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

Form 10-Q

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

For the quarterly period ended June 30, 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
*(State or other jurisdiction of
incorporation or organization)*

13-3607736
*(I.R.S. Employer
Identification No.)*

25134 Rye Canyon Loop Suite 300
Valencia, California
(Address of principal executive offices)

91355
(Zip Code)

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

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

As of August 1, 2016, there were 478,048,448 shares of the registrant's common stock, \$0.01 par value per share, outstanding.

MANKIND CORPORATION
Form 10-Q
For the Quarterly Period Ended June 30, 2016
TABLE OF CONTENTS

	<u>Page</u>
PART I: FINANCIAL INFORMATION	
Item 1. Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets: June 30, 2016 and December 31, 2015	2
Condensed Consolidated Statements of Operations: Three and six months ended June 30, 2016 and 2015	3
Condensed Consolidated Statements of Comprehensive Loss: Three and six months ended June 30, 2016 and 2015	4
Condensed Consolidated Statements of Cash Flows: Six months ended June 30, 2016 and 2015	5
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3. Quantitative and Qualitative Disclosures About Market Risk	25
Item 4. Controls and Procedures	25
PART II: OTHER INFORMATION	
Item 1. Legal Proceedings	26
Item 1A. Risk Factors	26
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	48
Item 3. Defaults Upon Senior Securities	48
Item 4. Mine Safety Disclosures	48
Item 5. Other Information	48
Item 6. Exhibits	48
SIGNATURES	51

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

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 63,733	\$ 59,074
Receivables from collaboration	—	23
Inventory	2,866	—
Deferred costs from collaboration	22,742	13,539
Prepaid expenses and other current assets	1,423	4,018
Total current assets	90,764	76,654
Property and equipment — net	47,422	48,749
Other assets	1,248	1,009
Total assets	<u>\$ 139,434</u>	<u>\$ 126,412</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,849	\$ 15,599
Accrued expenses and other current liabilities	10,252	7,929
Facility financing obligation	75,452	74,582
Deferred sales from collaboration	26,882	17,503
Deferred payments from collaboration	135,229	140,231
Purchase commitment loss — current	20,986	12,475
Warrant liability	18,056	—
Total current liabilities	289,706	268,319
Note payable to principal stockholder	49,521	49,521
Sanofi loan facility and profit/loss share obligation	69,978	62,371
Senior convertible notes	27,623	27,613
Non-current purchase commitment loss	52,515	53,692
Other liabilities	16,668	15,225
Total liabilities	<u>506,011</u>	<u>476,741</u>
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2016 and December 31, 2015	—	—
Common stock, \$0.01 par value — 700,000,000 and 550,000,000 shares authorized at June 30, 2016 and December 31, 2015, respectively; 477,741,850 and 428,670,943 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	4,777	4,287
Additional paid-in capital	2,546,727	2,508,633
Accumulated other comprehensive loss	(21)	(20)
Accumulated deficit	(2,918,060)	(2,863,229)
Total stockholders' deficit	<u>(366,577)</u>	<u>(350,329)</u>
Total	<u>\$ 139,434</u>	<u>\$ 126,412</u>

See notes to condensed consolidated financial statements.

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,310	7,737	9,440	17,115
Selling, general and administrative	11,110	10,623	18,460	21,102
Product manufacturing	3,704	5,691	11,236	7,573
Total operating expenses	19,124	24,051	39,136	45,790
Loss from operations	(19,124)	(24,051)	(39,136)	(45,790)
Other (expense) income	(5,959)	(10)	(5,892)	1,403
Interest expense on note payable to principal stockholder	(721)	(721)	(1,443)	(1,435)
Interest expense on notes	(4,181)	(4,131)	(8,401)	(13,753)
Interest income	26	3	41	6
Net loss	<u>\$ (29,959)</u>	<u>\$ (28,910)</u>	<u>\$ (54,831)</u>	<u>\$ (59,569)</u>
Net loss per share — basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>	<u>\$ (0.12)</u>	<u>\$ (0.15)</u>
Shares used to compute basic and diluted net loss per share	<u>455,305</u>	<u>401,018</u>	<u>442,082</u>	<u>399,972</u>

See notes to condensed consolidated financial statements.

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

	<u>Three months ended</u>		<u>Six months ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Net loss	\$(29,959)	\$(28,910)	\$(54,831)	\$(59,569)
Other comprehensive loss:				
Cumulative translation (loss) gain	(2)	1	(1)	(6)
Other comprehensive (loss) gain	(2)	1	(1)	(6)
Comprehensive loss	<u>\$(29,961)</u>	<u>\$(28,909)</u>	<u>\$(54,832)</u>	<u>\$(59,575)</u>

See notes to condensed consolidated financial statements.

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

	Six months ended	
	June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(54,831)	\$ (59,569)
Adjustments to reconcile net loss to net cash provided by (used) in operating activities:		
Depreciation and accretion	2,058	6,359
Stock-based compensation expense	2,628	3,778
Interest incurred through borrowings under Sanofi Loan Facility	2,604	265
Loss on disposal of property and equipment	—	12
Loss on foreign currency exchange	2,023	—
Warrant fair value adjustment	5,306	—
Warrant issuance cost	653	—
Interest on note payable to principal stockholder	1,443	1,435
Other, net	717	(6)
Changes in assets and liabilities:		
Inventory	(2,866)	(10,146)
Receivables from Collaboration	23	45,688
Prepaid expenses and other current assets	2,595	6,130
Deferred costs from collaboration	—	(10,831)
Other assets	(238)	(866)
Accounts payable	(12,532)	(2,236)
Accrued expenses and other current liabilities	2,663	(7,800)
Deferred sales from collaboration	9,379	12,968
Purchase commitment loss - current	8,312	—
Non-current purchase commitment loss	(12,204)	—
Other liabilities	—	30
Net cash used in operating activities	<u>(42,267)</u>	<u>(14,789)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,144)	(8,737)
Proceeds from sale of property and equipment	17	—
Net cash used in investing activities	<u>(1,127)</u>	<u>(8,737)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	734	12,820
Proceeds from direct placement	50,000	—
Issuance costs associated with the direct placement	(2,678)	—
Milestone payment	—	(4,220)
Other	—	40
Proceeds from issuance of common stock pursuant to ATM issuance	—	2,050
Payment of employment taxes related to vested restricted stock units	(3)	(818)
Net cash provided by financing activities	<u>48,053</u>	<u>9,872</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	\$ 4,659	\$ (13,654)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	59,074	120,841
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 63,733</u>	<u>\$ 107,187</u>
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	4,608	6,644
Non-cash construction in progress and property and equipment	—	623
Reclassification of deferred payments from collaboration to Sanofi Loan Facility and loss share obligation	5,003	—
Reclassification of deferred costs from loss on purchase commitment to deferred costs from collaboration	9,202	—

See notes to condensed consolidated financial statements.

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

1. Description of business and basis of presentation

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

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and six months ended June 30, 2016 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets and deferred 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) inhalation powder, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the “FDA”) on June 27, 2014 to improve glycemic control in adult patients with diabetes.

Basis of Presentation — The Company’s primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, raising capital, and commercial manufacturing. In addition, the Company recently commenced commercial sales and marketing activities related to Afrezza. It is costly to develop and conduct clinical studies for therapeutic products, as well as to establish and maintain commercial sales and marketing capabilities. As of June 30, 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”).

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

At June 30, 2016, the Company’s capital resources consisted of cash and cash equivalents of \$63.7 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 (see Note 13 — Facility Agreement) requires the Company to maintain at least \$25.0 million in cash and cash equivalents or available borrowings under the loan arrangement, dated as of October 2, 2007, between The Company and The Mann Group LLC (as amended, restated, or otherwise modified as of the date hereof, “The Mann Group Loan Arrangement”), as of the last day of each fiscal quarter. 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.

[Table of Contents](#)

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

The Sanofi License Agreement and Sanofi Supply Agreement terminated, effective April 4, 2016, following which the Company assumed responsibility for the worldwide development and commercialization of Afrezza from Sanofi. Under the terms of the transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until the Company began distributing MannKind-branded product to major wholesalers during the week of July 25, 2016. The Company expects to commence recognition, likely within the third quarter of 2016, the deferred sales from collaboration, deferred costs from collaboration, and deferred payments from collaboration deferred as of June 30, 2016, as a result of the termination of the transition agreement.

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 5 — Related-party arrangements). The Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company is seeking and will need to raise additional capital, whether through a sale of equity or debt securities, a strategic business collaboration with a pharmaceutical company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the development and commercialization of Afrezza and 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.

Certain prior year balances in the Statement of Cash Flows have been reclassified to conform to current year presentation. Specifically Interest incurred through borrowing under Sanofi Loan Facility and interest on note payable to principal stockholder have been reclassified from Accrued and other current liabilities and Other liabilities, respectively.

