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

Form 10-Q

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

For the quarterly period ended June 30, 2014

Or

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

For the transition period from _____ to _____.

Commission file number: 000-50865

MannKind Corporation
(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
28903 North Avenue Paine Valencia, California	**91355**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

As of August 4, 2014, there were 402,380,752 shares of the registrant’s common stock, $0.01 par value per share, outstanding.

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MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended June 30, 2014

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AFREZZA®, MedTone® and Technosphere® are our registered trademarks in the United States. We have also applied for and have registered company trademarks in other jurisdictions, including Europe and Japan.

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

	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,214	$ 70,790
Prepaid expenses and other current assets	3,696	5,485
Total current assets	44,910	76,275
Property and equipment — net	183,533	176,557
State research and development credit exchange receivable	463	298
Other assets	7,400	5,516
Total	$ 236,306	$ 258,646
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 5,086	$ 3,860
Accrued expenses and other current liabilities	20,579	21,634
Facility financing obligation	37,744	102,300
Share-based compensation liability	55,824	—
Total current liabilities	119,233	127,794
Senior convertible notes	98,889	98,439
Note payable to principal stockholder	49,521	49,521
Other liabilities	15,040	13,605
Total liabilities	282,683	289,359
Commitments and contingencies		
Stockholders' equity (deficit):		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2014 and December 31, 2013	—	—
Common stock, $0.01 par value — 550,000,000 shares authorized at June 30, 2014 and December 31, 2013; 394,036,984 and 369,391,972 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	3,964	3,697
Additional paid-in capital	2,371,487	2,261,996
Accumulated other comprehensive loss	(4)	(4)
Deficit accumulated during the development stage	(2,421,824)	(2,296,402)
Total stockholders' equity (deficit)	(46,377)	(30,713)
Total	$ 236,306	$ 258,646

See notes to condensed consolidated financial statements.

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

	Three months ended June 30,		Six months ended June 30,		Cumulative period from February 14, 1991 (date of inception) to
	2014	2013	2014	2013	June 30, 2014
Revenue	$ —	$ —	$ —	$ —	$ 3,166
Operating expenses:					
Research and development	37,323	27,052	63,506	53,450	1,640,798
General and administrative	32,523	14,533	47,752	24,572	533,138
In-process research and development costs	—	—	—	—	19,726
Goodwill impairment	—	—	—	—	151,428
Total operating expenses	69,846	41,585	111,258	78,022	2,345,090
Loss from operations	(69,846)	(41,585)	(111,258)	(78,022)	(2,341,924)
Other income (expense)	(370)	15	(6,260)	38	(9,162)
Interest expense on note payable to principal stockholder	(721)	(1,689)	(1,435)	(3,378)	(46,569)
Interest expense on notes	(2,429)	(2,866)	(6,471)	(5,729)	(61,557)
Interest income	1	1	2	2	37,006
Loss before benefit for income taxes	(73,365)	(46,124)	(125,422)	(87,089)	(2,422,206)
Income tax benefit	—	—	—	—	382
Net loss	(73,365)	(46,124)	(125,422)	(87,089)	(2,421,824)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	—	—	—	—	(22,260)
Accretion on redeemable preferred stock	—	—	—	—	(952)
Net loss applicable to common stockholders	$ (73,365)	$ (46,124)	$(125,422)	$ (87,089)	$ (2,445,036)
Net loss per share applicable to common stockholders — basic and diluted	$ (0.19)	$ (0.16)	$ (0.33)	$ (0.31)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	380,770	284,044	374,810	282,062	

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	Three months ended June 30,		Six months ended June 30,		Cumulative period from February 14, 1991 (date of inception) to June 30, 2014
	2014	2013	2014	2013	
Net Loss	$(73,365)	$(46,124)	$(125,422)	$(87,089)	$ (2,421,824)
Other comprehensive loss:					
Cumulative translation (loss) gain	—	—	—	(2)	(4)
Unrealized gain (loss) on investments:					
Unrealized holding gain (loss) during the period	—	—	—	—	48
Less: reclassification adjustment for gains (losses) included in net loss	—	—	—	—	(48)
Net unrealized gain on investments	—	—	—	—	—
Other comprehensive loss	—	—	—	(2)	(4)
Comprehensive loss	$(73,365)	$(46,124)	$(125,422)	$(87,091)	$ (2,421,828)

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six months ended June 30,		Cumulative Period from February 14, 1991 (Date of Inception) to June 30, 2014
	2014	2013	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(125,422)	$(87,089)	$ (2,421,824)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and accretion	12,614	6,668	153,448
Stock-based compensation expense	51,583	15,362	234,687
Stock expense for shares issued pursuant to research agreement	—	—	3,018
(Gain) loss on sale, abandonment/disposal or impairment of property and equipment	—	686	25,070
Accrued interest on investments, net of amortization of discounts	—	—	(191)
In-process research and development	—	—	19,726
Goodwill impairment	—	—	151,428
Loss on available-for-sale securities	—	—	990
Write-off of derivative liability	(363)	—	(363)
Litigation settlement in stock	—	—	6,494
Fair value of forward purchase contract	—	—	1,237
Other, net	—	(2)	1,101
Changes in assets and liabilities:			
State research and development credit exchange receivable	(165)	(157)	(462)
Prepaid expenses and other current assets	1,789	1,337	(1,746)
Other assets	(131)	—	(361)
Accounts payable	1,567	(974)	4,914
Accrued expenses and other current liabilities	(3,315)	2,398	35,409
Other liabilities	1,435	—	2,024
Net cash used in operating activities	(60,408)	(61,771)	(1,785,401)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	—	—	(796,779)
Sales and maturities of marketable securities	—	—	796,393
Purchase of property and equipment	(9,667)	(1,591)	(345,400)
Proceeds from sale of property and equipment	—	—	454
Net cash used in investing activities	(9,667)	(1,591)	(345,332)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net of issuance costs	20,622	30,499	1,564,946
Collection of Series C convertible preferred stock subscriptions receivable	—	—	50,000
Issuance of Series B convertible preferred stock for cash	—	—	15,000
Cash received for common stock to be issued	—	—	3,900
Repurchase of common stock	—	—	(1,028)
Put shares sold to majority stockholder	—	—	623
Borrowings under lines of credit	—	—	4,220
Payment of 2013 notes	—	—	(115,000)
Proceeds from notes receivables	—	—	1,742
Proceeds from issuance of facility financing obligation & milestone rights	—	—	119,500
Proceeds from issuance of Tranche B of the facility financing obligation	20,000	—	20,000
Facility financing obligation & milestone rights issuance costs	—	—	(598)
Borrowings on notes payable to principal stockholder	—	—	387,750
Principal payments on notes payable to principal stockholder	—	—	(70,000)
Borrowings on notes payable	—	—	3,460
Principal payments on notes payable	—	—	(1,667)
Proceeds from senior convertible notes	—	—	207,050
Payment of employment taxes related to vested restricted stock units	(123)	(448)	(17,951)
Net cash provided by financing activities	40,499	30,051	2,171,947

	Six months ended June 30,		Cumulative Period from February 14, 1991 (Date of Inception) to June 30, 2014
	2014	2013	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$(29,576)	$(33,311)	$ 41,214
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	70,790	61,840	—
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 41,214	$ 28,529	$ 41,214
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$ —	$ —	$ 26
Interest paid in cash, net of amounts capitalized	5,296	5,006	77,900
Accretion on redeemable convertible preferred stock	—	—	(952)
Issuance of common stock upon conversion of notes payable	—	—	3,331
Increase in additional paid-in capital resulting from merger	—	—	171,154
Issuance of common stock for notes receivable	—	—	2,758
Issuance of common stock pursuant to conversion of facility financing obligation	93,500	—	100,000
Issuance of put option by stockholder	—	—	(2,949)
Put option redemption by stockholder	—	—	1,921
Issuance of Series C convertible preferred stock subscriptions	—	—	50,000
Issuance of Series A redeemable convertible preferred stock	—	—	4,296
Conversion of Series A redeemable convertible preferred stock	—	—	(5,248)
Non-cash construction in progress and property and equipment	2,965	4,605	2,965
Capitalization of interest on note payable to principal stockholder	—	—	22,105
Reduction of principal on note payable to principal stockholder upon issuance of common stock and exercise of warrants	—	—	290,334
Forward purchase contract contribution to APIC	—	—	29,317
Reclassification of forward purchase contract to APIC	—	—	28,080
Reclassification of share-based awards to liability	(19,926)	—	(19,926)
Tranche B Commitment Asset	1,753	—	1,753

In connection with the Company's initial public offering, all shares of Series B and Series C convertible preferred stock, in the amount of $15.0 million and $50.0 million, respectively, automatically converted into common stock in August 2004.

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
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" or the "Company"), 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, 2013 filed with the SEC on March 3, 2014 (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. Interim financial results 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 for impairment, accrued expenses, including clinical study expenses, valuation of forward purchase contracts, valuation of the facility financing obligation, commitment asset, milestone rights, 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 **—** The Company is a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes. The Company's lead product, AFREZZA (insulin human) inhalation powder, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration ("FDA") on June 27, 2014 to improve glycemic control in adult patients with diabetes.

Basis of Presentation **—** The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. It is costly to develop therapeutic products and conduct clinical studies for these products. From its inception through June 30, 2014, the Company had accumulated net losses of $2.4 billion, which include a goodwill impairment charge of $151.4 million and cumulative negative cash flow from operations of $1.8 billion. At June 30, 2014, the Company's capital resources consisted of cash and cash equivalents of $41.2 million. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

As of June 30, 2014, the Company had $30.1 million principal amount of available borrowings under its loan arrangement (the "Loan Arrangement") with The Mann Group LLC ("The Mann Group") although the Company anticipates using a portion of these available borrowings to capitalize accrued interest into principal as it becomes due and payable under the Loan Arrangement, upon mutual agreement of the parties. As of June 30, 2014, the Company had accrued $2.0 million of interest related to the Loan Arrangement.

