MANNKIND CORP
Form 10-Q
November 10, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 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 x No ¨

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

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

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

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

As of November 3, 2014, there were 405,699,862 shares of the registrant s common stock, $0.01 par value per share, outstanding.

Table of Contents

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended September 30, 2014

TABLE OF CONTENTS

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.

Table of Contents

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)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 172,465	$ 70,790
State research and development tax credit exchange receivable current	803	
Prepaid expenses and other current assets	20,253	5,485
Total current assets	193,521	76,275
Property and equipment net	190,923	176,557
State research and development credit exchange receivable	260	298
Other assets	2,114	5,516
Total	$ 386,818	$ 258,646
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 17,389	$ 3,860
Accrued expenses and other current liabilities	27,269	21,634
Facility financing obligation		102,300
Senior convertible notes current	99,120	
Deferred up-front payment from collaboration agreement	150,000	
Total current liabilities	293,778	127,794
Facility financing obligation	72,625	
Senior convertible notes		98,439
Note payable to principal stockholder	49,521	49,521
Other liabilities	11,572	13,605
Total liabilities	427,496	289,359

Commitments and contingencies

Stockholders deficit:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2014 and December 31, 2013		
Common stock, $0.01 par value 550,000,000 shares authorized at September 30, 2014 and December 31, 2013; 405,469,034 and 369,391,972 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	4,055	3,697
Additional paid-in capital	2,413,621	2,261,996
Accumulated other comprehensive loss	(11)	(4)
Deficit accumulated during the development stage	(2,458,343)	(2,296,402)
Total stockholders deficit	(40,678)	(30,713)
Total	$ 386,818	$ 258,646

See notes to condensed consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30, 2014
	2014	2013	2014	2013	
Revenue	$	$	$	$	$ 3,166
Operating expenses:					
Research and development	19,178	27,281	82,684	80,731	1,659,976
General and administrative	19,088	17,481	66,840	42,053	552,226
In-process research and development costs					19,726
Goodwill impairment					151,428
Total operating expenses	38,266	44,762	149,524	122,784	2,383,356
Loss from operations	(38,266)	(44,762)	(149,524)	(122,784)	(2,380,190)
Other income (expense)	7,898	10	1,638	48	(1,264)
Interest expense on note payable to principal stockholder	(729)	(1,745)	(2,164)	(5,123)	(47,298)
Interest expense on notes	(5,424)	(4,323)	(11,895)	(10,052)	(66,981)
Interest income	1	2	4	4	37,008
Loss before benefit for income taxes	(36,520)	(50,818)	(161,941)	(137,907)	(2,458,725)
Income tax benefit					382
Net loss	(36,520)	(50,818)	(161,941)	(137,907)	(2,458,343)
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	$ (36,520)	$ (50,818)	$ (161,941)	$ (137,907)	$ (2,481,555)
Net loss per share applicable to common stockholders basic and diluted	$ (0.09)	$ (0.17)	$ (0.42)	$ (0.48)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	394,163	296,386	381,332	286,889	

See notes to condensed consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30, 2014
	2014	2013	2014	2013	
Net Loss	$ (36,520)	$ (50,818)	$ (161,941)	$ (137,907)	$ (2,458,343)
Other comprehensive loss:					
Cumulative translation (loss) gain	(7)	(1)	(7)	(3)	(11)
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	(7)	(1)	(7)	(3)	(11)
Comprehensive loss	$ (36,527)	$ (50,819)	$ (161,948)	$ (137,910)	$ (2,458,354)

See notes to condensed consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine months ended September 30,		Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2014
	2014	2013	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (161,941)	$ (137,907)	$ (2,458,343)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and accretion	15,574	10,109	156,408
Stock-based compensation expense	46,755	31,304	229,859
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)
Income from sale of intellectual property	(9,250)		(9,250)
Litigation settlement in stock			6,494
Fair value of forward purchase contract			1,237
Interest expense related to milestone payment	1,850		1,850
Other, net	(7)	(3)	1,094
Changes in assets and liabilities:			
State research and development credit exchange receivable	(765)	242	(1,062)
Prepaid expenses and other current assets	(14,768)	(708)	(18,303)
Other assets	(130)		(360)
Accounts payable	13,692	(1,929)	17,039
Accrued expenses and other current liabilities	(3,003)	3,525	35,721
Deferred up-front payment from collaboration agreement	150,000		150,000
Other liabilities	2,186		2,775