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 8 – Fair Value of Financial Instruments.

Deferred costs from collaboration — Deferred costs from collaboration represent the costs of product manufactured and sold to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi. Such costs are deferred to the extent they are deemed recoverable through the recognition of future revenue associated with the collaboration and will be amortized as the associated revenue is recognized.

Loss on purchase commitments — The Company assesses whether losses on long term purchase commitments should be accrued. Losses that are expected to arise from firm, non-cancellable, commitments for the future purchases of inventory items are recognized unless recoverable through firm sales contracts. When making the assessment, the Company considers whether it is able to renegotiate with its vendors and considering the Company’s lower of cost or market analysis.

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

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

In May 2014, the FASB issued ASU No. 2014-09 related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard requires a company to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus

[Table of Contents](#)

Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. The Company is assessing the potential impact of the new standards on its consolidated financial statements and has not yet selected a method of adoption.

In August 2014, the FASB issued ASU No. 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. The Company is evaluating the impact the adoption of ASU No. 2014-15 will have on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments 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 No. 2015-11 will have on its consolidated financial statements.

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

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

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

2. Inventories

Inventories consist of the following (in thousands):

	June 30, 2016	December 31, 2015
Raw materials	\$ 1,491	\$ —
Work-in-process	1,155	—
Finished goods	220	—
Total Inventory	<u>\$ 2,866</u>	<u>\$ —</u>

[Table of Contents](#)

3. Property and equipment

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

	Estimated Useful Life (Years)	June 30, 2016	December 31, 2015
Land	—	\$ 3,435	\$ 3,435
Buildings	39-40	21,590	21,590
Building improvements	5-40	60,584	60,584
Machinery and equipment	3-15	67,761	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		437	586
		167,440	168,262
Less accumulated depreciation and amortization		(120,018)	(119,513)
Property and equipment — net		\$ 47,422	\$ 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 and six months ended June 30, 2016 and 2015 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Depreciation and amortization expense	\$ 589	\$ 2,740	\$1,179	\$5,117

4. Accrued expenses and other current liabilities

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

	June 30, 2016	December 31, 2015
Salary and related expenses	\$ 6,536	\$ 5,662
Accrued interest	602	615
Construction in progress	—	238
Other	3,114	1,414
Accrued expenses and other current liabilities	\$10,252	\$ 7,929

5. Related-party arrangements

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

[Table of Contents](#)

As of June 30, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was \$49.5 million, and the amount available for future borrowings was \$30.1 million. Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized as additional borrowings at any time and would be classified as non-current upon mutual agreement of both parties. As of June 30, 2016, the Company had accrued \$7.8 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 six months ended June 30, 2016, there were no additional borrowings under or amendments to The Mann Group Loan Arrangement.

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

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

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Lease payments	<u>\$ 67</u>	<u>\$ 65</u>	<u>\$ 133</u>	<u>\$ 65</u>

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

6. Senior convertible notes

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

	June 30, 2016	December 31, 2015
Senior Convertible notes		
Principal amount	\$27,690	\$ 27,690
Unamortized premium	545	660
Unaccreted debt issuance costs	(612)	(737)
Net carrying amount	<u>\$27,623</u>	<u>\$ 27,613</u>

Issuance of 5.75% Senior Convertible Subordinated Exchange Notes due 2018

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

[Table of Contents](#)

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

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

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

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

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

Accretion of debt issuance expense in connection with the 2018 notes during the three and six months ended June 30, 2016 were \$64,000 and \$126,000, respectively, and there was no accretion of debt issuance expense in connection with the 2018 notes during the three and six months ended June 30, 2015.

7. 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. Under terms of the transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until the Company began distributing MannKind-branded product to major wholesalers during the week of July 25, 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

[Table of Contents](#)

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 June 30, 2016 the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the profit and 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 June 30, 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 June 30, 2016 the Company has recorded \$26.9 million in Afrezza product shipments to Sanofi recorded as deferred sales from collaboration and recorded \$22.7 million as deferred costs from collaboration. Deferred costs represent the costs directly related to the collaboration, not to exceed the amount of deferred sales, for which recognition of revenue has been deferred. During the quarter ended June 30, 2016, the Company's portion of the profit sharing was \$0.3 million, which resulted in the reclassification from current deferred payments from collaboration to Sanofi loan facility and profit/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.

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 \$17.6 million as of June 30, 2016.

Advances under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum and are payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. The Company is required to make mandatory prepayments on the outstanding loans under the Sanofi Loan Facility from its share of any profits (as defined in the Sanofi License Agreement) under the Sanofi License Agreement within 30 days of receipt of its share of any such profits. No advances may be made under the Sanofi Loan 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 \$70.0 million, of which \$70.3 million was borrowed under the Sanofi Loan Facility as of June 30, 2016. For the three months ended June 30, 2016, the Company's portion of the profit sharing was \$0.3 million under

[Table of Contents](#)

the Sanofi License Agreement, which is required to be applied as a prepayment against the balance owed under the Sanofi Loan Facility. The total amount owed to Sanofi is \$70.0 million, which includes \$4.3 million in paid-in-kind interest capitalized as principal.

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

8. Fair Value of Financial Instruments

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

Level 1— Quoted prices for identical instruments in active markets.

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

Level 3— Significant inputs to the valuation model are unobservable.

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

Cash 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 June 30, 2016 and December 31, 2015, the Company held \$63.7 million and \$59.1 million, respectively, of cash and cash equivalents, consisting primarily of money market funds of \$56.8 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.

[Table of Contents](#)

Financial liabilities

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

	As of June 30, 2016			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Senior convertible notes	\$ —	\$ —	\$ 21.8	\$ 21.8
Facility financing obligation	—	—	79.9	79.9
Milestone rights	—	—	15.6	15.6
Sanofi Loan Facility	—	—	62.0	62.0
Warrant liability	—	—	18.1	18.1
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$197.4</u>	<u>\$197.4</u>

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial liabilities:				
Senior convertible notes	\$ —	\$ —	\$ 21.3	\$ 21.3
Facility financing obligation	—	—	78.4	78.4
Milestone rights	—	—	14.4	14.4
Sanofi Loan Facility	—	—	36.5	36.8
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$150.6</u>	<u>\$150.6</u>

Senior convertible notes

The estimated fair value of the 2018 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company's stock price and yields on U.S. Treasury notes and actively traded bonds, and non-observable, such as the Company's longer-term historical volatility, and estimated yields implied from any available market trades of the Company's issued debt instruments. As there is no current active and observable market for the 2018 notes, the Company determined the estimated fair value using a convertible bond valuation model within a lattice framework. The convertible bond valuation model combined expected cash flows based on terms of the notes with market-based assumptions regarding risk-free rate, risk-adjusted yields (20%), stock price volatility (87.5%) and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible (Level 3 in the fair value hierarchy).

Facility Agreement

As discussed in Note 13 — Facility Agreement, 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 June 30, 2016 the market discount rate was recalculated at 11.0% for the 2019 notes and 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).

[Table of Contents](#)

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 (14.0%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of June 30, 2016, the carrying value of the Milestone Rights is \$8.9 million, classified as a long-term liability in other liabilities and the fair value is estimated at \$15.6 million.

Sanofi Loan Facility

As discussed in Note 7 — Collaboration arrangement, the Sanofi Loan Facility consists of a senior secured revolving promissory note and a guaranty and security agreement with an affiliate of Sanofi which provides the Company with a secured loan facility of up to \$175.0 million to fund the Company’s share of net losses under the Sanofi License Agreement. The estimated fair value was determined using a discounted cash flow model in which time outstanding and discount rate were primary variables. This method considered the key elements of the contractual terms of the Sanofi Loan Facility, market-based estimated cost of capital, and time value of money, namely the amount of time to settlement and the estimated discount rate (11%) appropriate for the liability (Level 3 in the fair value hierarchy). As of June 30, 2016 the carrying value of the Sanofi Loan Facility is \$70.3 million and the fair value is estimated at \$62.0 million.

Warrant liability

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

9. Accounting for stock-based compensation

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

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Stock-based compensation	\$ 1,355	\$ 1,775	\$ 2,628	\$ 3,778

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

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

As of June 30, 2016, there was \$5.6 million and \$7.1 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.

During the three months ended June 30, 2016, the Company granted certain executives stock options to purchase an aggregate of 4,015,000 shares of common stock at a weighted average exercise price of \$0.91 per share. These awards contain performance conditions based on achieving certain product sales targets. The grant date fair value of these awards is \$3.0 million with a grant date fair value of \$0.74 per share, as determined using a Black-Scholes option pricing model. As of June 30, 2016, no compensation cost has been recognized related to these awards as they are not considered probable of achievement within the next twelve months.