On July 1, 2013, the Company entered into a 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"), providing for the sale of up to $160.0 million of Senior Convertible Notes due 2019 (the "2019 notes") to Deerfield in four equal tranches of $40.0 million principal amount. As of June 30, 2014, Deerfield had purchased the first three tranches of 2019 notes in the aggregate principal amount of $120.0 million leaving $40.0 million of 2019 notes unsold. On February 28, 2014, the Company entered into a First Amendment to Facility Agreement and Registration Rights Agreement (the "Amendment"). The Amendment modified the terms of the Facility Agreement to provide for the issuance of an additional tranche of notes (the "Tranche B notes") to Deerfield. Pursuant to the terms of the Amendment and the subsequent occurrence of certain events specified in the Amendment, the Company may issue to Deerfield up to $90.0 million aggregate principal amount of Tranche B notes, subject to the satisfaction of certain conditions. On May 6, 2014, Deerfield purchased $20.0 million aggregate principal amount of the potential $90.0 million Tranche B notes in accordance with the provisions of the Facility Agreement, as amended.

On July 18, 2014, Deerfield purchased the fourth and final tranche of 2019 notes in the aggregate principal amount of $40.0 million. Deerfield's obligation to purchase the fourth tranche of 2019 notes was subject to (i) the Company's receipt of marketing approval of AFREZZA from the FDA, which occurred June 27, 2014, and (ii) the shares of the Company's common stock issuable upon conversion of all previously sold 2019 notes being freely tradable pursuant to an effective registration statement filed with the SEC or pursuant to Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"). The Facility Agreement, as amended, 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. On August 11, 2014 the Company entered into a second amendment to the Facility Agreement to provide for a $175.0 million secured loan facility to be provided by an affiliate of Sanofi in connection the Sanofi License Agreement (as defined below).

Additional capital resources potentially available to the Company include proceeds from the exercise of warrants issued in its February 2012 public offering, the Company's at-the-market issuance sales agreements, and up to $70.0 million of additional sales of Tranche B notes to Deerfield (see Note 11 – Facility financing agreement).

On August 11, 2014, the Company entered into a license and collaboration agreement (the "Sanofi License Agreement") with Sanofi-Aventis Deutschland GmbH ("Sanofi") pursuant to which the Company will receive a $150.0 million upfront fee and may earn up to an aggregate of $775.0 million upon the achievement of certain development, manufacturing, regulatory and sales milestones. Worldwide profits and losses will be shared 65% by Sanofi and 35% by the Company. Pursuant to a separate supply agreement, the Company will manufacture AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product. In addition, the Company received a commitment letter from an affiliate of Sanofi to provide 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 "Sanofi Loan Facility").

Based on its current expectations, the Company believes that its existing capital resources, without considering payments under the collaboration with Sanofi, will enable it to continue planned operations at least into the first quarter of 2015. However, 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 may 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 its ongoing activities related to the commercialization of AFREZZA and the development of other product candidates. However, the Company cannot provide assurances that such additional capital will be available on favorable terms, or at all.

Fair Value of Financial Instruments **—** The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, accounts payable and accrued liabilities approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to related party, senior convertible notes, and the Facility Agreement are discussed in Note 13, "Fair Value Measurements."

Recently Issued Accounting Standards **—** In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of the new requirement did not have a significant impact on the Company's consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this ASU remove all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the removal of Topic 915, Development Stage Entities, from the FASB Accounting Standards Codification. In addition, the ASU: (a) adds an example disclosure in Topic 275, Risks and Uncertainties, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company's current activities; and (b) removes an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity. The presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-10 will have on its consolidated financial statements.

2. Accrued expenses and other current liabilities

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

	June 30, 2014	December 31, 2013
Salary and related expenses	$ 9,745	$ 12,193
Research and clinical trial costs	1,421	1,311
Accrued interest	2,396	2,082
Construction in progress	2,812	342
Other	4,205	5,706
Accrued expenses and other current liabilities	$20,579	$ 21,634

3. 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, 2014 and 2013 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Stock-based compensation	$40,644	$10,172	$51,583	$15,362

During the three months ended March 31, 2014, the Company issued stock awards to employees primarily with a four-year vesting schedule. The grant date fair value of the 46,400 restricted stock units and 17,700 stock options issued were $296,000 and $81,000, respectively, with a grant date fair value per share of $6.39 and $4.58, respectively.

During the three months ended June 30, 2014, the Company issued stock awards to employees primarily with a four-year vesting schedule as well as non-employee directors primarily with a three-year vesting schedule. The grant date fair value of the 158,600 restricted stock units and 252,600 stock options issued were $1.23 million and $1.32 million, respectively. The grant date fair value per share was $7.76 for restricted stock units, $5.31 for employee stock options and $5.22 for non-employee director stock options.

On June 30, 2014, the Company modified certain performance grants to allow 124 employees to withhold in excess of the minimum statutory requirements for performance-based restricted stock units at the employee's discretion through December 31, 2014. The modification resulted in the reclassification of these performance grants from equity awards to liability awards, which require re-measurement at the end of each reporting period through settlement. Consequently, as of June 30, 2014, the reclassification and re-measurement of these performance-based restricted stock units resulted in an increase in stock-based compensation expense of $35.9 million.

As of June 30, 2014, there was $7.5 million of unrecognized compensation cost related to options and $6.7 million and $6.9 million of unrecognized compensation cost related to equity and liability classified restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 2.03 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period. As of June 30, 2014, there were $107,000 and $3.7 million of unrecognized expenses related to performance options and restricted stock units, respectively, for milestones not considered probable of achievement.

4. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned to Bank of America, N.A. under a share lending arrangement (see Note 7 — Common and preferred stock). As of June 30, 2014, 9,000,000 shares of the Company's common stock loaned to Bank of America, N.A. pursuant to the terms of a share lending agreement as described in Note 7, were issued and are outstanding, and holders of the borrowed shares have all the rights of a holder of the Company's common stock. However, because the share borrower must return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof), the borrowed shares are not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying condensed consolidated statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 56,844,341 shares and 129,432,728 shares as of June 30, 2014 and 2013, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement.

5. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. There were no current estimated amounts receivable under the program at June 30, 2014 and December 31, 2013, respectively. Long-term estimated amounts receivable under the program were $463,000 and $298,000 at June 30, 2014 and December 31, 2013, respectively.

6. Property and equipment

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

	Estimated Useful Life (Years)	June 30, 2014	December 31, 2013
Land	—	$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	114,131	114,099
Machinery and equipment	3-15	81,960	82,189
Furniture, fixtures and office equipment	5-10	5,087	5,046
Computer equipment and software	3	11,265	11,289
Leasehold improvements	4	17	17
Construction in progress		26,651	14,756
		299,332	287,617
Less accumulated depreciation and amortization		(115,799)	(111,060)
Property and equipment — net		$ 183,533	$ 176,557

Leasehold improvements are amortized over four years which is the shorter of the term of the lease or the service lives of the improvements.

Depreciation and amortization expense related to property and equipment for the three and six months ended June 30, 2014 and 2013 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Depreciation and amortization expense	$ 2,449	$ 2,956	$4,972	$5,946

7. Common and preferred stock

The Company is authorized to issue 550,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company's board of directors. No other class of capital stock is authorized. As of June 30, 2014 and December 31, 2013, 394,036,984 and 369,391,972 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding. Included in the common stock outstanding as of June 30, 2014 and December 31, 2013 are 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 (the "2015 Notes") (see Note 10 — Senior convertible notes). Bank of America is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company on or about the 45th business day following the date as of which the entire principal amount of the 2015 notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America's option. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of $0.01 per share from Bank of America for the use of borrowed shares.

On July 1, 2013, the Company entered into the Facility Agreement with Deerfield providing for the sale of up to $160.0 million of 2019 notes to Deerfield in four equal tranches of $40.0 million principal amount.

On February 28, 2014, the Company amended the Facility Agreement to, among other things, allow Deerfield, subject to certain limitations, to convert up to an additional $60.0 million principal amount under the then-outstanding 2019 notes into the Company's common stock after the effective date of the Amendment. The Company also agreed to register for resale up to 12,000,000 shares of common stock issuable upon conversion of the outstanding 2019 notes, with a minimum conversion price of $5.00 per share unless the Company otherwise consents. The conversion price was determined by the average of the volume weighted average prices per share during the three trading days immediately preceding the election to convert. As of June 30, 2014, Deerfield had converted $100.0 million of 2019 notes into the Company's common stock (see Note 11 – Facility financing agreement) and no additional principal amount of the 2019 notes is convertible.

8. 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.

***Litigation* —** The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of the date hereof, 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. The Company maintains liability insurance coverage to protect the Company's assets from losses arising out of or involving activities associated with ongoing and normal business operations. In accordance with ASC 450 *Contingencies*, the Company would record 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.

***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 certain rights (the "Milestone 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 (see Note 11 – Facility financing agreement).

9. Related-party arrangements

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. The Loan Arrangement has been amended from time to time. On October 31, 2013, the promissory note underlying the 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 Loan Arrangement to December 31, 2019, increase the aggregate borrowing amount under the Loan Arrangement from $350.0 million to $370.0 million and provide that repayments or cancellations of principal under the Loan Arrangement will not be available for reborrowing.