Net cash provided by (used in) operating activities	39,830	(94,681)	(1,685,163)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities			(796,779)
Sales and maturities of marketable securities			796,393
Purchase of property and equipment	(19,134)	(1,821)	(354,867)
Proceeds from sale of intellectual property	9,250		9,250
Proceeds from sale of property and equipment			454
Net cash used in investing activities	(9,884)	(1,821)	(345,549)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net of issuance costs	38,573	51,658	1,582,897
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	40,000	79,500	159,500
Proceeds from issuance of Tranche B of the facility financing obligation	20,000		20,000
Facility financing obligation & milestone rights issuance costs		(598)	(598)
Borrowings on notes payable to principal stockholder			387,750
Principal payments on notes payable to principal stockholder			(70,000)

Table of Contents

	Nine months ended September 30,		Cumulative Period from February 14, 1991 (Date of Inception) to
	2014	2013	September 30, 2014
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	(26,844)	(2,095)	(44,672)
Net cash provided by financing activities	71,729	128,465	2,203,177
NET INCREASE IN CASH AND CASH EQUIVALENTS	$ 101,675	$ 31,963	$ 172,465
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	70,790	61,840	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 172,465	$ 93,803	$ 172,465
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 26
Interest paid in cash, net of amounts capitalized	9,740	7,862	82,344
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	3,809	5,523	3,089
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	22,963		22,963
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.

Table of Contents

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 September 30, 2014, the Company had accumulated net losses of $2.5 billion, which include cumulative negative cash flow from operations of $1.7 billion and a goodwill impairment charge of $151.4 million.

On August 11, 2014, the Company entered into a license and collaboration agreement (the Sanofi License Agreement) with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement

to Sanofi-Aventis U.S. LLC (Sanofi)), pursuant to which Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. Under the Sanofi License Agreement, the Company received a $150.0 million up-front 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 with respect to AFREZZA will be shared 65% by Sanofi and 35% by the Company. Pursuant to a supply agreement, the Company will manufacture AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi s demand for the product. The Sanofi License Agreement became effective on September 23, 2014 following completion of the U.S. Federal Trade Commission s review of the transactions contemplated by the Sanofi License Agreement under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the Hart-Scott-Rodino Act) and the completion of documentation related to the $175.0 million secured loan facility being provided to the Company by an affiliate of Sanofi (the Sanofi Loan Facility) to fund the Company s share of net losses under the Sanofi License Agreement.

At September 30, 2014, the Company s capital resources consisted of cash and cash equivalents of $172.5 million. The Company expects to continue to incur significant expenditures to support commercial launch of AFREZZA and the development of other product candidates as contemplated under the Sanofi License Agreement. In addition, the Company s 5.75% Senior Convertible Notes due 2015 (the 2015 notes) in the aggregate principal amount of $100.0 million have a maturity date of August 15, 2015, and payment on the outstanding amount is due in full on that date (see Note 10 Senior convertible notes).

Table of Contents

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. Additional funding sources that are, or in certain circumstances may be available to the Company, include approximately $30.1 million principal amount of available borrowings under its loan arrangement (the Loan Arrangement) with The Mann Group LLC (The Mann Group) (see note 9 Related-party arrangements), potential proceeds from the exercise of warrants issued in its February 2012 public offering of approximately $20 million, the Company s at-the-market issuance sales agreements which allow the Company to sell up to $50 million in common stock, and pursuant to the facility agreement (the Facility Agreement) with Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design International II, L.P. (collectively, Deerfield) and the First Amendment to Facility Agreement and Registration Rights Agreement (the First Amendment) additional sales of an additional tranche of notes (the Tranche B notes) of up to $70 million which must be purchased prior to December 30, 2014 (see Note 11 Facility Agreement).

