidelines which call into question the patentability of biological inventions that had previously been considered patentable. While none of this has an immediately apparent impact on our core technology and patents, the full and ultimate effect of these developments is not yet known. We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that our inventions and assignment agreements and our confidentiality agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

If we become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, we would be required to devote substantial time and resources to prosecute or defend such proceedings.

Competitors may infringe our patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. A court may also decide to award us a royalty from an infringing party instead of issuing an injunction against the infringing activity. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the USPTO, may be necessary to determine the priority of inventions with respect to our 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) has resulted in a higher rate of claim invalidation as compared to re-examination, due in part to the much reduced opportunity to repair claims by amendment. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. Litigation, post-grant review, or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. 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. We may not prevail in any litigation, post-grant review, or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

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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 were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially

affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock and other securities may decline.

In addition, patent litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline.

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We may not obtain trademark registrations for our potential trade names.

We have not selected trade names for some of our product candidates; therefore, we have not filed trademark registrations for such potential trade names for our product candidates, nor can we assure that we will be granted registration of any potential trade names for which we do file. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere, or once registered that, prior to our being able to enter a particular market, they will not be cancelled for non-use. Nor can we give assurances, that the use of any of our trademarks will confer a competitive advantage in the marketplace.

Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

*We may not be able to generate sufficient cash to service all of our indebtedness. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.**

Our ability to make scheduled payments on or to refinance our debt obligations will depend on our financial and operating performance, which is subject to the commercial success of AFREZZA, the extent to which we are able to successfully develop and commercialize our Technosphere drug delivery platform and any other product candidates that we develop, prevailing economic and competitive conditions, and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due.

*Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and adversely impact the market price of our common stock and other securities.**

If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities. Any such sales of our common stock in the public market may affect the price of our common stock or the market price of our other securities.

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for: issuance upon the exercise of stock options and the vesting of restricted stock unit awards; the purchase of shares of common stock under our employee stock purchase program; and the issuance of shares upon exchange or conversion of the 2018 notes or any other convertible debt we may issue. We

cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

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

At March 31, 2016, the estate of Alfred E. Mann beneficially owned approximately 35.7% of our outstanding shares of capital stock, including shares held in the Alfred E. Mann Living Trust, Mann Group LLC, Mannco LLC, Biomed Partners, LLC and Biomed Partners II, LLC (collectively, the Mann Affiliated Entities).

Mr. Mann passed away on February 25, 2016. All of the shares beneficially owned by Mr. Mann in the Alfred E. Mann Living Trust, The Mann Group LLC and Mannco LLC are controlled by a trust during the period of administration of Mr. Mann s estate. The trustees of the administrative trust are Mr. Mann s wife and two other trustees. The trustees have the power to sell the shares or deal with them as an owner. Relatives and other individuals may receive bequests of shares under Mr. Mann s trust. The residuary beneficiary of the trust is the Alfred E. Mann Family Foundation, a charitable organization under section 501(c)(3) of the Internal Revenue Code that is a private foundation under section 509 of the Code. The same three trustees control the Alfred E. Mann Family Foundation. The Alfred E. Mann Family Foundation will have the power to sell the shares or deal with them as an owner. If not sold by the trust, the shares owned by the trust may be distributed to one or more of the individual or charitable beneficiaries of the trust.

The managing members of Biomed Partners, LLC and Biomed Partners II, LLC are now controlled by trusts for which the same individuals described above are the trustees. Biomed Partners, LLC and Biomed Partners II, LLC will have the power to sell the shares or deal with them as an owner.

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

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

Since January 1, 2013, our closing stock price as reported on The NASDAQ Global Market has ranged from $0.66 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 develop and commercialize AFREZZA on our own in the United States;

our ability to find collaboration partners for the development and commercialization of AFREZZA in foreign jurisdictions;

the progress of the commercial launch of AFREZZA and other events or circumstances that we or others estimate will impact the future commercialization of AFREZZA;

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

our ability to successful commercialize our Technosphere drug delivery platform;

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the progress of preclinical and clinical studies of our product candidates and the 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;

the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; and

discussion of AFREZZA, our other product candidates, competitors products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.

Any of these risks, as well as other factors, could cause the market value of our common stock and other securities to decline.

*If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from The NASDAQ Global Market, which could have an adverse impact on the liquidity and market price of our common stock.**

Our common stock is currently listed on The NASDAQ Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the NASDAQ listing requirements in the future, including, for example, if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, NASDAQ could determine to delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. A delisting of our common stock could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence in our company.

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.

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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 May 2, 2016, we had 429,161,347 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock and other securities may decline. Likewise the issuance of additional shares of our common stock upon the exchange or conversion of some or all of our 2018 notes or upon the exercise of outstanding warrants, could adversely affect the market price of our common stock and other securities. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities.

In addition, we will need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities or additional convertible debt, the market price of our common stock and other securities may decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We are incorporated in Delaware. Certain anti-takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders or the holders of our other securities. Our anti-takeover provisions include provisions such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on any investment in our common stock.

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Pursuant to the Facility Agreement, we are subject to contractual restrictions on the payment of dividends. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of any investment in our common stock.

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

Our amended and restated certificate of incorporation currently authorizes us to issue up to 550,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of May 2, 2016, we had a total of 120,838,653 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, our equity plans and our 2018 notes. As described in our definitive Proxy Statement for our 2016 Annual Meeting of Stockholders filed with the SEC on April 21, 2016, we are presenting a proposal for stockholder vote during the 2016 Annual Meeting to approve an amendment to our amended and restated certificate of incorporation to increase the authorized number of shares of common stock from 550,000,000 to 700,000,000 shares. There is no guarantee that this proposal will be approved by our stockholders. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our amended and restated certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), originally filed with the SEC on August 9, 2007).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Quarterly report on Form 10-Q (File No. 000-50865), originally filed with the SEC on August 2, 2010).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on May 22, 2012).

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Exhibit Number	Description of Document
3.5	Amended and Restated Bylaws (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on November 19, 2007).
4.1	Form of common stock certificate (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 18, 2013).
4.2	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.3	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 3, 2014).
4.4	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).
4.5	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.6	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.7	Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.8	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 3, 2014).
4.9	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).
4.10	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind Corporation and Aventisub LLC (incorporated by reference to Exhibit 99.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.11	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind Corporation, MannKind LLC and Aventisub LLC (incorporated by reference to Exhibit 99.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.12	

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).

4.13 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).

4.14 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).

10.1+ Separation Agreement, dated March 11, 2016, by and between MannKind and Juergen Martens (incorporated by reference to Exhibit 10.8 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).

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Exhibit

Number	Description of Document
10.2+	Offer Letter, dated March 9, 2016, by and between MannKind and Michael Castagna (incorporated by reference to Exhibit 10.38 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
10.3	At Market Issuance Sales Agreement, by and between MannKind and FBR Capital Markets & Co., dated April 26, 2016 (incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on April 26, 2016).
31	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

+ Indicates management contract

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SIGNATURE

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

Dated: May 9, 2016

MANNKIND CORPORATION

By: /s/ MATTHEW J. PFEFFER
Matthew J. Pfeffer
Chief Executive Officer and Chief Financial Officer

(Principal Financial and Accounting Officer)