As of June 30, 2014, the total principal amount outstanding under the 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, 2014, the Company had accrued $2.0 million of interest in other liabilities related to the Loan Arrangement. The Mann Group can require the Company to prepay up to $200.0 million in advances that have been outstanding for at least 12 months (less approximately $105.0 million aggregate principal amount that has been cancelled in connection with two common stock purchase agreements). If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice (or the number of days to maturity of the note if less than 90 days) to prepay such advances. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. In addition, The Mann Group entered into a

subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under the 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 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 Loan Arrangement are unsecured. The Loan Arrangement contains no financial covenants.

During the six months ended June 30, 2014, there were no additional borrowings under or amendments to the Loan Arrangement.

10. Senior convertible notes

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

	June 30, 2014	December 31, 2013
2015 notes		
Principal amount	$100,000	$ 100,000
Unaccreted debt issuance expense	(1,111)	(1,561)
Net carrying amount	$ 98,889	$ 98,439

On August 18, 2010, the Company completed a Rule 144A offering of $100.0 million aggregate principal amount of 2015 notes. The 2015 notes are governed by the terms of an indenture dated as of August 24, 2010 (the "2015 Note Indenture"). The 2015 notes bear interest at the rate of 5.75% per year on the principal amount, payable in cash semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2011. In connection with the 2015 notes, the Company had accrued interest of $2.4 million and $2.4 million as of June 30, 2014 and December 31, 2013, respectively. The 2015 notes are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company's secured debt, to the extent of the value of the assets securing such debt and to the debt and all other liabilities of the Company's subsidiaries. The maturity date of the 2015 notes is August 15, 2015 and payment is due in full on that date for unconverted securities. Holders of the 2015 notes may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding principal into shares of the Company's common stock at an initial conversion rate of 147.0859 shares per $1,000 principal amount, which is equal to a conversion price of approximately $6.80 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the 2015 notes converted in connection with a fundamental change by increasing the conversion rate on such 2015 notes, which amount, if any, will be based on the Company's common stock price and the effective date of the fundamental change, and (2) each holder of 2015 notes will have the option to require the Company to repurchase all or any portion of such holder's 2015 notes at a repurchase price of 100% of the principal amount of the 2015 notes to be repurchased plus accrued and unpaid interest, if any. The Company may elect to redeem some or all of the 2015 notes if the closing stock price has equaled 150% of the conversion price for at least 20 of the 30 consecutive trading days ending on the trading day before the Company's redemption notice. The redemption price will equal 100% of the principal amount of the 2015 notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, plus a make-whole payment equal to the sum of the present values of the remaining scheduled interest payments through and including August 15, 2015 (other than interest accrued up to, but excluding, the redemption date). The Company will be obligated to make the make-whole payment on all the 2015 notes called for redemption and converted during the period from the date the Company mailed the notice of redemption to and including the redemption date. The Company may elect to make the make-whole payment in cash or shares of its common stock, subject to certain limitations. Under the terms of the 2015 Note Indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the contract, 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 contract period under other existing commitments. Applying the Company's sequencing policy, the Company performed an analysis at the time of the offering of the 2015 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 contract period under existing commitments.

The Company incurred approximately $4.2 million in issuance costs which are recorded as an offset to the 2015 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 2015 notes.

The 2015 notes provide that upon an acceleration of certain indebtedness, including the 2019 notes and the Tranche B notes described in Note 11, the holders may elect to accelerate the Company's repayment obligations under the 2015 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.

Accretion of debt issuance expense in connection with the 2015 notes during the three and six months ended June 30, 2014 and 2013 were as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Accretion expense	$ 227	$ 212	$ 450	$ 421

11. Facility financing agreement

The significant activity related to the facility financing agreement during the six months ended June 30, 2014 consist of the following (in thousands):

	June 30, 2014
Facility financing obligation	
Carrying value at December 31, 2013	$102,300
Principal converted to equity	(93,500)
Accretion of debt discount and debt issuance expense	7,191
Adjustment to debt discount related to modification of the 2019 notes	2,921
Tranche B principal amount	20,000
Debt discount related to Tranche B purchase	(1,168)
Net carrying value of facility financing obligation	$ 37,744
Commitment Asset	
Commitment asset fair value balance at December 31,2013	$ 5,157
Tranche B commitment asset fair value	2,921
Less commitment asset portion associated with the receipt of Tranche B notes	(1,168)
Commitment asset value included in other assets	$ 6,910

Accretion of debt issuance cost and debt discount in connection with the facility financing agreement during the three and six months ended June 30, 2014 are as follows (in thousands):

	Three months ended June 30, 2014	Six months ended June 30, 2014
Accretion expense- debt issuance cost	$ 27	$ 309
Accretion expense- debt discount	$ 516	$ 6,883

On July 1, 2013, the Company entered into the Facility Agreement providing for the sale of up to $160.0 million of 2019 notes to Deerfield in four equal tranches of $40.0 million principal amount. The 2019 notes accrue interest at a rate of 9.75% per annum until maturity in 2019 or their earlier repayment, repurchase, or conversion. As of June 30, 2014, Deerfield had purchased the first three tranches of 2019 notes in the aggregate principal amount of $120.0 million. Deerfield's obligation to purchase the fourth tranche of the 2019 notes was subject to (i) the Company's receipt of marketing approval of AFREZZA from the FDA, which occurred on June 27, 2014, and (ii) the shares of the Company's common stock issuable upon conversion of all previously sold 2019 notes being freely tradable pursuant to an effective registration statement filed with the SEC or pursuant to Rule 144 under the Securities Act. Subsequent to June 30, 2014, on July 18, 2014, Deerfield purchased the fourth tranche of 2019 notes in the aggregate principal amount of $40.0 million (See Note 14 — Subsequent Events).

On February 28, 2014, the Company entered into the Amendment, which modified the terms of the Facility Agreement to provide for the issuance of Tranche B notes to Deerfield. Pursuant to the terms of the Amendment and the subsequent occurrence of certain events specified in the Amendment, the Company may issue to Deerfield up to $90.0 million aggregate principal amount of Tranche B notes. The Tranche B notes bear interest at the rate of 9.75% per year, subject to reduction to 8.75% if the Company enters into a

collaboration with a third party to commercialize AFREZZA, on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The Company is required to repay 25% of the original principal amount of any Tranche B notes on the third, fourth, fifth and sixth anniversaries of the applicable issue dates of such notes, provided that the entire outstanding principal amount of all Tranche B notes will become due and payable no later than December 31, 2019. The Tranche B notes can be prepaid without penalty or premium commencing two years after issuance thereof. On May 6, 2014, Deerfield purchased an aggregate principal amount of $20.0 million in Tranche B notes in accordance with the provisions of the Facility Agreement, as amended.

In addition, pursuant to the Amendment, the outstanding first tranche of 2019 notes (the "Tranche 1 notes") and third tranche of 2019 notes (the "Tranche 3 notes") held by Deerfield were amended and restated to permit Deerfield to convert up to an additional $60.0 million principal amount under such 2019 notes into the Company's common stock after the effective date of the Amendment. The Company also agreed to register for resale up to 12,000,000 shares of the Company's common stock issuable upon conversion of the outstanding 2019 notes, as amended and restated, as of the date of the Amendment. In March 2014, Deerfield elected to convert the full $40.0 million of outstanding principal amount of the Tranche 3 notes and $12.5 million principal amount of the Tranche 1 notes. In April 2014, Deerfield elected to convert the remaining $7.5 million principal amount of the Tranche 1 notes.

On August 11, 2014 the Company entered into a second amendment to the Facility Agreement to permit for the Sanofi Loan Facility.

Milestone Rights

In connection with the execution of the Facility Agreement, on July 1, 2013, the Company issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures. The payments due under the Milestone Rights are subject to pro rata reduction in the event of certain funding failures by Deerfield under the Facility Agreement.

The Milestone Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to AFREZZA. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement.

The 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, 2014, there have been no material changes to facts and circumstances that would impact the valuation or classification of the Milestone Rights.

Commitment Asset

In connection with the issuance of the Tranche 1 notes and the Milestone Rights, the Company recorded a commitment asset (the "Commitment Asset"), on July 1, 2013. As a result of the Amendment, the Company recorded an additional commitment asset with an estimated fair value equal to $2.9 million. The Commitment Asset remaining as of June 30, 2014 represented the right to receive $40.0 million funding under tranche 4 of the 2019 notes (the "Tranche 4 Notes") and up to $70.0 million of funding remaining under the Facility Agreement, as amended, from the sale of the Tranche B notes. The Commitment Asset is derecognized and recorded as a debt discount on the 2019 notes and Tranche B notes when issued and amortized using the effective interest rate method over the life of the respective notes. Prior to derecognition occurring, the Company monitors the Commitment Asset on an ongoing basis to determine whether an impairment indicator is present that would result in a full or partial write down of the Commitment Asset as a result of events that may lead to the subsequent tranches of notes not being issued. Based on the monitoring procedures performed through June 30, 2014, the Company did not identify any indicators of impairment.

Amendment to the outstanding Tranche 1 notes and Tranche 3 notes

The amendment and restatement of the outstanding Tranche 1 notes and Tranche 3 notes, pursuant to the Amendment, did not represent a troubled debt restructuring of the 2019 notes because the Amendment did not result in Deerfield granting a concession to the Company. In addition, the Amendment did not result in a substantial modification to the terms of the Tranche 1 notes and Tranche 3 notes.

The impact of the Amendment to the Tranche 1 notes and Tranche 3 notes is being accounted for as a prospective yield adjustment. Specifically, the value of the Tranche B notes commitment asset (the "Tranche B Commitment Asset") was considered a fee received from the creditor as consideration for the Amendment and is being amortized as an adjustment of interest expense over the remaining term of the Tranche 1 notes and Tranche 3 notes using the effective interest method. Further, the value of the Tranche B Commitment Asset, which decreased the amount of debt discount in the Tranche 1 notes and Tranche 3 notes, was allocated between the Tranche 1 notes and Tranche 3 notes in a manner which resulted in the Tranche 1 notes and Tranche 3 notes having a new effective interest rate of 11.63%.