Although we believe that our existing cash and cash equivalents and available debt financing will be sufficient to finance our operational cash needs through at least the next twelve months, should our results not meet our current operating plan, it could negatively impact our liquidity and we may need to raise additional capital or seek additional financing sources as discussed above. There can be no assurance that we would be able to raise such additional financing or additional capital on acceptable terms, or at all, and if we are not able to raise adequate additional financing or capital to continue to fund our ongoing operations, we will need to defer, reduce or eliminate significant planned expenditures or significantly curtail our operations, and there may be substantial doubt about our ability to continue as a going concern.

Prepaid expenses and other current assets Prepaid expenses and other current assets primarily consist of prepaid expenses for goods and services to be received. As of September 30, 2014, prepaid and other current assets had a balance of $20.3 million, mainly comprised of a $15.0 million prepayment for 2015 quantities of insulin, prepaid insurance, and prepaid clinical trial expenses.

On July 31, 2014, the Company entered into a Supply Agreement (the 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 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. As part of the Supply Agreement, the Company paid a $15.0 million deposit to Amphastar as prepayment for 2015 quantities of insulin.

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

Table of Contents

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.

Sale of intellectual property On July 18, 2014, the Company entered into an assignment agreement with a third party whereby the third party acquired all proprietary rights, technology and know-how that related to a small molecule inhibitor compound and all pre-clinical data and results related thereto. Under the terms of the assignment agreement, the Company received total consideration of $9.3 million, which was offset by $1.4 million of expense associated with the sale of the intellectual property related to oncology.

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 elements of the Facility Agreement are discussed in Note 13, Fair value of financial instruments.

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 May 2014, a new standard was issued related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective on January 1, 2017. Early adoption is not permitted. The new standard allows for either full retrospective adoption, whereby the new standard is applied to each prior reporting period presented or modified retrospective adoption, whereby the new standard is only applied to the most current period presented with the cumulative effect of the change recognized at the date of the initial application. The Company is assessing the potential impact of the new standard on its consolidated statements of financial position and results of operations and comprehensive income (loss) and has not yet selected a transition method.

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 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.

On August 27, 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-15 will have on its consolidated financial statements.

Table of Contents

2. Accrued expenses and other current liabilities

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

	September 30, 2014	December 31, 2013
Salary and related expenses	$ 10,287	$ 12,193
Research and clinical trial costs	1,011	1,311
Accrued interest	958	2,082
Construction in progress	2,739	342
Other	12,274	5,706
Accrued expenses and other current liabilities	$ 27,269	$ 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 nine months ended September 30, 2014 and 2013 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Stock-based compensation	$ (4,827)	$ 15,943	$ 46,755	$ 31,304

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.

During the three months ended September 30, 2014, the performance shares related to the modification settled. The performance grants were re-measured on their respective settlement dates, which resulted in a credit to stock

compensation expense of $12.9 million. As of September 30, 2014, there were no remaining liability awards.

During the three months ended September 30, 2014, the Company issued stock awards to employees primarily with a four-year vesting schedule. The grant date fair value of the 720,000 restricted stock units and 1,053,900 stock options issued were $5.1 million and $4.9 million, respectively, with a grant date fair value per share of $7.09 and $4.66, respectively.

As of September 30, 2014, there was $10.3 million of unrecognized compensation cost related to options and $12.5 million of unrecognized compensation cost related to restricted stock units, which are expected to be recognized over the remaining weighted average vesting period of 3.0 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 September 30, 2014, there were no awards with milestones not considered probable of achievement.

Table of Contents

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 September 30, 2014, 9,000,000 shares of the Company s common stock loaned to Bank of America pursuant to the terms of a share lending agreement as described in Note 7, were issued and are outstanding, and the holder of the borrowed shares has 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 47,820,744 shares and 133,944,425 shares as of September 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. Current estimated amounts receivable under the program were $803,000 at September 30, 2014, and there was no current portion at December 31, 2013. Long-term estimated amounts receivable under the program were $260,000 and $298,000 at September 30, 2014 and December 31, 2013, respectively.