10. 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 periods prior to the third quarter of 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 three or six months ended June 30, 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

[Table of Contents](#)

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. In November 2015, the Company issued warrants to purchase 159,304 shares of the Company's common stock to the placement agent in exchange for services related to the Company's offering to select investment funds in Israel.

In May 2016, the Company issued Series A warrants ("A Warrants") to purchase 36,407,765 shares of the Company's common stock and Series B warrants ("B Warrants") to purchase 12,135,921 shares of the Company's common stock to certain institutional investors. These warrants remain outstanding at June 30, 2016 (see Note 14 – Warrants).

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

	June 30,	
	2016	2015
Exercise of common stock options	28,219,831	19,985,768
Vesting of restricted stock units	4,553,757	2,198,173
Exercise of common stock warrants	48,702,990	4,090,013
Conversion of senior convertible notes into common stock	4,072,809	14,708,590
	<u>85,549,387</u>	<u>40,982,544</u>

11. Commitments and contingencies

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

Litigation — The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of June 30, 2016, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company and no accrual has been recorded. The Company maintains liability insurance coverage to protect the Company's assets from losses arising out of or involving activities associated with ongoing and normal business operations. The Company records a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company's policy is to accrue for legal expenses in connection with legal proceedings and claims as they are incurred.

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in the Company's stock price, several complaints were filed in the U.S. District Court for the Central District of California (the "District Court") against the Company and certain of its officers and directors on behalf of certain purchasers of its common stock. These complaints have now been consolidated into a single action. The amended complaint includes claims asserted under Sections 10(b) and 20(a) of the Exchange Act and has 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. The Company 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 in the Company's stock price, two motions were submitted to the district court at Tel Aviv (Economic Department) for the certification of a class action against the Company and certain of its officers and directors. In general, the complaints allege that the Company and certain of its officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. The Company will vigorously defend against the claims advanced.

Subsequent to the filing of the federal securities class action against the Company, a shareholder derivative complaint 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 defendants will vigorously defend against the claims advanced.

[Table of Contents](#)

Contingencies — In connection with the Facility Agreement, on July 1, 2013 the Company also entered into a Milestone Rights Purchase Agreement (the “Milestone Agreement”) with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, the “Milestone Purchasers”), pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to \$90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an Afrezza product in the United States and the achievement of specified net sales figures (see Note 13 – Facility Agreement).

Commitments — On July 31, 2014, the Company entered into a supply agreement (the “Insulin Supply Agreement”) with Amphastar France Pharmaceuticals S.A.S., a French corporation (“Amphastar”), pursuant to which Amphastar manufactures for and supplies to the Company certain quantities of recombinant human insulin for use in Afrezza. Under the terms of the Insulin Supply Agreement, Amphastar is responsible for manufacturing the insulin in accordance with the Company’s specifications and agreed-upon quality standards. The Company has agreed to purchase annual minimum quantities of insulin through 2019 under the Insulin Supply Agreement of an aggregate total of approximately €120.1 million, of which €95.1 million is remaining at June 30, 2016. The annual minimum quantity for 2016 is €28.8 million, of which €3.4 has been purchased as of June 30, 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 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 1 — Summary of Significant accounting policies). The company also has other firm commitments with other suppliers for an aggregate of \$1.9 million. Based on the Company’s firm purchase commitments outstanding and lower of cost or market analysis, the Company has recorded a loss on purchase commitments amounting to \$73.5 million and \$66.2 million as of June 30, 2016 and December 31, 2015, respectively. These balances include losses in foreign currency at June 30, 2016, the Company recognized a loss on foreign currency translation of \$2.0 million for the six months ended June 30, 2016.

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 Option”). On April 14, 2016, the Company provided Sanofi with written notice that it was exercising the Insulin Put Option. To date, \$9.2 million was received for the sale of insulin inventory in connection with the Insulin Put Option, which was recorded as deferred payments from collaboration. As future insulin purchases are made under the purchase commitment and subject to the terms of the Insulin Put Option, additional amounts will be invoiced to Sanofi.

12. Income taxes

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

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.

13. Facility Agreement

As of June 30, 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 an annual rate of 9.75% and the Tranche B notes accrue interest at an annual rate of 8.75%. The Facility Agreement principal repayment schedule is comprised of annual payments beginning on July 1, 2016 and ending December 9, 2019. The repayment dates correspond to the dates on which the 2019 notes or Tranche B notes, as applicable, were issued.

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 June 30, 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 and six months ended June 30, 2016 and 2015 are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Accretion expense- debt issuance cost	\$ 9	\$ 9	\$ 17	\$ 17
Accretion expense- debt discount	\$ 433	\$ 380	\$ 852	\$ 745

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 sufficient resources to comply with the aforementioned covenant, the 2019 notes have been classified as current liabilities in the accompanying balance sheet as of June 30, 2016. In the event of non-compliance, Deerfield may declare all or any portion of the 2019 notes and/or Tranche B notes to be immediately due and payable.

14. Warrants

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

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

As of May 12, 2016 and June 30, 2016, the fair value of the A Warrants liability was \$12.8 million and \$18.1 million, respectively, and was estimated using a Monte Carlo valuation pricing model. The Company recognized a loss of \$5.3 million to reflect the fair value adjustment of the A Warrant liability from the date of issuance, May 12, 2016 to June 30, 2016. As of May 12, 2016 the fair value of the B Warrants at issuance was \$5.0 million.

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

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

As of June 30, 2016, we had an accumulated deficit of \$2.9 billion and a stockholders' deficit of \$366.6 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, 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.

Our business is subject to significant risks, including but not limited to our ability to successfully commercialize and manufacture sufficient quantities of Afrezza, 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.

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

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

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

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, in addition to the warrant policy for the three months ended June 30, 2016.

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

Recently Issued Accounting Standards

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

RESULTS OF OPERATIONS**Three and six months ended June 30, 2016 and 2015****Revenue**

During the three and six months ended June 30, 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 commence recognition, likely within the third quarter of 2016, the deferred sales from collaboration and deferred costs from collaboration and deferred payments from collaboration deferred as of June 30, 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 and six months ended June 30, 2016 and 2015 (dollars in thousands):

	Three months ended June 30,		\$ Change	% Change
	2016	2015		
Clinical	\$2,379	\$ 2,134	\$ 245	11%
Manufacturing process development	258	3,951	(3,693)	(93%)
Research	1,126	1,190	(64)	(5%)
Research and development tax credit	(47)	(88)	41	(47%)
Stock-based compensation expense	593	550	43	8%
Research and development expenses	<u>\$4,309</u>	<u>\$ 7,737</u>	<u>\$ (3,428)</u>	(44%)
	Six months ended June 30,		\$ Change	% Change
	2016	2015		
Clinical	\$4,843	\$ 5,960	\$ (1,117)	(19%)
Manufacturing process development	1,777	7,357	(5,580)	(76%)
Research	1,769	2,593	(824)	(32%)
Research and development tax credit	(137)	(176)	39	(22%)
Stock-based compensation expense	1,188	1,381	(193)	(14%)
Research and development expenses	<u>\$9,440</u>	<u>\$17,115</u>	<u>\$ (7,675)</u>	(45%)

[Table of Contents](#)

The decrease in research and development expenses of \$3.4 million for the three months ended June 30, 2016 compared to the three months ended June 30, 2015 was primarily due to a reduction in force in 2015 following the completion of the Afrezza registration trials.

The decrease in research and development expenses of \$7.7 million for the six months ended June 30, 2016 compared to the six months ended June 30, 2015 was primarily due to the reduction in force in 2015 and the transition from development to commercial activities.

We anticipate our overall research and development expenses will decrease in 2016 compared to 2015 as we continue to focus our efforts on the commercialization of Afrezza for the remainder of this year with minimal incremental cost associated with our development pipeline.

Selling, General and Administrative Expenses

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

	Three months ended June 30,		\$ Change	% Change
	2016	2015		
Salaries and employee related expenses	\$ 3,629	\$ 4,888	\$ (1,259)	(26%)
Professional fees and other general expenses	6,727	4,510	2,217	49%
Stock-based compensation expense	754	1,225	(471)	(38%)
Selling, general and administrative expenses	<u>\$ 11,110</u>	<u>\$ 10,623</u>	<u>\$ 487</u>	5%

	Six months ended June 30,		\$ Change	% Change
	2016	2015		
Salaries and employee related expenses	\$ 5,822	\$ 8,372	\$ (2,550)	(30%)
Professional fees and other general expenses	11,205	10,333	872	8%
Stock-based compensation expense	1,433	2,397	(964)	(40%)
Selling, general and administrative expenses	<u>\$ 18,460</u>	<u>\$ 21,102</u>	<u>\$ (2,642)</u>	(13%)

The increase in selling, general and administrative expenses of \$0.5 million for the three months ended June 30, 2016 compared to general and administrative expenses for the three months ended June 30, 2015 was mainly due to sales and marketing expenses, offset by decreased salaries and employee related expenses of \$1.3 million from the reduction in force in 2015. Stock-based compensation decreased by \$0.5 million due to the reduced number of employees as a result of restructuring measures taken in 2015 which impacted 2016.