Conversion Option

For accounting purposes, the Company evaluated the embedded conversion option in the 2019 notes as a redemption feature because the number of shares issuable upon conversion was based on the volume weighted average prices for specified periods prior to the conversion date (as opposed to being fixed). Accordingly, conversions by Deerfield were treated as redemptions of the 2019 notes and, the Company analyzed whether the conversion option required bifurcation as an embedded redemption feature.

As of December 31, 2013, Deerfield had converted $6.5 million principal amount of the second tranche of the 2019 notes (the "Tranche 2 notes") for equity, resulting in an issuance of 1,293,224 shares of the Company's common stock. Upon the conversion, the principal balance of the notes were recorded in equity and an expense was recognized in the Statement of Operations in the amount of $0.6 million for the difference between the principal amount of the notes converted and their carrying amount (which included unamortized discount and debt issuance costs).

During January 2014, Deerfield elected to convert the remaining $33.5 million of Tranche 2 notes, which resulted in the issuance of 6,559,251 shares of the Company's common stock. During the six months ended June 30, 2014, the Company recorded an expense of $3.0 million for the difference between the principal amount of the notes converted and their carrying amount (which included unamortized discount and debt issuance costs).

In March 2014, following the Amendment, which allowed Deerfield to convert up to an additional $60.0 million principal amount under the outstanding Tranche 1 notes and Tranche 3 notes, Deerfield elected to convert the full $40.0 million of outstanding principal amount of the Tranche 3 notes and $12.5 million of principal amount of the Tranche 1 notes, pursuant to which the Company issued Deerfield 7,121,120 and 2,142,709 shares of the Company's common stock, respectively. As a result of these conversions, the Company recorded the principal balance of the notes in equity and an expense of $3.0 million for the difference between the principal amount of the notes converted and their carrying amount (which included the unamortized discount and debt issuance costs) and the write-off of the derivative liability that was previously bifurcated from the Tranche 3 notes.

In April 2014, Deerfield elected to convert the remaining $7.5 million principal amount of the Tranche 1 notes, pursuant to which the Company issued Deerfield 1,500,000 shares of the Company's common stock. As a result of this conversion, the Company recorded the principal amount being converted under the Tranche 1 notes in equity and an expense of $0.4 million for the difference between the principal amount of the notes converted and their carrying amount (which included the unamortized discount and debt issuance costs).

Further, upon Deerfield converting the remaining $7.5 million principal amount of the Tranche 1 notes, the full $60.0 million principal amount of the Tranche 1 notes and Tranche 3 notes that Deerfield was permitted to convert pursuant to the Amendment was converted. Therefore, as of June 30, 2014, no additional principal amount of the 2019 notes is convertible.

12. Income taxes

As required by ASC 740 *Income Taxes* ("ASC 740"), management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded, in accordance with the applicable accounting standards, that net deferred tax assets should be fully reserved.

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

13. 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, 2014 and December 31, 2013, the Company held $41.2 million and $70.8 million, respectively, of cash and cash equivalents, consisting primarily of money market funds of $41.1 million and $67.7 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).

The following is a summary of the carrying values and estimated fair values of the 2015 notes and the facility financing obligation (i.e., the 2019 notes and Tranche B notes) (in millions):

	June 30, 2014		December 31, 2013	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2015 notes	$ 98.9	$ 161.2	$ 98.4	$ 102.2
Facility financing obligation	$ 37.7	$ 38.0	$ 102.3	$ 107.0

Senior Convertible Notes

The estimated fair value of the 2015 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company's stock price, and non-observable, such as the Company's longer-term historical volatility, which was estimated to be 85% (Level 3 in the fair value hierarchy). As there is no current observable market for the 2015 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 outflows with market-based assumptions regarding risk-adjusted yields, stock price volatility and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible.

Facility financing agreement

As discussed in Note 11 — Facility financing agreement, in connection with the Facility Agreement, the Company issued 2019 notes and Milestone Rights and recorded the Commitment Asset on July 1, 2013. In addition, on February 28, 2014, the Company entered into the Amendment, and recorded an additional commitment asset, which represented the increase in borrowing capacity that the Company received as consideration for the modifications made to the Facility Agreement and the Tranche 1 notes and Tranche 3 notes. 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 of 12.7% at December 31, 2013 for the 2019 notes and a selected market discount rate of 11.9% at the inception of the Tranche B notes (Level 3 in the fair value hierarchy). On June 30, 2014, the market discount rate was recalculated at 12.4% for the Tranche 1 notes and 12.3% for the Tranche B notes. The Tranche 2 and Tranche 3 notes were fully converted by the end of the first quarter of 2014.

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 (17.5%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data.

The fair value of the Commitment Asset was estimated using the income approach by estimating the fair value of the future tranches using a market debt rate (12.0%) commensurate with the risk of the future tranches and the fair value of the cash expected to be received by the Company and assessing the probability of the commitments being funded in the future based on the operational hurdles required for funding being met (Level 3 in the fair value hierarchy).

At June 30, 2014, as there had been no material changes to the established estimates, the carrying value of the Milestone Rights and Commitment Asset approximates their respective estimated fair values.

The fair value of the Commitment Asset was estimated using a discounted cash flow analysis under the income approach. Specifically, the fair value of the additional Tranche B Commitment Asset was determined by estimating the fair value of the future tranche using a market yield (11.9%) commensurate with the risk of the future tranche and the fair value of the cash expected to be received by the Company and assessing the probability of the commitment being funded in the future based on the operational hurdles required for funding being met as well as consideration of alternative funding options (Level 3 in the fair value hierarchy). As of February 28, 2014, the additional commitment asset was valued at $2.9 million.

On May 6, 2014, Deerfield purchased $20.0 million aggregate principal amount of Tranche B notes in accordance with the provisions of the Facility Agreement, as amended. Accordingly, the $1.2 million portion of the Commitment Asset associated with the $20.0 million purchased was derecognized and recorded as debt discount on the Tranche B notes. Consequently, the remaining carrying value of the Tranche B Commitment Asset was $1.8 million. At June 30, 2014, as there have been no material changes to the established estimates, the carrying value of the Tranche B Commitment Asset approximates its respective estimated fair value.

There were no material re-measurements to fair value during the six months ended June 30, 2014 and 2013 of financial assets and liabilities that are not measured at fair value on a recurring basis. There were no transfers of assets or liabilities between the fair value measurement levels during the six months ended June 30, 2014 and 2013.

14. Subsequent Events

Facility Agreement

On July 18, 2014, following receipt of approval of AFFREZZA® from the FDA on June 27, 2014 and the satisfaction of certain other conditions, Deerfield purchased the Tranche 4 notes, which constituted the fourth and final tranche of 2019 notes, in the aggregate principal amount of $40.0 million in accordance with the terms of the Facility Agreement.

On August 11, 2014 the Company entered into a second amendment to the Facility Agreement to provide for the Sanofi Loan Facility.

Supply Agreement with Amphastar

On July 31, 2014, the Company entered into a Supply Agreement with Amphastar France Pharmaceuticals S.A.S., a French corporation (“Amphastar”), pursuant to which Amphastar will manufacture for and supply to the Company certain quantities of recombinant human insulin (“Insulin”) for use in AFREZZA. Under the terms of the Supply Agreement, Amphastar will be responsible for manufacturing the Insulin in accordance with the Company’s specifications and agreed-upon quality standards. The Company has agreed to purchase annual minimum quantities of Insulin under the Supply Agreement of an aggregate of approximately €120.1 million in calendar years 2015 through 2019. The Company may request to purchase additional quantities of Insulin over such annual minimum quantities.

Unless earlier terminated, the term of the 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 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 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.

License and Collaboration Agreement with SANOFI-AVENTIS Deutschland GmbH

On August 11, 2014, the Company entered into the Sanofi License Agreement pursuant to which it will receive $150.0 million upfront fee and may earn potential payments of up to an aggregate of $775.0 million upon the achievement of certain development, manufacturing, regulatory and sales milestones. Worldwide profits and losses will be shared 65% by Sanofi and 35% by the Company. Pursuant to a separate supply agreement, the Company will manufacture AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi’s demand for the product. In addition, the Company received a commitment letter from an affiliate of Sanofi to provide 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 commitment letter provides that our obligations under the Sanofi Loan Facility would be secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located at our facility in Danbury, Connecticut 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 commitment is subject to customary conditions, including the effectiveness of the Sanofi License Agreement, the finalization of loan documentation and the entry into satisfactory intercreditor agreement with Deerfield.

The effectiveness of the Sanofi License Agreement and the Supply Agreement is contingent upon satisfaction of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the entry into the definitive loan documents relating to the Sanofi Loan Facility (unless we terminate the commitment letter for the Sanofi Loan Facility).

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

The following discussion contains forward-looking statements, which involve risks and uncertainties. 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, 2013 and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K, or 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 and development of therapeutic products for diseases such as diabetes. Our only approved product, AFREZZA, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration, or FDA, on June 27, 2014 to improve glycemic control in adult patients with diabetes. On August 11, 2014, we entered into a license and collaboration agreement, or the Sanofi License Agreement, with Sanofi-Aventis Deutschland GmbH, or Sanofi, pursuant to which Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. MannKind will manufacture AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product. In addition, the companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary. In connection with the Sanofi License Agreement, we received a commitment letter from an affiliate of Sanofi to provide us with a secured loan facility, or the Sanofi Loan Facility, of up to $175.0 million to fund our share of net losses under the Sanofi License Agreement.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of June 30, 2014, we have incurred a cumulative net loss of $2.4 billion and have stockholders' deficit of $46.4 million. To date, we have not generated any product revenues and have funded our operations through the sale of equity securities and convertible debt securities; through our facility agreement, or the Facility Agreement, with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P., referred to collectively as Deerfield; and through borrowings under our loan arrangement with The Mann Group LLC, or the Loan Arrangement. As discussed below in "Liquidity and Capital Resources," if we are unable to obtain additional funding in the future, there will continue to be substantial doubt about our ability to continue as a going concern.