6. Property and equipment

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

	Estimated Useful Life (Years)	September 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	82,068	82,189
Furniture, fixtures and office equipment	5-10	5,087	5,046
Computer equipment and software	3	11,335	11,289
Leasehold improvements	4	17	17
Construction in progress		36,214	14,756

	309,073	287,617
Less accumulated depreciation and amortization	(118,150)	(111,060)
Property and equipment net	$ 190,923	$ 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 nine months ended September 30, 2014 and 2013 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Depreciation and amortization expense	$ 2,414	$ 2,874	$ 7,386	$ 8,820

Table of Contents

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 September 30, 2014 and December 31, 2013, 405,469,034 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 September 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 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 First 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 September 30, 2014, Deerfield had converted $100.0 million of 2019 notes into 18,616,304 shares of the Company s common stock which resulted in total expense of $6.4 million for the nine months ended September 30, 2014 and $0.6 million for the twelve months ended December 31, 2013 for the difference between the principal amount of the notes converted and their carrying amount (see Note 11 Facility Agreement). No additional principal amount of 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 in the United States and the achievement of specified net sales figures (see Note 11 Facility 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.

Table of Contents

As of September 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 upon mutual agreement of both parties and would be classified as non-current. As of September 30, 2014, the Company had accrued $2.8 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 nine months ended September 30, 2014, there were no additional borrowings under or amendments to the Loan Arrangement.

10. Senior convertible notes

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

	September 30, 2014	December 31, 2013
2015 notes		
Principal amount	$ 100,000	$ 100,000
Unaccreted debt issuance expense	(880)	(1,561)
Net carrying amount	$ 99,120	$ 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 $1.0 million and $2.4 million as of September 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. Because the 2015 notes are

due within twelve months, the Company reclassified the 2015 notes from a long term liability to a current liability at September 30, 2014. 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

Table of Contents

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 nine months ended September 30, 2014 and 2013 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Accretion expense	$ 231	$ 216	$ 681	$ 637

11. Facility Agreement

The significant activity related to the Facility Agreement during the nine months ended September 30, 2014 consisted of the following (in thousands):

	September 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	7,507
	2,921

Adjustment to debt discount related to modification of the 2019 notes		
Tranche B principal amount		20,000
Debt discount related to Tranche B purchase		(1,168)
Tranche 4 principal amount		40,000
Debt discount related to Tranche 4 purchase		(5,435)
Net carrying value of facility financing obligation	$	72,625
Commitment Asset		
Commitment asset 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 4 and Tranche B notes		(6,325)
Commitment asset value included in other assets	$	1,753

Table of Contents

Accretion of debt issuance cost and debt discount in connection with the Facility Agreement during the three and nine months ended September 30, 2014 were as follows (in thousands):

	Three months ended September 30, 2014	Nine months ended September 30, 2014
Accretion expense- debt issuance cost	$ 9	$ 318
Accretion expense- debt discount	$ 306	$ 7,189

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 September 30, 2014, Deerfield had purchased the four tranches of 2019 notes in the aggregate principal amount of $160.0 million.

On February 28, 2014, the Company entered into the First 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 First Amendment and the subsequent occurrence of certain events specified in the First Amendment, prior to December 30, 2014, the Company may request that Deerfield purchase up to $90.0 million aggregate principal amount of Tranche B notes. The Tranche B notes initially accrued interest at the rate of 9.75% per year on the outstanding principal amount, subject to reduction to 8.75% if the Company entered into a collaboration with a third party to commercialize AFREZZA. Pursuant to the terms of the First Amendment, the interest rate was subsequently reduced to 8.75% on September 23, 2014 following completion of the U.S. Federal Trade Commission s review of the transactions contemplated by the Sanofi License Agreement under the Hart-Scott-Rodino Act and the completion of documentation related to the $175.0 million secured loan facility being provided to the Company. The interest on the outstanding principal amount of notes under the Facility Agreement is 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. On July 18, 2014, Deerfield purchased an aggregate principal amount of $40.0 million of the fourth and final tranche of 2019 notes (the Tranche 4 notes) in accordance with the provisions of the Facility Agreement, as amended, which 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.