The decrease in selling, general and administrative expenses of \$2.6 million for the six months ended June 30, 2016 compared to general and administrative expenses for the six months ended June 30 2015 was primarily due to decreased salaries and personnel related expenses related to the reduction in force and reduced professional fees related to strategic planning activities in 2015, offset by an increase of \$0.9 million in 2016 for sales and marketing expense. Stock compensation decreased by \$1.0 million due to reduced number of employees as a result of restructuring measures taken in 2015 which impacted 2016.

We will continue to incur sales and marketing expenses in the second half of 2016 related to our commercial launch of Afrezza. We expect other general and administrative expenses to remain relatively flat in 2016 as compared to 2015 due to the effects of the reduction in force, which will be offset by increased professional fees related to the Sanofi termination.

Product Manufacturing Expenses

Manufacturing of commercial product resumed in the second quarter of 2016, in preparation for the relaunch of Afrezza in the third quarter of 2016, resulting in the recognition of product manufacturing costs of \$3.7 million including inventory write-offs for the three months ended June 30, 2016. With limited production and underutilization of the manufacturing facility in the same period of 2015, product manufacturing costs were \$5.7 million for the second quarter of 2015 due to 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.

Product manufacturing expenses were \$11.2 million for the six months ended June 30, 2016 and \$7.6 million for the six months ended June 30, 2015, due to product manufacturing costs associated with Afrezza product sales, which cannot be capitalized. 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.

[Table of Contents](#)

2015 due to under absorbed labor and overhead, which are expected in the period in which they are incurred rather than as a portion of the inventory cost.

We expect product manufacturing expenses to remain relatively flat as compared to the same period last year as we continue to manufacture commercial product.

Other (Expense) Income

Other expense of \$6.0 million and \$5.9 million for the three and six months ended June 30, 2016, respectively, is primarily due to fair value re-measurement of \$5.2 million associated with warrants issued in May 2016.

Other income for the six months ended June 30, 2015 was \$1.4 million attributable to 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.

Interest Income and Expense

Interest expense was \$4.9 million for the three months ended June 30, 2016 and the three months ended June 30, 2015. During the three months ended June 30, 2016, Sanofi loan facility interest increased by \$1.2 million and interest expense associated with the 2015 notes decreased as a result of the 2015 notes maturing in the third quarter of 2015.

Interest expense decreased by \$5.3 million for the six months ended June 30, 2016 compared to the six months ended June 30, 2015. The decrease was primarily driven by a \$5.8 million milestone payment resulting from the achievement and re-measurement of the second milestone under the Milestone Agreement in the first quarter of 2015, with no such payment in 2016. During the six months ended June 30, 2016, Sanofi loan facility interest increased by \$2.3 million, other interest increased by \$0.5 million, and interest expense associated with the 2015 notes decreased by \$2.4 million as compared to the six months ended June 30, 2015.

LIQUIDITY AND CAPITAL RESOURCES

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

As of June 30, 2016, we had \$227.5 million principal amount of outstanding debt, consisting of:

- \$27.7 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;
- \$60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, \$5.0 million of which was paid 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
- \$70.3 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

As of June 30, 2016, the amount available for future borrowings under The Mann Group Loan Arrangement was \$30.1 million. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable. As of June 30, 2016, the accrued and unpaid interest under The Mann Group Loan Arrangement was \$7.8 million.

As of June 30, 2016, all profits and losses from Afrezza sales by Sanofi or its affiliates after April 9, 2016, the effective termination date will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement until the end of the transition agreement to be leased on or before October 1, 2016. Our total share of the net losses are \$70.3 million, classified as Sanofi loan facility and loss share obligation, of which \$70.3 million has been borrowed under the Sanofi Loan Facility. Subsequent to June 30, 2016, we applied \$0.3 million to the Sanofi Loan Facility as a prepayment equal to our share of the net profit for the second quarter of 2016. The balance remaining under the Sanofi Loan Facility is \$70.0 million, which includes \$4.3 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 further profits received from Sanofi 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.

Table of Contents

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

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

Pursuant to our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019, for an aggregate total purchase price of approximately €120.1 million, of which €95.1 million is remaining at June 30, 2016. The annual minimum quantity for 2016 is €28.8 million, of which €3.4 million had been purchased as of June 30, 2016, and the remaining annual minimum quantities will be €23.3 million for the years ending 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

[Table of Contents](#)

30 days following the termination date, Sanofi is obligated to purchase up to \$50 million of the Company's insulin inventory as a percentage of each lot received or receivable by the Company (the "Insulin Put Option"). On April 14, 2016, the Company provided Sanofi with written notice that it was exercising the Insulin Put Option. To date, \$9.2 million was received for the sale of insulin inventory in connection with the Insulin Put Option. As future insulin purchases are made under the purchase commitment and subject to the terms of the Insulin Put Option, additional amounts will be invoiced to Sanofi.

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 six months ended June 30, 2016, we used \$42.3 million of cash for our operating activities as a result of our net loss of \$54.8 million, adjusted by non-cash charges of \$17.4 million and a net decrease in assets and liabilities of \$4.8 million. The non-cash charges included \$4.7 million of depreciation and accretion and stock-based compensation, \$2.0 million loss on foreign currency exchange, \$2.6 million of interest accrued through borrowings under Sanofi Loan Facility, \$5.3 million from fair valuation of warrants, \$0.7 million from warrant issuance costs, \$1.4 million interest accrued through borrowings from related party, and \$0.7 million of impairment charges. The changes in net assets and liabilities was due to a decrease in accounts payable of \$12.5 million, \$12.2 million in non-current purchase commitment loss, and an increase of \$2.9 million in inventory, offset by an increase of \$9.2 million in deferred upfront payments, \$8.3 million in purchase commitment loss — current, \$2.6 million in prepaid expenses and other current assets, and \$2.7 million increase in accrued expenses and other liabilities.

During the six months ended June 30, 2015, we used \$14.8 million of cash for our operating activities as a result of our net loss of \$59.6 million, adjusted by non-cash charges of \$10.7 million and a net decrease in assets and liabilities of \$34.1 million. The non-cash charges included \$10.4 million of depreciation and accretion and stock-based compensation. The change in net assets and liabilities was predominately due to the receipt of a \$50.0 million milestone payment from Sanofi, earned as of December 31, 2014 offset by an increase in inventory, deferred product costs from collaboration, and other accrued expenses and current liabilities.

We used \$1.1 million of cash for investing activities during the six months ended June 30, 2016, compared to \$8.7 million for the six months ended June 30, 2015. The \$7.6 million decrease was due to a decrease in purchase of machinery and equipment.

Our financing activities provided \$48.0 million of cash for the six months ended June 30, 2016, as compared to \$9.9 million for the same period in 2015. For the six months ended June 30, 2016, cash provided by financing activities was primarily from \$47.4 million in net proceeds received from the sale of stock and warrants pursuant to an underwritten public offering of 48,543,687 common shares. Each share of common stock was sold together with a warrant to purchase 0.75 of a share of common stock (A Warrants) and a warrant to purchase 0.25 of a share of common stock (B Warrants) for a combined purchase price of \$1.03. Additionally \$0.7 million was received from exercises of stock options.

Financing activities for the six months ended June 30, 2015 provided \$9.9 million of cash, \$2.4 million from the exercises of stock options, \$9.7 million from the exercise of warrants, \$0.7 million from issuance of shares under our employee stock purchase program and \$2.1 million provided from at the market sales of stock. This was 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 \$0.8 million for the payment of employment taxes related to vested restricted stock units.

As of June 30, 2016, we had \$63.7 million in cash and cash equivalents. We expect to expend our capital resources for the manufacturing, sales and marketing of Afrezza and to develop our 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 product candidates or Afrezza for commercialization outside of the United States, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital when needed or on acceptable terms, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in

[Table of Contents](#)

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 June 30, 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 and six months ended June 30, 2016 was a fixed rate equal to 5.84%. As of June 30, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was \$49.5 million. We also have debt related to the 2018 notes at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75%, and debt related to the Tranche B notes at a fixed interest rate of 8.75%.