We and our marketing partner, Sanofi, have not yet begun to commercialize AFREZZA. We currently do not have the required approvals to market any of our other product candidates, and we may not receive such approvals. We may not be able to achieve positive cash flow from operations even if we succeed in commercializing our product candidates. We expect to make substantial expenditures and to incur additional operating losses for at least the next several years as we:

- support the launch of AFREZZA through our marketing partner;
- expand our manufacturing capabilities as dictated by the growth in demand for AFREZZA; and
- develop additional applications of our proprietary Technosphere formulation technology for the pulmonary delivery of other drugs.

Our business is subject to significant risks, including but not limited to the risks inherent in our potential inability to support the commercialization of AFREZZA in a timely manner. Additional significant risks also include the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, 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 and related activities. This staff is located in our facilities in Valencia, California; Paramus, New Jersey; and Danbury, Connecticut. We expense research and development costs as we incur them.

Clinical development timelines, likelihood of success and total costs vary widely. To date, we have focused on advancing AFREZZA through regulatory approval.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates other than AFREZZA, which was recently approved by the FDA, we are unable to estimate with any certainty the costs that we will incur in the continued development of our product candidates.

GENERAL AND ADMINISTRATIVE EXPENSES

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

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 our Annual Report on Form 10-K for the year ended December 31, 2013. There have been no material changes to our critical accounting policies during the three and six months ended June 30, 2014.

Recently Issued Accounting Standards — In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of the new requirement did not have a significant impact on the Company's consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this ASU remove all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the removal of Topic 915, Development Stage Entities, from the FASB Accounting Standards Codification. In addition, the ASU: (a) adds an example disclosure in Topic 275, Risks and Uncertainties, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company's current activities; and (b) removes an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity. The presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-10 will have on our consolidated financial statements.

RESULTS OF OPERATIONS

Three and six months ended June 30, 2014 and 2013

Revenue

We did not recognize any revenue for the six months ended June 30, 2014 or 2013. We do not anticipate sales of any product prior to the commercialization of AFREZZA.

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, 2014 and 2013 (dollars in thousands):

	Three months ended June 30,			
	2014	2013	$ Change	% Change
Clinical	$ 6,736	$10,978	$ (4,242)	(39%)
Manufacturing	11,102	9,724	1,378	14%
Research	1,769	1,773	(4)	0%
Research and development tax credit	(83)	(78)	(5)	(6%)
Stock-based compensation expense	17,799	4,655	13,144	282%
Research and development expenses	$37,323	$27,052	$10,271	38%

	Six months ended June 30,			
	2014	2013	$ Change	% Change
Clinical	$15,915	$24,260	$ (8,345)	(34%)
Manufacturing	21,850	19,114	2,736	14%
Research	3,259	3,089	170	6%
Research and development tax credit	(166)	(156)	(10)	(6%)
Stock-based compensation expense	22,648	7,143	15,505	217%
Research and development expenses	$63,506	$53,450	$10,056	19%

The increase in research and development expenses for the three months ended June 30, 2014 compared to the three months ended June 30, 2013 was primarily due to an increase of $13.1 million in stock-based compensation expense resulting from the modification of the settlement terms, or the Modification, for certain performance-based restricted stock units on June 30, 2014. The Modification resulted in the reclassification of these performance grants from equity awards to liability awards, which required re-measurement on the modification date and resulted in incremental stock-based compensation expense. The increase is also due to increased manufacturing spending of $1.4 million for supply and non-capital spare parts purchases related to commercialization preparation. These increases were partially offset by a decrease of $4.2 million in clinical spending as a result of the completion of two Phase 3 studies in the second quarter of 2013.

The increase in overall research and development expenses for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, was primarily due to an increase of $15.5 million in stock-based compensation expense resulting from the Modification. In addition, manufacturing spending increased $2.7 million due to supply and non-capital spare parts purchases related to commercialization preparation. These increases were offset by an $8.3 million decrease in clinical spending as a result of the completion of two Phase 3 studies in the second quarter of 2013.

We anticipate our overall research and development expenses will increase in 2014 compared to 2013 due to the ongoing preparation for the commercialization of AFREZZA and increased stock compensation expense.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the three and six months ended June 30, 2014 and 2013 (dollars in thousands):

	Three months ended June 30,			
	2014	2013	$ Change	% Change
Salaries and employee related expenses	$ 4,602	$ 4,298	$ 304	7%
Professional fees and other general expenses	5,076	4,718	358	8%
Stock-based compensation expense	22,845	5,517	17,328	314%
General and administrative expenses	$32,523	$14,533	$17,990	124%

	Six months ended June 30,			
	2014	2013	$ Change	% Change
Salaries and employee related expenses	$ 8,669	$ 7,734	$ 935	12%
Professional fees and other general expenses	10,149	8,620	1,529	18%
Stock-based compensation expense	28,934	8,218	20,716	252%
General and administrative expenses	$47,752	$24,572	$23,180	94%

General and administrative expenses for the three months ended June 30, 2014 increased compared to the three months ended June 30, 2013 primarily due to an increase in stock-based compensation expense of $17.3 million resulting from the Modification.

General and administrative expenses for the six months ended June 30, 2014 increased compared to the six months ended June 30, 2013 primarily due to an increase of $20.7 million in stock-based compensation driven by the Modification and legal and consulting fees increased by $1.5 million due to costs associated with financing, related filings, and other legal matters.

We expect general and administrative expenses overall to be higher in 2014 as compared to 2013 as a result of increased stock compensation expense.

Other Income (Expense)

Other income was $15,000 for the three months ended June 30, 2013 and other expense was $0.4 million for the three months ended June 30, 2014. Other income was $37,710 for the six months ended June 30, 2013 and other expense was $6.3 million for the six months ended June 30, 2014. Other expense of $0.4 million for the three months ended June 30, 2014 was the unamortized discount and debt issuance costs upon conversion of the remaining amount available of the Tranche 1 notes. Other expense of $6.4 million for the six months ended June 30, 2014 was the unamortized discount and debt issuance costs upon conversion of the remaining balance of the Tranche 2 notes, the full conversion of the Tranche 3 notes, and the partial conversion of the Tranche 1 notes.

Interest Income and Expense

Interest expense decreased by $1.4 million from the three months ended June 30, 2013 compared to the three months ended June 30, 2014 and by $1.2 million from the six months ended June 30, 2013 compared to the six months ended June 30, 2014. The decrease for the three and six months ended June 30, 2014 was due to a lower carrying value in 2014 on the Loan Arrangement with The Mann Group and the repayment of the Senior Convertible Notes due 2013 on December 9, 2013.

LIQUIDITY AND CAPITAL RESOURCES

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

As of June 30, 2014, the total principal amount outstanding under the Loan Arrangement was $49.5 million, and the amount available for future borrowings was $30.1 million. We anticipate using a portion of these available borrowings to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under the Loan Arrangement.

On July 1, 2013, we entered into the Facility Agreement with Deerfield providing for the sale of up to $160.0 million of 9.75% Senior Convertible Notes due 2019, or the 2019 notes in four equal tranches of $40.0 million principal amount.

As of June 30, 2014, Deerfield had purchased the first three tranches of 2019 notes in the aggregate principal amount of $120.0 million leaving $40.0 million of the 2019 notes unsold. Subsequent to June 30, 2014, Deerfield purchased the fourth tranche of 2019 notes in the aggregate principal amount of $40.0 million.

On February 28, 2014, we amended the Facility Agreement to provide for the issuance of an additional tranche of notes, or the Tranche B notes, to Deerfield. Pursuant to the terms of the amendment and the subsequent occurrence of certain events specified in

the amendment, we may issue to Deerfield up to $90.0 million aggregate principal amount of Tranche B notes, subject to the satisfaction of certain conditions. The Tranche B notes bear interest at the rate of 9.75% per year, subject to reduction to 8.75% if we enter into a collaboration with a third party to commercialize AFREZZA, on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The amended Facility Agreement also provided Deerfield with the option, subject to certain limitations, to convert up to an additional $60.0 million of the 2019 notes issued and outstanding on the date of the amendment into shares of our common stock following the effective date of the amendment.

On April 2, 2014, Deerfield elected to convert an aggregate of $7.5 million of principal amount of the outstanding first tranche of the 2019 notes, or the Tranche 1 notes, pursuant to which we issued Deerfield 1,500,000 shares of our common stock. As a result of this election, Deerfield has fully exercised the conversion option under the Facility Agreement, as amended, by converting the additional $60.0 million of the Tranche 1 notes and the outstanding third tranche of the 2019 notes, or the Tranche 3 notes, allowable into 10,763,829 shares of our common stock in the aggregate.

In March 2014, we entered into an At-The-Market Issuance Sales Agreement with MLV & Co. LLC, or MLV, and an At-The-Market Issuance Sales Agreement with Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.), or Brinson Patrick. We refer to the foregoing agreements as the “ATM Agreements.” Under each ATM Agreement, we may issue or sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through MLV or Brinson Patrick, as our sales agents, provided in no event may we sell more than $50.0 million of common stock under both agreements in the aggregate. We expect that all or substantially all sales of our common stock made under the ATM Agreements will be made in “at the market” offerings as defined in Rule 415 of the Securities Act. We have not yet sold or issued any shares of our common stock under the ATM Agreements. There can be no assurance that we will be able to access capital through the ATM Agreements on a timely basis, or at all.