In addition, pursuant to the First 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 First 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 First 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 the incurrence of additional secured debt under 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 in the United States 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 September 30, 2014, the first milestone triggering event was achieved following the Company s entry into the Sanofi License Agreement, which resulted in a $1.9 million incremental charge to interest expense due to the increase in carrying value of the liability to the required $5.0 million payment, which was paid to Deerfield subsequent to September 30, 2014 pursuant to the terms of the Milestone Agreement. As of September 30, 2014, the short-term portion of the liability had a balance of $9.2 million and the long-term portion of the liability had a balance of $8.9 million.

Table of Contents

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 First Amendment, the Company recorded an additional Tranche B notes commitment asset (the Tranche B Commitment Asset) with an estimated fair value equal to $2.9 million. The Commitment Asset remaining as of September 30, 2014 represented the right to receive 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 September 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 First Amendment, did not represent a troubled debt restructuring of the 2019 notes because the First Amendment did not result in Deerfield granting a concession to the Company. In addition, the First Amendment did not result in a substantial modification to the terms of the Tranche 1 notes and Tranche 3 notes.

The impact of the First 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 Commitment Asset was considered a fee received from the creditor as consideration for the First 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 that 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 September 30, 2014, Deerfield had converted $100.0 million of 2019 notes into 18,616,304 shares of the Company s common stock and 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:

Table of Contents

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 September 30, 2014 and December 31, 2013, the Company held $172.5 million and $70.8 million, respectively, of cash and cash equivalents, consisting primarily of money market funds of $169.7 million and $67.7 million, respectively, and the remaining in non-interest bearing checking accounts. The carrying value approximates the fair value. 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):

	September 30, 2014		December 31, 2013	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2015 notes	$ 99.1	$ 113.9	$ 98.4	$ 102.2
Facility financing obligation	$ 72.6	$ 75.3	$ 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 Agreement

As discussed in Note 11 Facility 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 First Amendment, and recorded the Tranche B 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 September 30, 2014, the market discount rate was recalculated at 12.4% for the Tranche 1 notes and the Tranche 4 notes and 11.9% for the Tranche B notes. The Tranche 2 and Tranche 3 notes were fully converted by the end of the first quarter of 2014.

Table of Contents

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. As of September 30, 2014, the fair value of the Milestone Rights is estimated at $23.1 million.

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 September 30, 2014, as Deerfield had purchased all four tranches of 2019 notes in the aggregate principal amount of $160.0 million, the carrying value of the Commitment Asset was zero.

The fair value of the Tranche B Commitment Asset was estimated using a discounted cash flow analysis under the income approach. Specifically, the fair value 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 the date it was recorded, the Tranche B 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. As of September 30, 2014, because 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 nine months ended September 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 nine months ended September 30, 2014 and 2013.

14. Collaboration arrangement

On August 11, 2014, the Company and Sanofi entered into a license and collaboration agreement, which became effective on September 23, 2014. Under the terms of the Sanofi License Agreement, the Company granted to Sanofi exclusive, worldwide licenses to certain of the Company s patents, trademarks and know-how for the development and commercialization of AFREZZA. Under the terms of the Sanofi License Agreement, Sanofi has the exclusive right and responsibility to develop AFREZZA worldwide, subject to certain development activities that will be performed by the Company. 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 supply agreement that the Company entered into with Sanofi concurrently with the Sanofi License Agreement, the Company will be responsible for the manufacture and supply to Sanofi of its requirements of AFREZZA.

Under the Sanofi License Agreement, Sanofi paid the Company an up-front cash payment of $150.0 million in the third quarter of 2014. If certain manufacturing, regulatory and sales milestones are achieved, the Company will also be eligible to receive up to $775.0 million in milestone payments, of which $75.0 million relates to certain development and manufacturing milestone events, $50.0 million relates to the filing and completion of regulatory approvals and $650.0 million relates to the achievement of certain product sales milestones. In addition, worldwide profits and losses, which are determined based on the difference between the net sales of AFREZZA and the costs and expenses incurred by the Company and Sanofi that are specifically attributable or related to the development, improvement, regulatory filings, manufacturing, and commercialization of AFREZZA will be shared 65% by Sanofi and 35% by the Company. In accordance with the terms of the Sanofi License Agreement, profit and loss sharing will commence the first full calendar quarter subsequent to the execution date of the agreement.