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

If a change in interest rates equal to 10% of the interest rates on June 30, 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 six months ended June 30, 2016, we made 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 were to have occurred on that date, this change would have resulted in a foreign currency impact to our pre-tax losses of approximately \$10.9 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 June 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

[Table of Contents](#)

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 June 30, 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. These complaints have now been consolidated into a single action. The amended complaint includes claims asserted under Sections 10(b) and 20(a) of the Exchange Act and has been pled as a putative shareholder class action. In general, the complaint alleges 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 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 U.S. 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.

Subsequent to the filing of the federal securities class action against the Company, a shareholder derivative complaint was filed in the Superior Court for the State of California, County of Los Angeles against certain of our 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 MannKind to make false and misleading statements or omissions of material fact regarding our business and the prospects for sales of Afrezza, thereby artificially inflating the price of our common stock. The plaintiff is seeking unspecified monetary damages and other relief, including reforms to our corporate governance and internal procedures. The defendants will vigorously defend against the claims advanced.

We are also subject to legal proceedings and claims which arise in the ordinary course of our business. As of the date hereof, we believe that the final disposition of such matters will not have a material adverse effect on our financial position, results of operations or cash flows. We maintain liability insurance coverage to protect our assets from losses arising out of or involving activities associated with ongoing and normal business operations.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. The risk factors set forth below marked with an asterisk () did not appear as separate risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of the Annual Report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.*

RISKS RELATED TO OUR BUSINESS

*Our prospects are heavily dependent on the successful commercialization of our only approved product, Afrezza. The continued commercialization and development of Afrezza will require substantial capital that we may not be able to obtain.**

We have expended significant time, money and effort in the development of our only approved product, Afrezza. We anticipate that in the near term our prospects and ability to generate significant revenues will heavily depend on our ability to successfully commercialize Afrezza in the United States. We anticipate that our near term revenues will also, to a much lesser extent, depend on our ability to enter into licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us.

[Table of Contents](#)

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

We have never, as an organization, launched or commercialized a product other than Afrezza, and there is no guarantee that we will be able to successfully do so with Afrezza. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established a commercial team and have hired a U.S. sales force through a contract sales organization, we will need to maintain and continue to build our commercialization capabilities in order to successfully commercialize Afrezza in the United States, and we may not have sufficient resources to do so. The market for skilled commercial personnel is highly competitive, and we may not be able to retain and find and hire all of the personnel we need on a timely basis. We have engaged a contract sales organization to conduct sales activities, but there are risks regarding whether a subcontractor will provide the level of effort and attention to Afrezza necessary for successful commercialization. In addition, Afrezza is a novel insulin therapy with a distinct profile and non-injectable administration, and we are therefore required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing Afrezza for the treatment diabetes to physicians and to ensure that a consistent and appropriate message about Afrezza is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of Afrezza and its proper administration, our efforts to successfully commercialize Afrezza could be put in jeopardy, which would negatively impact our ability to generate product revenues.

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

We are also responsible for the NDA for Afrezza and its maintenance. Prior to the termination of the Sanofi License Agreement in April 2016, we had no experience with the maintenance of an NDA and may fail to comply with maintenance requirements, including timely submitting required reports. Furthermore, we are responsible for the conduct of the remaining required post-approval trials of Afrezza. Our financial and other resource constraints may result in delays or adversely impact the reliability and completion of these trials.

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

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

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

While Afrezza has been approved in the United States by the FDA for glycemic control in adult patients with diabetes, it has not been approved in any other jurisdiction. In order to market Afrezza outside of the United States, we must obtain regulatory approval in each applicable foreign jurisdiction, and we may never be able to obtain such approvals. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical products outside the United States are subject to extensive regulation by foreign regulatory authorities, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for Afrezza, and we have not yet identified all of the requirements that we will need to satisfy to submit Afrezza for approval for other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support the NDA for Afrezza.

Our current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are appropriate commercial opportunities. It may be difficult to find collaboration partners that are able and willing to devote the time and resources necessary to

[Table of Contents](#)

successfully commercialize Afrezza. Collaborations with third parties may require us to relinquish material rights, including revenue from commercialization, on terms that we view to be less than attractive or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, especially in the current market, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of Afrezza in foreign jurisdictions and could have a material and adverse impact on our business, financial condition and results of operations and the market price of our common stock and other securities could decline.

We may not be successful in our efforts to develop and commercialize our 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 June 30, 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 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 €95.1 million is remaining at June 30, 2016. The annual minimum quantity for 2016 is €28.8 million, of which €3.4 million had been purchased as of June 30, 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 June 30, 2016, we had stockholders' deficit of \$366.6 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.

Table of Contents

*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 our Facility Agreement with Deerfield, which requires us to maintain at least \$25.0 million in cash and cash equivalents or available borrowings under The Mann Group Loan Arrangement as of the last day of each fiscal quarter. It may be difficult for us to raise additional funds on favorable terms, or at all. As of June 30, 2016, we had stockholders' deficit of \$366.6 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, in connection with product sales by Sanofi 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.

[Table of Contents](#)

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, holders of our common stock or other securities may lose the entire value of their investment.

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

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

As of June 30, 2016, we had \$227.5 million principal amount of outstanding debt, consisting of:

- \$27.7 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;
- \$60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, \$5.0 million of which was paid 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
- \$70.3 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

We may borrow an additional \$30.1 million under The Mann Group Loan Arrangement. The available borrowings may be used to capitalize accrued interest into principal upon mutual agreement of the parties, as accrued interest becomes due and payable under The Mann Group Loan Arrangement. As of June 30, 2016 the accrued and unpaid interest under The Mann Group Loan Arrangement was \$7.8 million.

All profits and losses from Afrezza product sales by Sanofi or its affiliates, if any, will 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 \$70.3 million as of June 30, 2016, classified as Sanofi loan facility and loss share obligation, and such amount has been borrowed under the Sanofi Loan Facility as of June 30, 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

[Table of Contents](#)

Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or the loans under The Mann Group Loan Arrangement or the Sanofi Loan Facility when required, we will be in default under the instrument for such debt securities or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

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

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

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

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

[Table of Contents](#)

or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders and the holders of our other securities. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations. If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

- safety and efficacy results obtained in our nonclinical and early clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing a product candidate or alter the marketing of an approved product;
- the analysis of data collected from clinical studies of our product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;
- after reviewing clinical data, we or any collaborators may abandon projects that we previously believed were promising; and
- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use once approved.

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

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

For the commercial manufacture of Afrezza, we need access to sufficient, reliable and affordable supplies of insulin, our Afrezza inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar and the only source of our proprietary inert excipient, FDKP (fumaryl diketopiperazine), which is the primary component of our Technosphere technology platform, is manufactured by Lonza Group Ltd. (Lonza). We must rely on our suppliers, including Amphastar, to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with the FDA's 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

[Table of Contents](#)

qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

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

*If Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payors and the healthcare community, we may be unable to generate significant revenue, if any.**

Afrezza and other products that we may develop in the future may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of Afrezza and other products that we may develop in the future depends on many factors, including the:

- approved labeling claims;
- effectiveness of efforts by us or any future marketing partner to educate physicians about the benefits and advantages of Afrezza or our other products and to provide adequate support for them, and the perceived advantages and disadvantages of competitive products;
- willingness of the healthcare community and patients to adopt new technologies;
- ability to manufacture the product in sufficient quantities with acceptable quality and cost;
- perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits compared to competing products or therapies;
- convenience and ease of administration relative to existing treatment methods;
- coverage and pricing and reimbursement relative to other treatment therapeutics and methods; and
- marketing and distribution support.

Because of these and other factors, Afrezza and any other product that we develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of Afrezza or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future marketing partner for Afrezza, and companies that are prospective collaborators for our product candidates, our ability to commercialize Afrezza and our product candidates under development may be adversely affected.

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of coverage and adequate reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for Afrezza and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to

[Table of Contents](#)

include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for Afrezza or any of our other product candidates that receives marketing approval from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

If we or any future marketing partner is unable to obtain coverage of, and adequate payment levels for, Afrezza or any of our other product candidates that receive marketing approval from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our and any future marketing partner's ability to successfully commercialize Afrezza and our ability to successfully commercialize any of our other product candidates that receives regulatory approval and impact our profitability, results of operations, financial condition, and prospects.

Healthcare legislation may make it more difficult to receive revenues.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. For example, in March 2010, the Patient Protection and Affordable Care Act ("PPACA") became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to us are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of certain drug-device combination products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a licensure framework for follow-on biological products;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report annually to the Centers for Medicare & Medicaid Services ("CMS") certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year;

[Table of Contents](#)

- a new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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

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

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

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

- the federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully offering soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including without limitation the civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

Table of Contents

- the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that Afrezza or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If 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.

Table of Contents

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

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

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

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

We face a consolidated complaint 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 complaint includes claims asserted under Sections 10(b) and 20(a) of the Exchange Act and has been pled as putative shareholder class actions. In general, the complaint alleges 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

[Table of Contents](#)

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

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

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

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development and commercialization of Afrezza work involves the controlled storage and use of hazardous materials, including chemical and biological materials. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to \$1.0 million per occurrence and \$2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further \$20.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition.