During the six months ended June 30, 2014, we used $60.4 million of cash for our operations and had a net loss of $125.4 million, which included $64.2 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. By comparison, during the six months ended June 30, 2013, we used $61.8 million of cash for our operations and had a net loss of $87.1 million, which included $22.0 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. The operating cash outflow decreased by $1.4 million primarily due to a decrease in accrued interest associated with our Loan Arrangement with The Mann Group partially offset by increases in accrued interest related to other financing arrangements. We expect our negative operating cash flow to continue at least until we achieve commercialization of AFREZZA.

We used $9.7 million of cash for investing activities during the six months ended June 30, 2014, compared to $1.6 million for the six months ended June 30, 2013. The $8.1 million increase was primarily due to $9.7 million in purchases of machinery and equipment for the preparation for commercialization of AFREZZA.

Our financing activities generated $40.5 million of cash for the six months ended June 30, 2014, compared to positive cash flow of $30.1 million for the six months ended June 30, 2013. Cash provided by financing activities during the six months ended June 30, 2014 was comprised of $20.0 million from the sale of Tranche B notes to Deerfield, $14.1 million from warrant exercises, and $6.5 million from the exercise of stock options. For the six months ended June 30, 2013, cash provided by financing activities was primarily from $28.3 million in warrant exercises.

As of June 30, 2014, we had $41.2 million in cash and cash equivalents. We believe that our existing capital resources will enable us to continue planned operations at least into the first quarter of 2015. However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of the capital resources more rapidly than we currently anticipate. We may 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 related to the commercialization of AFREZZA and the development of other product candidates. However, we cannot provide assurances that such additional capital will be available through these or other means.

We intend to use our capital resources to support the commercialization of AFREZZA. We are expending a portion of our capital resources to scale up our manufacturing capabilities in our Danbury facilities and to develop our other product candidates. We also intend to use our capital resources for general corporate purposes.

On August 11, 2014, we entered into the Sanofi License Agreement with Sanofi pursuant to which we will receive a $150.0 million upfront fee and may earn potential payments of up to an aggregate of $775.0 million upon the achievement of certain development, manufacturing, regulatory and sales milestones. Worldwide profits and losses will be shared 65% by Sanofi and 35% by us. Pursuant to a separate supply agreement, the Company will manufacture AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi’s demand for the product. In addition, we received a commitment letter from an affiliate of Sanofi to provide us with a secured loan facility of up to $175.0 million to fund our share of net losses under the Sanofi License Agreement. On August 11, 2014, we entered into a second amendment to the Facility Agreement to provide for the $175.0 million secured loan facility to be provided by an affiliate of Sanofi in connection the Sanofi License Agreement.

If we enter into strategic business collaborations with respect to our other product candidates, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to

pursue the sale of equity and/or debt securities, including sales of our common stock through the ATM Agreements, or the establishment of other funding facilities, including the Sanofi Loan Facility. 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, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

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

Contractual Obligations and Commitments

As of June 30, 2014, there were no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as contained in our Annual Report. However, subsequent to June 30, 2014, we incurred additional contractual obligations pursuant to the issuance of the fourth tranche of $40.0 million aggregate principal amount of 2019 notes to Deerfield on July 28, 2014 and the entry into our supply agreement with Amphastar on July 31, 2014, which contains annual minimum purchase obligations of an aggregate of approximately €120.1 million in calendar years 2015 through 2019. We also expect to incur additional contractual obligations pursuant to the Sanofi Loan Facility.

Off-Balance Sheet Arrangements

As of June 30, 2014, we did not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Due to the fixed interest rates of our debt, we do not currently have any exposure to changes in our interest expense as a result of changes in interest rates. The interest rate on amounts borrowed under our loan arrangement with The Mann Group for the year ended December 31, 2013 and the six months ended June 30, 2014 was a fixed rate equal to 5.84%. As of December 31, 2013, the total principal amount outstanding under the Loan Arrangement was $49.5 million. We also have debt related to our 5.75% Senior Convertible Notes due 2015, or 2015 notes, at a fixed interest rate of 5.75% and debt related to the Facility Agreement at a fixed interest rate of 9.75%.

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 10% change in interest rates were to have occurred June 30, 2014, 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.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive and financial officers, 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, 2014. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2014, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management determined that, as of June 30, 2014, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

Item 1A. *Risk Factors*

You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors previously disclosed in Item 1A to our Annual Report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

RISKS RELATED TO OUR BUSINESS

We depend heavily on the successful commercialization of our only approved product, AFREZZA.*

To date, we have not commercialized any product candidates. We have expended significant time, money and effort in the development of our only approved product, AFREZZA, which was approved by the FDA on June 27, 2014 to improve glycemic control in adult patients with diabetes. Our other product candidates are generally in early clinical or preclinical development. We anticipate that in the near term, our ability to generate revenues will depend on the successful commercialization of AFREZZA in the United States, which we have not yet begun to commercialize. On August 11, 2014, we entered into the Sanofi License Agreement pursuant to which Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. MannKind will manufacture Afrezza at its manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product. In addition, the companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary. We must receive the necessary approvals from foreign regulatory agencies before AFREZZA can be marketed outside of the United States.

Even with regulatory approval, we and our marketing partner, Sanofi, 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. If we fail to commercialize AFREZZA successfully, our business, financial condition and results of operations will be materially and adversely affected.

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.

A significant portion of the research that we have conducted involves new compounds and 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 successfully commercialize AFREZZA or develop our other product candidates, or if we are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

If Sanofi does not perform satisfactorily under the Sanofi License Agreement or if our collaboration fails, commercialization of AFREZZA may be delayed and our business could be harmed.*

We have entered into the Sanofi License Agreement to provide for the future development and commercialization of AFREZZA. However, the effectiveness of the Sanofi License Agreement and the related supply agreement is contingent upon satisfaction of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR, and the entry into the definitive loan documents relating to the Sanofi Loan Facility (unless the Company terminates the commitment letter for the Sanofi Loan Facility). There can be no assurance that the HSR conditions will be satisfied and the Sanofi License Agreement may never become effective. If the Sanofi License Agreement does not become effective, our requirements for capital could substantially increase and our commercialization prospects, financial condition and business could be materially harmed. If the Sanofi License Agreement becomes effective, we will have less control over the timing, planning and other aspects of our post-marketing clinical studies, and the sale and marketing of AFREZZA. Sanofi may enter into arrangements that would make it a potential competitor. Sanofi also may breach its agreement with us, exercise at-will termination rights or fail to perform under the agreements, which could delay our progress or harm our business.

We have a history of operating losses, we expect to continue to incur losses and we may never generate positive cash flow from operations.*

We have never been profitable or generated positive cash flow from operations and, as of June 30, 2014, we had incurred a cumulative net loss of $2.4 billion. The cumulative net loss 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 support the commercialization of AFREZZA, including costs and expenses to manufacture AFREZZA on a commercial scale. In addition, we have agreed to purchase annual minimum quantities of Insulin under our supply agreement with Amphastar of an aggregate of approximately €120.1 million in calendar years 2015 through 2019. We may not have the necessary capital resources on hand in order to service this contractual commitment, and we may become obligated to make additional payments under the supply agreement in the event of its termination under certain scenarios. Our cumulative net loss may therefore increase significantly. 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, 2014, we had stockholders' deficit of $46.4 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends upon successfully commercializing AFREZZA in collaboration with our marketing partner. We may not generate positive cash flow from operations or be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

We will be required 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.*

Based on our current expectations, we believe that our existing capital resources will enable us to continue planned operations at least into the first quarter of 2015. We cannot assure you 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. We may 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 related to the commercialization of AFREZZA and the development of other product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. As of June 30, 2014, we had stockholders' deficit of $46.4 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 election of any or all of the holders of the 2015 notes or the 2019 notes to require us to repay or repurchase such notes if and when required;
- our ability to refinance existing indebtedness, including indebtedness under the 2015 notes which mature in August 2015;
- the extent to which the 2015 notes are converted into shares of our common stock;
- 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 Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL, referred to collectively as the Milestone Purchasers pursuant to our Milestone Rights Purchase Agreement dated July 1, 2013, or the Milestone Agreement;
- our obligation to bear our share of net losses under the Sanofi License Agreement;
- our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;
- our degree of success in commercializing AFREZZA;
- actions taken by the FDA and other regulatory authorities affecting AFREZZA and our product candidates and competitive products;
- the costs of preparing applications for regulatory approvals for our product candidates, either ourselves or with any commercialization partner;
- 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. We may in the future pursue the sale of additional equity and/or debt securities, including sales of our common stock through the ATM Agreements, 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 may 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 may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we will 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, investors in our stock may lose the entire value of their investment.

We do not anticipate generating operating cash flow prior to commercial launch of AFREZZA, and therefore cannot provide assurances that changed or unexpected circumstances, including, among other things, delays in manufacturing on a commercial scale, will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we may 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 planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financings or entering into strategic business collaborations, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there will be continued substantial doubt about our ability to continue as a going concern.

We have a substantial amount of debt pursuant to our 2015 notes, 2019 notes and Tranche B notes, we may incur additional indebtedness in connection with the Sanofi and may be unable to make required payments of interest and principal as they become due.*

As of June 30, 2014, we had $140.0 million of outstanding debt pursuant to our 2015 notes and 2019 notes, consisting of:

- $100.0 million principal amount of 2015 notes bearing interest at 5.75% per annum and maturing on August 15, 2015;
- $20.0 million principal amount of 2019 notes bearing interest at 9.75% per annum and maturing between 2016 and July 1, 2019; and
- $20.0 million principal amount of Tranche B notes bearing interest at 9.75% per annum and maturing between 2017 and December 31, 2019.