Table of Contents

On September 23, 2014, the Company entered into the Sanofi Loan Facility, consisting of a senior secured revolving promissory note (the Note) and a guaranty and security agreement (the Security Agreement) with an affiliate of Sanofi which provides the Company with a secured loan facility of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement.

The obligations of the Company under the Sanofi Loan Facility are guaranteed by the Company s wholly-owned subsidiary, MannKind LLC, and are secured by a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which the Company purchases or has purchased such insulin, and a second priority security interest in the Company s assets that secure the Company s obligations under the Facility Agreement, as amended. In addition, the Company agreed to grant to Sanofi, as additional security for the obligations under the Sanofi Loan Facility, a first priority mortgage on the Company s facility in Valencia, California, by December 22, 2014.

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

The outstanding principal of all loans under the Sanofi Loan Facility, if not prepaid, will become due and payable on September 23, 2024 unless accelerated pursuant to the terms of the Sanofi Loan Facility. Additionally, if the Company sells its Valencia facility, the Company is required to prepay the loans under the Sanofi Loan Facility in an amount equal to 100% of the net cash proceeds of the sale within five business days of receipt.

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

The Company analyzed the up-front cash payment of $150.0 million under the provisions of ASC 605, *Revenue Recognition*, to determine whether the up-front cash payment, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. In addition, revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

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

Table of Contents

In order for revenue to be recognized, the seller s price to the buyer must be fixed and determinable and thus not subject to refund or adjustment. Given that as of September 30, 2014, the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement, the Company believes this requirement for revenue recognition is not met.

As such, the Company did not recognize any revenue pursuant to the Sanofi License Agreement for the three months ended September 30, 2014. The Company recorded the $150.0 million up-front payment as a deferred up-front payment from the Sanofi License Agreement.

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 executed a license and collaboration agreement, or the Sanofi License Agreement, with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to sanofi-aventis U.S. LLC, or Sanofi), pursuant to which Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. The Sanofi License Agreement became effective on September 23, 2014. We will manufacture AFREZZA at our 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, an affiliate of Sanofi provided 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.

Under the Sanofi License Agreement, Sanofi paid us an up-front cash payment of $150.0 million in the third quarter of 2014. As of September 30, 2014, no products or services had been delivered or performed pursuant to the agreement. In addition, the up-front cash payment of $150.0 million does not represent a fixed fee, as a result of the loss share provision, and because we do not have the ability to estimate the amount of costs that would potentially be incurred related to the Sanofi License Agreement, the amount of up-front cash payment that could be recognized as revenue is not fixed or determinable. Based on these factors, the requirements for revenue recognition had not been met as of September 30, 2014. Accordingly, the entire $150.0 million up-front payment was recorded on the balance sheet as a liability.

If certain manufacturing, regulatory and sales milestones are achieved we will also be eligible to receive up to $775.0 million in milestone payments under the Sanofi License Agreement. None of the milestones have been met as of September 30, 2014.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2014, we have incurred a cumulative net loss of $2.5 billion and have stockholders deficit of $40.7 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, and through the $150.0 million up-front payment we received pursuant to the Sanofi License Agreement.

Table of Contents

As of September 30, 2014, we and our marketing partner, Sanofi, have not yet begun to commercialize AFREZZA. We anticipate that commercialization of AFREZZA will commence in the first quarter of 2015. 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

To date, our research and development expenses have consisted 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. Our recent research and development expenses have also included certain commercial readiness costs. 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. Prior to the FDA s approval of AFREZZA, we 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 generally accepted accounting principles in the United States, or 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 for the year ended December 31, 2013. There has been one material change to our critical accounting policies during the three and nine months ended September 30, 2014.

License and collaboration agreements

Pursuant to the Sanofi License Agreement, we granted to Sanofi exclusive, worldwide licenses to certain of our patents, trademarks and know-how for the development and commercialization of AFREZZA. The terms of the Sanofi License Agreement provide for consideration to us in the form of a non-refundable up-front payment, manufacturing, regulatory and sales milestone payments and profit and loss sharing.