When we purchased the facilities located in Danbury, Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection. During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of \$1.6 million. It has conducted at its expense all work and will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business, financial condition and results of operations may be harmed.

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;

[Table of Contents](#)

- product labeling;
- product storage and shipping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

The requirements governing the conduct of clinical studies and manufacturing and marketing of Afrezza and our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical study designs. Foreign regulatory approval processes include essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot be certain if or when regulatory agencies might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical studies of our product candidates may not be completed on schedule, regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical studies may not be sufficient to support regulatory approval of our product candidates. Even if we believe the data collected from our clinical studies are sufficient, regulatory agencies have substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

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

The FDA and other regulatory authorities impose significant restrictions on approved products through regulations on advertising, promotional and distribution activities. This oversight encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving the Internet. Regulatory authorities may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA and other regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with such regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Failure to comply with state requirements may affect our ability to promote or sell our products in certain states.

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

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

[Table of Contents](#)

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;
- 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.

[Table of Contents](#)

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

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

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

There are also a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or potentially competitive with, our 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.

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 inventor to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The full effects of these changes are currently unclear as the United States Patent and Trademark Office, or USPTO, must still implement various regulations, the courts have only begun to interpret these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

[Table of Contents](#)

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

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

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

Interference proceedings brought by the USPTO, may be necessary to determine the priority of inventions with respect to our 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, due in part to the much reduced opportunity to repair claims by amendment as compared to re-examination, as well as the lower standard of proof used at the USPTO as compared to the federal courts. With the passage of time an increasing number of patents related to successful pharmaceutical products are being subjected to IPR. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. 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.

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

[Table of Contents](#)

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.

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

[Table of Contents](#)

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

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

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

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for: issuance upon the exercise of stock options, warrant exercises, and the vesting of restricted stock unit awards; the purchase of shares of common stock under our employee stock purchase program; and the issuance of shares upon exchange or conversion of the 2018 notes or any other convertible debt we may issue. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

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

At June 30, 2016, the estate of Alfred E. Mann beneficially owned approximately 32.1% 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.

[Table of Contents](#)

The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- the progress of our recent commercial launch of Afrezza in the United States and other events or circumstances that we or others estimate will impact the future commercial success of Afrezza;
- our ability to obtain marketing approval for Afrezza outside of the United States and to find collaboration partners for the commercialization of Afrezza in foreign jurisdictions;
- our future estimates of Afrezza sales, prescriptions or other operating metrics;
- our ability to successfully commercialize our Technosphere drug delivery platform;
- the progress of preclinical and clinical studies of our product candidates and of post-approval studies of Afrezza required by the FDA;
- the results of preclinical and clinical studies of our product candidates;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing Afrezza or other product candidates;
- developments or disputes concerning our relationship with any of our current or future collaborators or third party manufacturers;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- announcements by us concerning our financial condition or operating performance;
- changes in securities analysts' estimates of our financial condition or operating performance;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- 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.

Table of Contents

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

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

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

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

As of August 1, 2016, we had 478,048,448 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.

Table of Contents

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

Our amended and restated certificate of incorporation currently authorizes us to issue up to 700,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of August 1, 2016, we had a total of 221,951,552 shares of common stock that were authorized but unissued, and we have currently reserved a significant number of these shares for future issuance pursuant to outstanding equity awards, outstanding warrants, our equity plans and our 2018 notes. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our amended and restated certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	Amended and Restated Certificate of Incorporation
3.2	Amended and Restated Bylaws (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on November 19, 2007).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of common stock certificate (incorporated by reference to MannKind's Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 18, 2013).
4.3	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind's current report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.4	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind's Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 3, 2014).
4.5	Form of Tranche B Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.8 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50856), filed with the SEC on May 12, 2014).

Table of Contents

<u>Exhibit Number</u>	<u>Description of Document</u>
4.6	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.7	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.8	Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.9	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to MannKind's Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 3, 2014).
4.10	Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.14 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
4.11	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind Corporation and Aventisub LLC (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.12	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind Corporation, MannKind LLC and Aventisub LLC (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.13	Indenture, by and between MannKind and U.S. Bank (as successor trustee to Wells Fargo, N.A., dated August 10, 2015 (incorporated by reference to Exhibit 4.18 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.14	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2018 (included in Exhibit 4.18 as Exhibit A thereto) (incorporated by reference to Exhibit 4.19 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.15	Form of Warrant to Purchase Common Stock issued November 16, 2015 (incorporated by reference to Exhibit 4.17 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
4.16	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
4.17	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
10.1+	MannKind Corporation 2013 Equity Incentive Plan, as amended.
10.2	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
10.3	Engagement Letter, dated May 8, 2016, by and between MannKind and H.C. Wainwright & Co. 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 May 10, 2016).
31	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Description of Document</u>
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

+ Indicates management contract

SIGNATURE

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

Dated: August 9, 2016

MANNKIND CORPORATION

By: /s/ MATTHEW J. PFEFFER

Matthew J. Pfeffer

Chief Executive Officer and Chief Financial Officer

(Principal Financial and Accounting Officer)

**AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
MANNKIND CORPORATION**

The undersigned, David B. Thomson, in accordance with the provisions of Sections 242 and 245 of the Delaware General Corporation Law (“**DGCL**”) hereby certifies that:

FIRST: He is the duly elected and acting Corporate Vice President, General Counsel and Corporate Secretary of MannKind Corporation, a Delaware corporation.

SECOND: The original name of this corporation was Pharmaceutical Discovery Corporation and the date of filing of the original Certificate of Incorporation of this corporation with the Secretary of State of the State of Delaware was February 14, 1991.

THIRD: This Amended and Restated Certificate of Incorporation (the “**Amended and Restated Certificate**”) has been duly approved and adopted by the Board of Directors of the Corporation (the “**Board**”) in accordance with the applicable provisions of Sections 242 and 245 of the DGCL.

FOURTH: This Amended and Restated Certificate has been duly approved and adopted by the stockholders of the Corporation in accordance with the applicable provisions of Sections 211, 242 and 245 of the DGCL.

FIFTH: The text of the Amended and Restated Certificate, as heretofore amended or supplemented, is hereby amended and restated in its entirety to read as follows:

I.

The name of this corporation is MannKind Corporation (the “**Corporation**”).

II.

The address of the registered office of the corporation in the State of Delaware is 2711 Centerville Road, Suite 400, City of Wilmington, County of New Castle, 19808 and the name of the registered agent of the Corporation in the State of Delaware at such address is the Corporation Service Company.

III.

The purpose of this Corporation is to engage in any lawful act or activity for which a corporation may be organized under the DGCL.

IV.

A. This Corporation is authorized to issue two classes of stock to be designated, respectively, “**Common Stock**” and “**Preferred Stock**.” The total number of shares which the Corporation is authorized to issue is seven hundred ten million (710,000,000) shares. Seven hundred million (700,000,000) shares shall be Common Stock, each having a par value of one cent (\$.01). Ten million (10,000,000) shares shall be Preferred Stock, each having a par value of one cent (\$.01).

B. The Preferred Stock may be issued from time to time in one or more series. The Board is hereby expressly authorized to provide for the issue of all or any of the remaining shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such shares and as may be permitted by the DGCL. The Board is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the Common Stock, without a vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.

C. Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; *provided, however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the number of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

V.

For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A. Board of Directors

1. The management of the business and the conduct of the affairs of the Corporation shall be vested in the Board. The number of directors which shall constitute the Board shall be fixed exclusively by resolutions adopted by a majority of the authorized number of directors constituting the Board.

2. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, directors shall be elected at each annual meeting of stockholders for a term of one year. Each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

3. Subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

4. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

B. Bylaw Amendments. The Board is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation. The stockholders shall also have power to adopt, amend or repeal the Bylaws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws of the Corporation.

C. Stockholder Action. No action shall be taken by the stockholders of the Corporation except at an annual or special meeting of stockholders called in accordance with the Bylaws. No action shall be taken by the stockholders by written consent or electronic transmission.

D. Advance Notice. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

VI.

A. The liability of the directors for monetary damages shall be eliminated to the fullest extent under applicable law. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the corporation shall be eliminated to the fullest extent permitted by the DGCL, as so amended.

B. Any repeal or modification of this Article VI shall be prospective and shall not affect the rights under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

VII.

A. The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph B. of this Article VII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

B. Notwithstanding any other provisions of this Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the Corporation required by law or by this Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI, and VII.