We may incur up to an additional $70.0 million principal amount of indebtedness under the Facility Agreement pursuant to the issuance of additional Tranche B notes to Deerfield. In addition, we received a commitment letter from an affiliate of Sanofi to provide the Sanofi Loan Facility, the proceeds of which would be used by us to fund our share of net losses under the Sanofi License Agreement.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2015 notes, 2019 notes or, Tranche B notes when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2015 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 notes will have the option to require us to repurchase all or any portion of such notes at a repurchase price of 100% of the principal amount of such notes to be repurchased plus accrued and unpaid interest, if any. The 2015 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, and the 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The Tranche B notes bear interest at the rate of 9.75% per year, subject to reduction to 8.75% if we enter into a collaboration with a third party to commercialize AFREZZA, on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. We expect that loans under the Sanofi Loan Facility will bear interest at a rate of 8.5% per annum, paid-in-kind on a quarterly basis (2.06% per quarter compounded). 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 2015 notes, 2019 notes or Tranche B notes, or if we fail to repay or repurchase the 2015 notes, 2019 notes or Tranche B notes when required, we will be in default under the indenture or other applicable instrument for such note(s), 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 the agreements governing the Sanofi Loan Agreement is expected to contain, covenants that we may not be able to meet and place restrictions on our operating and financial flexibility.*

Our indebtedness under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes and any additional indebtedness we incur as the result of our sale of additional Tranche B notes is 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 certain mortgages on our facilities in Danbury, Connecticut and Valencia, California, with the mortgage on our facility in Valencia, California expected to be released as a result of issuance of fourth tranche of the 2019 notes. The commitment letter relating to the Sanofi Loan Facility provides that our obligations under the Sanofi Loan Facility will be secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located at our facility in Danbury, Connecticut and any contractual rights and obligations pursuant to which we purchases 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 our loan arrangement with The Mann Group, falling below $25.0 million as of the last day of any fiscal quarter. 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. The agreements governing the Sanofi Loan Facility are expected to include customary representations, warranties and covenants, including restrictions on our ability to incur additional indebtedness and grant certain liens.

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, if we obtain the Sanofi Loan Facility, 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 appointed 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. 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 2015 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 2015 notes, 2019 notes and Tranche B notes and if we obtain the Sanofi Loan Facility, 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 debt would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business will be harmed and the market price of our common stock 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 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 will 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 announce and expect (or within the timeframes expected by analysts or investors), our business and results of operations will be harmed and the market price of our common stock may decline.

We may not be able to compete successfully, and AFREZZA may be rendered obsolete by rapid technological change.*

A number of established pharmaceutical companies have or are developing technologies for the treatment of diabetes.

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 and AFREZZA less competitive, uneconomical or obsolete. Our future success will depend not only on our ability to develop our product candidates but to improve them and keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

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

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

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical studies or in much larger populations may not be consistent with the earlier clinical results. For example, with the approval of AFREZZA, the FDA has required a five-year, randomized, controlled trial in 8,000 -10,000 patients with type 2 diabetes, the primary objective of which is to compare the incidence of pulmonary malignancy observed with AFREZZA to that observed in a standard of care control group. If long-term use of a drug results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our 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 and results of operations and the market price of our common stock may decline.

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

For AFREZZA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA's current Good Manufacturing Practices, or cGMPs for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with Quality System Regulations, or 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. Any such events could delay market introduction and subsequent sales of AFREZZA and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

We have never manufactured AFREZZA in commercial quantities, and if we fail to develop an effective manufacturing capability or to engage third-party manufacturers with this capability, we may be unable to commercialize 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 will utilize a contract packager to do the final kitting and cartoning of foil pouched blisters containing cartridges, as well as inhalers and the package insert. Although the Danbury facility has been qualified and undergone two inspections by the FDA, our facility may need to undergo further inspection before we can distribute AFREZZA commercially. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to effectively commercialize AFREZZA. 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 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 any 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 our other product candidates 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 our other product candidates will depend on many factors, including the:

- approved labeling claims;
- effectiveness of our or our third party collaborator(s) efforts 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 any other product that we get approved may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of AFREZZA or our other product candidates and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of our marketing partner for AFREZZA, Sanofi, 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 reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for AFREZZA and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We would 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 one or 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 EU 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 are 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 our 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. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, 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 drug-device combination products;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- 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 beginning in 2014 and by adding new mandatory eligibility categories for certain 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 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, with reporting to the Centers for Medicare & Medicaid Services, or CMS, required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and 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.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. 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. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or 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. These new laws 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 fail 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 pertaining to fraud and abuse and patients' rights are and will be applicable to our business. 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:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, 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 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 third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 liability insurance in the amount of $10.0 million. In addition, we carry local policies per study in each country in which we conduct clinical studies that require us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales of AFREZZA. However, we may not be able to obtain insurance coverage that will 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 and results of operations would be harmed and the market price of our common stock 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. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel on acceptable terms, if at all.

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

We have relationships with scientific advisors at academic and other institutions to conduct research or assist us in formulating our research, development or clinical strategy. These scientific advisors are not our employees and may have commitments to, and other obligations with, other entities that may limit their availability to us. We have limited control over the activities of these scientific advisors and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our programs could harm our business. In addition, these advisors are not prohibited from, and may have arrangements with, other companies to assist those companies in developing technologies that may compete with AFREZZA or our product candidates.

If our Chairman and Chief Executive Officer is unable to devote sufficient time and attention to our business, our operations and our ability to execute our business strategy could be materially harmed.

Alfred Mann, our Chairman and Chief Executive Officer, is involved in many other business and charitable activities. As a result, the time and attention Mr. Mann devotes to the operation of our business varies, and he may not expend the same time or focus on our activities as other, similarly situated chief executive officers. If Mr. Mann is unable to devote the time and attention necessary to running our business, we may not be able to execute our business strategy and our business could be materially harmed.

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

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. In addition, we are headquartered in Valencia, California. This facility contains our principal executive offices and is used to provide support for the development of our Technosphere technology programs. 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 and adversely affect, which may include stopping, our readiness for commercial production.

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 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 $4.0 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 and results of operations may be harmed.

RISKS RELATED TO GOVERNMENT REGULATION

Our product candidates must undergo costly and time-consuming rigorous nonclinical and clinical testing and we must obtain regulatory approval prior to the sale and marketing of any product in each jurisdiction. The results of this testing or issues that develop in the review and approval by a regulatory agency may subject us to unanticipated delays or prevent us from marketing any products.*

Our research and development activities, as well as the manufacturing and marketing of AFREZZA and our product candidates, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulations of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

- product design, development, manufacture and testing;
- product labeling;
- product storage and shipping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

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

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

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

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to criminal prosecution, fined or forced to remove a product from the market 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 is requiring the following post-marketing studies for AFREZZA:

- a clinical trial to evaluate pharmacokinetics, safety and efficacy in pediatric patients;
- 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);
- two pharmacokinetic-pharmacodynamic studies, one to characterize dose-response and one to characterize within-subject variability.

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 and results of operations will be harmed and the market price of our common stock may decline.

We are subject to stringent, ongoing government regulation.*

The manufacture, marketing and sale of AFREZZA are subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning the safety or efficacy of a product appear following approval. We cannot be sure that FDA and United States Congressional initiatives or actions by foreign regulatory bodies pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

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 and results of operations.

Our suppliers will be subject to FDA inspection.*

When 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. We also depend on suppliers for other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements including QSR, and is subject to inspection by the FDA. There can be no assurance, in the conduct of an inspection of any of our suppliers that the agency 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.

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 our other product candidates.*

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 and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company's products or product candidates.

There are also a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical studies could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business and results of operations and cause the market price of our common stock 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 our AFREZZA inhalation powder expired in 2012. Other patents providing similar protection have terms extending into 2020, 2030 and 2031. 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.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted, subjected to post-grant challenge, and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO is continuing to develop regulations and procedures to govern administration of the Leahy-Smith Act, and while all of the substantive changes to patent law associated with the Leahy-Smith Act have become effective, many changes have only recently become effective. Moreover there will be a transitional period of many years during which some applications may be eligible for prosecution under the previous rules. There are many ambiguities in this new law and how the courts will interpret it cannot be

predicted with confidence. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, patent law continues to evolve. Several further changes to patent law are before Congress. The United States Supreme Court has exhibited an increased interest in patent law and several of its recent decisions have tended to narrow the scope of patentable subject matter related to medical products and methods. In March 2014 the USPTO, in response to Supreme Court decisions, issued new examination guidelines which call into question the patentability of biological inventions that had previously been considered patentable. While none of this has an immediately apparent impact on our core technology and patents, the full and ultimate effect of these developments is not yet known. We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these 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. 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 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.

Biotechnology patents are numerous and may, at times, conflict with one another. As a result, it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner’s patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry.

Patent lawsuits can be expensive and would consume time and other resources. There is a risk that a court would decide that we are infringing a third party’s patents and would order us to stop the activities covered by the patents, including the commercialization of our products. In addition, there is a risk that we would have to pay the other party damages for having violated the other party’s patents (which damages may be increased, as well as attorneys’ fees ordered paid, if infringement is found to be willful), or that we will be required to obtain a license from the other party in order to continue to commercialize the affected products, or to design our products in a manner that does not infringe a valid patent. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms or at all, requiring cessation of activities that were found to infringe a valid patent. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Moreover, certain components of AFREZZA may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B), or a 337 action, with the International Trade Commission, or 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 relating to pulmonary insulin delivery that may trigger an allegation of infringement upon 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 would be harmed and our profitability could be materially 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 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 and results of operations and cause the market price of our common stock 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 all of our potential trade names for our product candidates in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. 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

Our stock price is volatile.

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- the progress and results of our clinical studies;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us 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 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;
- the existence of, and the issuance of shares of our common stock pursuant to, the share lending agreement and the short sales of our common stock effected in connection with the sale of our 2015 notes;
- the conversion of any of our 2015 notes into shares of our common stock; 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 price of our common stock to decline.

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

Public companies in general and companies included on the NASDAQ Global Market in particular have experienced extreme 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 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.

Our Chairman and Chief Executive Officer and principal stockholder can individually control our direction and policies, and his interests may be adverse to the interests of our other stockholders. After his death, his stock will be left to his funding foundations for distribution to various charities, and we cannot assure you of the manner in which those entities will manage their holdings.*

At June 30, 2014, our Chairman and Chief Executive Officer, Alfred E. Mann beneficially owned 38.7% of our outstanding shares of capital stock. By virtue of his holdings, Mr. Mann may be able to continue to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

Subject to compliance with United States federal and state securities laws, Mr. Mann is free to sell the shares of our stock he holds at any time. Upon his death, we have been advised by Mr. Mann that his shares of our capital stock will be left to the Alfred E. Mann Medical Research Organization, or AEMMRO, and AEM Foundation for Biomedical Engineering, or AEMFBE, not-for-profit medical research foundations that serve as funding organizations for Mr. Mann's various charities, including the Alfred Mann Foundation, or AMF, and the Alfred Mann Institutes at the University of Southern California, the Technion-Israel Institute of Technology, and Purdue University, and that may serve as funding organizations for any other charities that he may establish. The AEMMRO is a membership foundation consisting of six members, including Mr. Mann, his wife, three of his children and Dr. Joseph Schulman, the chief scientist of the AEMFBE. The AEMFBE is a membership foundation consisting of five members, including Mr. Mann, his wife, and the same three of his children. Although we understand that the members of AEMMRO and AEMFBE have been advised of Mr. Mann's objectives for these foundations, once Mr. Mann's shares of our capital stock become the property of the foundations, we cannot assure you as to how those shares will be distributed or how they will be voted.

The future sale of our common stock, the conversion of our 2015 notes into common stock or the exercise of our warrants for common stock could negatively affect our stock price.*

As of August 4, 2014, we had 402,380,752 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 may decline. Likewise the issuance of additional shares of our common stock upon the conversion of some or all of our 2015 notes, or upon the exercise of some or all of the warrants we issued in February 2012, could adversely affect the trading price of our common stock. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

In addition, we may need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities, including through the ATM Agreements, or additional convertible debt, the market price of our common stock may decline and our existing stockholders may experience significant dilution.

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. 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 your investment.

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. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of your investment in our common stock.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. OTHER INFORMATION

On August 11, 2014, we entered into the Sanofi License Agreement pursuant to which we granted to Sanofi exclusive, worldwide licenses to certain of our patents, trademarks and know-how for the development and commercialization of AFREZZA.

Under the terms of the Sanofi License Agreement, upon effectiveness of the Sanofi License Agreement, Sanofi will have the exclusive right and responsibility to develop AFREZZA worldwide, subject to certain development activities that will be performed by us. Sanofi will also be obligated to use commercially reasonable efforts to file for, obtain and maintain marketing approvals for AFREZZA in certain major markets and countries. In addition, Sanofi will have exclusive, worldwide rights to commercialize AFREZZA and will be obligated to use commercially reasonable efforts to market, promote and commercialize AFREZZA in all countries in the world where regulatory approval for AFREZZA has been received. Pursuant to the terms of a separate supply agreement that we entered into with Sanofi concurrently with the Sanofi License Agreement, we will be responsible for the manufacture and supply to Sanofi of its requirements of AFREZZA.

In consideration for the rights granted to Sanofi by us under the Sanofi License Agreement, upon effectiveness of the Sanofi License Agreement, we will receive an upfront payment of $150.0 million. If certain manufacturing, regulatory and sales milestones are achieved, we will also eligible to receive up to $775.0 million in milestone payments, of which $75.0 million in milestone payments relate to certain development and manufacturing milestone events, $50.0 million in milestone payments relate to the filing and completion of regulatory approvals and $650.0 million in milestone payments relate to the achievement of certain product sales milestones. In addition, worldwide profits and losses be shared 65% by Sanofi and 35% by us.

Under the terms of the Sanofi License Agreement, we granted to Sanofi a right of first negotiation in the event we propose to grant to any third party a license to develop or exploit an inhaled glucagon-like peptide-1 agonist. In addition, if our board of directors determines to pursue a change of control of MannKind, we will be required notify Sanofi of such determination within a certain period of time so that Sanofi may, at is discretion, negotiate with us for a potential acquisition of MannKind by Sanofi.

In addition, we received a commitment letter from an affiliate of Sanofi to provide the Sanofi Loan Facility. The commitment letter provides for a $175.0 million secured revolving loan facility to fund our share of net losses under the Sanofi License Agreement. Pursuant to the commitment letter, loans under the Sanofi Loan Facility would bear interest at a rate of 8.5% per annum, paid-in-kind on a quarterly basis (2.06% per quarter compounded) and would become due and payable in full on the tenth anniversary of the effective date of the Sanofi License Agreement. We would be required to prepay any loans with net profits received under the Sanofi License Agreement. The commitment letter provides that our obligations under the Sanofi Loan Facility would be secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located at our facility in Danbury, Connecticut 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 commitment is subject to customary conditions, including the effectiveness of the Sanofi License Agreement, the finalization of loan documentation and the entry into satisfactory intercreditor agreement with Deerfield.

The effectiveness of the Sanofi License Agreement and the Supply Agreement is contingent upon satisfaction of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the entry into the definitive loan documents relating to the Sanofi Loan Facility (unless we terminate the commitment letter for the Sanofi Loan Facility).

The Sanofi License Agreement will remain in effect unless either party terminates the Sanofi License Agreement in accordance with its terms. Either party may terminate the Sanofi License Agreement for a material breach the other party if such breach remains uncured for 90 days, or 45 days in the case of a non-payment breach; provided that if Sanofi breaches the Sanofi License Agreement for failure to comply with its obligation to use commercially reasonable efforts to file for, obtain and maintain regulatory approval for AFREZZA in certain major markets and countries and to market, promote and commercialize AFREZZA in countries where regulatory approval has been received, as set forth in the Sanofi License Agreement, with respect to (i) the United States, we may terminate the Sanofi License Agreement in its entirety, and (ii) certain major markets or countries, we may terminate the Sanofi License Agreement only with respect to such markets or countries and not in its entirety. Either party may also terminate the Sanofi License Agreement upon written notice to the other party in the event of the other party's insolvency. Sanofi may terminate the Sanofi License Agreement at any time on or after January 1, 2016 (a) upon 90 days' written notice if Sanofi determines in good faith that the commercialization of AFREZZA is no longer economically viable in the United States, and (b) without cause upon six months' written notice in its entirety or on a country-by-country basis other than with respect to the United States, subject to certain exceptions. In addition, Sanofi may terminate the Sanofi License Agreement on a country-by-country basis upon 30 days' written notice for certain safety or regulatory reasons.

On August 11, 2014 we entered into a second amendment to the Facility Agreement to provide for the Sanofi Loan Facility.

The foregoing description is only a summary of the Sanofi License Agreement and the second amendment to the Facility Agreement and is qualified in its entirety by the terms of the Sanofi License Agreement and the second amendment to the Facility Agreement, copies of which will be filed as exhibits to our

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.5 to MannKind's Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2007).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to MannKind's Quarterly report on Form 10-Q (File No. 000-50865), originally filed with the SEC on August 2, 2010).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 4, 2011).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 24, 2012).
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
4.1	Form of common stock certificate (incorporated by reference to Exhibit 4.4 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 18, 2013).
4.2	Registration Rights Agreement, dated October 15, 1998 by and among CTL Immuno Therapies Corp., Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended (incorporated by reference to Exhibit 4.2 to MannKind's Registration Statement on Form S-1 (File No. 333-115020), filed with the SEC on April 30, 2004, as amended).
4.3	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), y filed with the SEC on August 24, 2010).
4.4	Form of 5.75% Senior Convertible Note due 2015 (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 August 24, 2010).
4.5	Form of Warrant to Purchase Common Stock issued February 8, 2012 (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 February 6, 2012).
4.6	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (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 July 1, 2013).
4.7	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.8	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. 000-50865), filed with the SEC on May 12, 2014).
4.9	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.10	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.11	Registration Rights Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.5 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.12	Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).

Exhibit Number	Description of Document
4.13	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.12 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

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 11, 2014

MANNKIND CORPORATION

By: /s/ MATTHEW J. PFEFFER

Matthew J. Pfeffer

Corporate Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

I, Alfred E. Mann, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended June 30, 2014 of MannKind Corporation;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2014

/s/ Alfred E. Mann

Alfred E. Mann
Chairman of the Board of Directors and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

I, Matthew J. Pfeffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended June 30, 2014 of MannKind Corporation;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2014

/s/ Matthew J. Pfeffer

Matthew J. Pfeffer
Corporate Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32

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

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended June 30, 2014, 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), Alfred E. Mann, Chairman of the Board of Directors and Chief Executive Officer of the Company, and Matthew J. Pfeffer, Corporate Vice President and Chief Financial Officer of the Company, each 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 11, 2014

In witness whereof, the undersigned have set their hands hereto as of the 11th day of August 2014.

/s/ Alfred E. Mann	/s/ Matthew J. Pfeffer
Alfred E. Mann	Matthew J. Pfeffer
Chairman of the Board of Directors and Chief Executive Officer	Corporate Vice President and Chief Financial Officer

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.