MANNKIND CORPORATION

2013 EQUITY INCENTIVE PLAN, AS AMENDED

ADOPTED BY THE BOARD OF DIRECTORS: MARCH 7, 2013

APPROVED BY THE STOCKHOLDERS: MAY 23, 2013

AMENDED BY THE BOARD: APRIL 4, 2016

AMENDMENT APPROVED BY THE STOCKHOLDERS: MAY 19, 2016

1. GENERAL.

(a) Successor to and Continuation of Prior Plan. The Plan is intended as the successor to and continuation of the MannKind Corporation 2004 Equity Incentive Plan (the "**Prior Plan**"). Following the Effective Date, no additional stock awards may be granted under the Prior Plan. Any unallocated shares remaining available for issuance pursuant to the exercise of options or issuance or settlement of stock awards not previously granted under the Prior Plan as of 12:01 a.m. Pacific time on the Effective Date (the "**Prior Plan's Available Reserve**") will cease to be available under the Prior Plan at such time and will be added to the Share Reserve (as further described in Section 3(a) below) and be then immediately available for issuance pursuant to Stock Awards granted hereunder. In addition, from and after 12:01 a.m. Pacific time on the Effective Date, all outstanding stock awards granted under the Prior Plan will remain subject to the terms of the Prior Plan; *provided, however*, that any shares subject to outstanding stock awards granted under the Prior Plan that (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited, cancelled or otherwise returned to the Company because of the failure to meet a contingency or condition required to vest such shares; or (iii) are reacquired, withheld (or not issued) to satisfy a tax withholding obligation in connection with an award or to satisfy the purchase price or exercise price of a stock award (the "**Returning Shares**") will immediately be added to the Share Reserve (as further described in Section 3(a) below) as and when such shares become Returning Shares, and become available for issuance pursuant to Awards granted hereunder. All Awards granted on or after 12:01 a.m. Pacific time on the Effective Date will be subject to the terms of this Plan.

(b) Eligible Award Recipients. Employees, Directors and Consultants are eligible to receive Awards under the Plan.

(c) Available Awards. The Plan provides for the grant of the following types of Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(d) Purpose. The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible recipients may benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including

when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or at which cash or shares of Common Stock may be issued).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not impair a Participant's rights under the Participant's then-outstanding Award without the Participant's written consent except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or to make the Plan or Awards granted under the Plan compliant with the requirements for Incentive Stock Options or exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. However, if required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (E) materially extends the term of the Plan, or (F) materially expands the types of Awards available for issuance under the Plan. Except as provided in the Plan (including Section 2(b)(viii)) or an Award Agreement, no amendment of the Plan will impair a Participant's rights under an outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding incentive stock options or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (B) to change the terms of an Incentive Stock Option, if such change results in impairment of the Award solely because it impairs the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; or (D) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or reconstitute in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, reconstitute in the Board some or all of the powers previously delegated.

(ii) Section 162(m) and Rule 16b-3 Compliance. The Committee may consist solely of two (2) or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two (2) or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) Delegation to an Officer. The Board may delegate to one (1) or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such Awards, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; *provided, however*, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Award Agreement most recently approved for use by the Committee or the Board, unless otherwise provided in the resolutions approving the delegation authority. The Board may not delegate authority to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) to determine the Fair Market Value pursuant to Section 13(w)(iii) below.

(e) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(f) Cancellation and Re-Grant of Stock Awards. Neither the Board nor any Committee will have the authority to: (i) reduce the exercise, purchase or strike price of any outstanding Option or SAR under the Plan, or (ii) cancel any outstanding Option or SAR that has an exercise price or strike price greater than the current Fair Market Value of the Common Stock in exchange for cash or other Stock Awards under the Plan, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve.

(i) Subject to Section 10(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date will not exceed (A) Thirty-Seven Million Five Hundred Ten Thousand Eight (37,510,008) shares, which number is equal to the

sum of (I) One Million Ten Thousand Eight (1,010,008) shares subject to the Prior Plan's Available Reserve and (II) an additional Twenty-One Million Five Hundred Thousand (21,500,000) shares that were approved by the Company's stockholders on the Effective Date, and (III) an additional Fifteen Million (15,000,000) new shares, *plus* (B) the Returning Shares, if any, which become available for grant under the Plan from time to time (such aggregate number of shares described in (A) and (B) above, the "**Share Reserve**").

(ii) For clarity, the Share Reserve in this Section 3(a) is a limitation on the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(iii) Subject to subsection 3(b), the number of shares available for issuance under the Plan shall be reduced by: (i) one (1) share for each share of stock issued pursuant to (A) an Option granted under Section 5, or (B) a Stock Appreciation Right granted under Section 5 with respect to which the strike price is at least one hundred percent (100%) of the Fair Market Value of the underlying Common Stock on the date of grant; and (ii) 1.3 shares for each share of Common Stock issued pursuant to a Restricted Stock Award, Restricted Stock Unit Award, Performance Stock Award or Other Stock Award.

(b) Reversion of Shares to the Share Reserve.

(i) Shares Available For Subsequent Issuance. If any shares of common stock issued pursuant to a Stock Award are forfeited back to the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited shall revert to and again become available for issuance under the Plan. Notwithstanding the provisions of this Section 3(b), to the extent (i) there is issued a share of Common Stock pursuant to a Stock Award under the Plan (other than an Option or Stock Appreciation Right), and (ii) there are any Returning Shares granted under the Prior Plan pursuant to an award other than an option or stock appreciation right, and such share of Common Stock becomes available for issuance under the Plan pursuant to Section 1(a), Section 3(a) or this Section 3(b), then the number of shares of Common Stock available for issuance under the Plan shall increase by 1.3 shares for each such share.

(ii) Shares Not Available For Subsequent Issuance. If any shares subject to a Stock Award are not delivered to a Participant because the Stock Award is exercised through a reduction of shares subject to the Stock Award (*i.e.*, "net exercised"), the number of shares that are not delivered to the Participant shall not remain available for issuance under the Plan. Also, any shares reacquired by the Company pursuant to Section 8(h) or as consideration for the exercise of an Option or SAR shall not again become available for issuance under the Plan.

(c) Incentive Stock Option Limit. Subject to the Share Reserve and Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options will be sixty million (60,000,000) shares of Common Stock.

(d) Section 162(m) Limitations. Subject to the Share Reserve and Section 9(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, the following limitations shall apply.

(i) A maximum of five million (5,000,000) shares of Common Stock subject to Options, SARs and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date any such Stock Award is granted may be granted to any Participant during any calendar year. Notwithstanding the foregoing, if any additional Options, SARs or Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date the Stock Award are granted to

any Participant during any calendar year, compensation attributable to the exercise of such additional Stock Awards will not satisfy the requirements to be considered “qualified performance-based compensation” under Section 162(m) of the Code unless such additional Stock Award is approved by the Company’s stockholders.

(ii) A maximum of three million (3,000,000) shares of Common Stock subject to Performance Stock Awards may be granted to any one Participant during any one calendar year (whether the grant, vesting or exercise is contingent upon the attainment during the Performance Period of the Performance Goals).

(iii) A maximum of three million dollars (\$3,000,000) may be granted as a Performance Cash Award to any one Participant during any one calendar year.

(e) **Limitation on Grants to Non-Employee Directors.** Subject to the Share Reserve and Section 9(a) relating to Capitalization Adjustments, a maximum of one hundred fifty thousand (150,000) shares of Common Stock subject to Stock Awards may be granted to any one Non-Employee Director during any one calendar year.

(f) **Source of Shares.** The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) **Eligibility for Specific Stock Awards.** Incentive Stock Options may be granted only to employees of the Company or a “parent corporation” or “subsidiary corporation” thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; provided, however, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any “parent” of the Company, as such term is defined in Rule 405, unless (i) the stock underlying such Stock Awards is treated as “service recipient stock” under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction) or (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from or alternatively comply with the distribution requirements of Section 409A of the Code.

(b) **Ten Percent Stockholders.** A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) **Term.** Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Award Agreement.

(b) **Exercise Price.** Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted.

Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or that otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if an Option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Award Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (and pursuant to Sections 5(e)(ii) and 5(e)(iii) below), and will be exercisable during

the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulations Section 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, upon the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, upon the death of the Participant, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death, Disability, or Retirement), the Participant may exercise the Participant's Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR will terminate.

(h) Extension of Termination Date. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of time (that need not be consecutive) equal to the applicable post-termination exercise

period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR (as applicable) will terminate.

(k) Termination due to Retirement. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Retirement, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twenty-four (24) months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(l) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising the Participant's Option or SAR from and after the time of such termination of Continuous Service.

(m) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six (6) months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement, in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six (6) months following the date of grant. The foregoing

provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from the employee's regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARs.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock underlying a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award (covering a number of shares not in excess of that set forth in Section 3(d)(ii)) that is payable (including that may be granted, vest or be exercised) contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the Participant's completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award (for a dollar value not in excess of that set forth in Section 3(d)(iii)) that is payable contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the Participant's completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Board Discretion. The Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for a Performance Period.

(iv) Section 162(m) Compliance. Unless otherwise permitted in compliance with Section 162(m) of the Code with respect to an Award intended to qualify as “performance-based compensation” thereunder, the Committee will establish the Performance Goals applicable to, and the formula for calculating the amount payable under, the Award no later than the earlier of (A) the date ninety (90) days after the commencement of the applicable Performance Period, and (B) the date on which twenty-five percent (25%) of the Performance Period has elapsed, and in any event at a time when the achievement of the applicable Performance Goals remains substantially uncertain. Prior to the payment of any compensation under an Award intended to qualify as “performance-based compensation” under Section 162(m) of the Code, the Committee will certify the extent to which any Performance Goals and any other material terms under such Award have been satisfied (other than in cases where the Performance Goals relate solely to the increase in the value of the Common Stock). Notwithstanding satisfaction or any completion of any Performance Goals, shares subject to Options, cash or other benefits granted, issued, retainable and/or vested under an Award on account of satisfaction of such Performance Goals may be reduced by the Committee on the basis of any further considerations as the Committee, in its sole discretion, will determine.

(d) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than one hundred percent (100%) of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards granted under Section 5 and this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan the authority required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock issued pursuant to Stock Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of the Participant's services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) Incentive Stock Option Limitations. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds one hundred thousand dollars (\$100,000) (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(g) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that the Participant is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of

the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(h) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(i) Electronic Delivery. Any reference herein to a “written” agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company’s intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(j) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant’s termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(k) Compliance with Section 409A of the Code. To the extent that the Board determines that any Award granted hereunder is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded and a Participant holding an Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount shall be made upon a “separation from service” before a date that is six (6) months following the date of such Participant’s “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the Participant’s death.

(l) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company’s securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for “good reason” or “constructive termination” (or similar term) under any agreement with the Company.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Section 3(d), (iv) the class(es) and maximum number of securities that may be awarded to any Non-Employee Director pursuant to Section 3(e) and (v) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, *provided, however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Corporate Transactions. The following provisions will apply to Stock Awards in the event of a Transaction unless otherwise provided in the Stock Award Agreement or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Transaction, then, notwithstanding any other provision of the Plan, the Board may take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective date of the Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Transaction; *provided, however*, that the Board may require Participants to complete and deliver to the Company a notice of exercise before the effective date of a Transaction, which exercise is contingent upon the effectiveness of such Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be zero (\$0) if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Common Stock in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. PLAN TERM; EARLIER TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may suspend or terminate the Plan at any time. No Incentive Stock Option will be granted after the tenth (10th) anniversary of the earlier of (i) the date the Plan is adopted by the Board, or (ii) the date the Plan is approved by the stockholders of the Company. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) **No Impairment of Rights.** Suspension or termination of the Plan will not impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant or as otherwise permitted in the Plan.

11. EFFECTIVE DATE OF PLAN.

This Plan will become effective on the Effective Date.

12. CHOICE OF LAW.

The laws of the State of California will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) **"Affiliate"** means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) **"Award"** means a Stock Award or a Performance Cash Award.

(c) **"Award Agreement"** means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) **"Board"** means the Board of Directors of the Company.

(e) “**Capitalization Adjustment**” means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) “**Cause**” will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant’s commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant’s attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant’s intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant’s unauthorized use or disclosure of the Company’s confidential information or trade secrets; or (v) such Participant’s gross misconduct. The determination that a termination of the Participant’s Continuous Service is either for Cause or without Cause will be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) “**Change in Control**” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company’s securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the “**Subject Person**”) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company will otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “**Incumbent Board**”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of this Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

(h) “**Code**” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) “**Committee**” means a committee of one (1) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(j) “**Common Stock**” means the common stock of the Company.

(k) “**Company**” means MannKind Corporation, a Delaware corporation.

(l) “**Consultant**” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(m) “**Continuous Service**” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, will not terminate a Participant’s Continuous Service; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant’s Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(n) “**Corporate Transaction**” means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(o) “**Covered Employee**” will have the meaning provided in Section 162(m)(3) of the Code.

(p) “**Director**” means a member of the Board.

(q) “**Disability**” means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(r) “**Effective Date**” means the effective date of this Plan document, which is the date of the annual meeting of stockholders of the Company held in calendar year 2013 provided the Plan is approved by the Company’s stockholders at such meeting.

(s) “**Employee**” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(t) “**Entity**” means a corporation, partnership, limited liability company or other entity.

(u) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(v) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities.

(w) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board,

the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(x) “**Incentive Stock Option**” means an option granted pursuant to Section 5 that is intended to be, and that qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

(y) “**Non-Employee Director**” means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“**Regulation S-K**”)), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

(z) “**Nonstatutory Stock Option**” means any option granted pursuant to Section 5 that does not qualify as an Incentive Stock Option.

(aa) “**Officer**” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(bb) “**Option**” means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(cc) “**Option Agreement**” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(dd) “**Optionholder**” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ee) “**Other Stock Award**” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(d).

(ff) “**Other Stock Award Agreement**” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(gg) “**Outside Director**” means a Director who either (i) is not a current employee of the Company or an “affiliated corporation” (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an “affiliated corporation” who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an “affiliated corporation,” and does not receive remuneration from the Company or an “affiliated corporation,” either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an “outside director” for purposes of Section 162(m) of the Code.

(hh) “Own,” “Owned,” “Owner,” “Ownership” A person or Entity will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ii) “Participant” means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(jj) “Performance Cash Award” means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(kk) “Performance Criteria” means the one or more criteria that the Board will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) total stockholder return; (v) return on equity or average stockholder’s equity; (vi) return on assets, investment, or capital employed; (vii) stock price; (viii) margin (including gross margin); (ix) income (before or after taxes); (x) operating income; (xi) operating income after taxes; (xii) pre-tax profit; (xiii) operating cash flow; (xiv) sales or revenue targets; (xv) increases in revenue or product revenue; (xvi) expenses and cost reduction goals; (xvii) improvement in or attainment of working capital levels; (xviii) economic value added (or an equivalent metric); (xix) market share; (xx) cash flow; (xxi) cash flow per share; (xxii) share price performance; (xxiii) debt reduction; (xxiv) implementation or completion of projects or processes; (xxv) customer satisfaction; (xxvi) stockholders’ equity; (xxvii) capital expenditures; (xxviii) debt levels; (xxix) operating profit or net operating profit; (xxx) workforce diversity; (xxxi) growth of net income or operating income; (xxxii) billings; and (xxxiii) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board.

(ll) “Performance Goals” means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated Performance Goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; and (5) to exclude the effects of any items that are unusual in nature or occur infrequently as determined under generally accepted accounting principles.

(mm) “Performance Period” means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(nn) “Performance Stock Award” means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(oo) “Plan” means this MannKind Corporation 2013 Equity Incentive Plan, as it may be amended from time to time.

(pp) “Restricted Stock Award” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(qq) “Restricted Stock Award Agreement” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(rr) “Restricted Stock Unit Award” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(ss) “Restricted Stock Unit Award Agreement” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(tt) “Retirement” means a Participant’s voluntary termination of Continuous Service after the Participant attains age fifty-five (55).

(uu) “Rule 16b-3” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(vv) “Rule 405” means Rule 405 promulgated under the Securities Act.

(ww) “Rule 701” means Rule 701 promulgated under the Securities Act.

(xx) “Securities Act” means the Securities Act of 1933, as amended.

(yy) “Stock Appreciation Right” or “SAR” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(zz) “Stock Appreciation Right Agreement” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(aaa) “Stock Award” means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

(bbb) “Stock Award Agreement” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ccc) “Subsidiary” means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

(ddd) “Ten Percent Stockholder” means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate.

(eee) “Transaction” means a Corporate Transaction or a Change in Control.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

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

I, Matthew J. Pfeffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended June 30, 2016 of MannKind Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusion about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2016

/s/ MATTHEW J. PFEFFER

Matthew J. Pfeffer

Chief Executive Officer and Chief Financial Officer

CERTIFICATION OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
RULE 13a-14(b) OR 15d-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AND SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (18 U.S.C. § 1350)

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended June 30, 2016, as filed with the Securities and Exchange Commission on or about the date hereof to which this certification is attached as Exhibit 32 (the "Report") and pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Matthew J. Pfeffer, Chief Executive Officer and Chief Financial Officer of MannKind Corporation (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2016

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

/s/ Matthew J. Pfeffer

Matthew J. Pfeffer

Chief Executive Officer and Chief Financial Officer

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