Table of Contents

We analyze consideration received under the provisions of ASC 605, Revenue Recognition, to determine whether the consideration, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. The arrangement s consideration that is fixed and determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price (BESP). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Given that, as of September 30, 2014, we did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement, we believe the fixed and determinable fee requirement for revenue recognition was not met.

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 our consolidated financial statements.

In May 2014, a new standard was issued related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective on January 1, 2017. Early adoption is not permitted. The new standard allows for either full retrospective adoption, whereby the new standard is applied to each prior reporting period presented or modified retrospective adoption, whereby the new standard is only applied to the most current period presented with the cumulative effect of the change recognized at the date of the initial application. We are assessing the potential impact of the new standard on its consolidated statements of financial position and results of operations and comprehensive income (loss) and has not yet selected a transition method.

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 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. We are evaluating the impact the adoption of ASU 2014-10 will have on our consolidated financial statements.

On August 27, 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern. The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. We are evaluating the impact the adoption of ASU 2014-15 will have on its consolidated financial statements.

Table of Contents

RESULTS OF OPERATIONS

Three and nine months ended September 30, 2014 and 2013

Revenue

We did not recognize any revenue for the nine months ended September 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 nine months ended September 30, 2014 and 2013 (dollars in thousands):

	Three months ended September 30,			
	2014	2013	$ Change	% Change
Clinical	$ 6,255	$ 8,249	$ (1,994)	(24%)
Manufacturing	13,167	10,240	2,927	29%
Research	1,349	1,601	(252)	(16%)
Research and development tax credit	(600)	(51)	(549)	1076%
Stock-based compensation expense	(993)	7,242	(8,235)	(114%)
Research and development expenses	$ 19,178	$ 27,281	$ (8,103)	(30%)

	Nine months ended September 30,			
	2014	2013	$ Change	% Change
Clinical	$ 22,170	$ 32,509	$ (10,339)	(32%)
Manufacturing	35,017	29,354	5,663	19%
Research	4,608	4,690	(82)	(2%)
Research and development tax credit	(766)	(207)	(559)	270%
Stock-based compensation expense	21,655	14,385	7,270	51%
Research and development expenses	$ 82,684	$ 80,731	$ 1,953	2%

The decrease in research and development expenses of $8.1 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 was primarily due to decreased stock-based compensation expense of $8.2 million resulting from a credit of $5.5 million for the settlement value of modified performance awards and an overall decrease in stock-based compensation expense of $2.7 million related to performance milestones that were substantially recorded in 2013 but were achieved and settled in 2014.

Overall research and development expenses for the nine months ended September 30, 2014 increased by $2.0 million compared to the nine months ended September 30, 2013 primarily due to increased stock-based compensation expense

of $7.3 million and increased spending on commercial readiness of $5.7 million partially offset by decreased clinical expenses of $10.3 million with the completion of two Phase 3 clinical studies of AFREZZA in 2013. The net effect of $10.4 million in increased stock-based compensation expense resulted from the modification and subsequent settlement value of performance awards which was partially offset by an overall decrease in stock-based compensation of $3.1 million. Manufacturing spending increased $5.7 million due to development supply purchases and increased headcount in preparation for commercialization offset by decreased clinical expenses of $10.3 million as a result of the completion of two Phase 3 studies in 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.

Table of Contents

General and Administrative Expenses

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

	Three months ended September 30,			
	2014	2013	$ Change	% Change
Salaries and employee related expenses	$ 4,552	$ 4,028	$ 524	13%
Professional fees and other general expenses	18,370	4,752	13,618	287%
Stock-based compensation expense	(3,834)	8,701	(12,535)	(144%)
General and administrative expenses	$ 19,088	$ 17,481	$ 1,607	9%

	Nine months ended September 30,			
	2014	2013	$ Change	% Change
Salaries and employee related expenses	$ 13,221	$ 11,763	$ 1,458	12%
Professional fees and other general expenses	28,519	13,371	15,148	113%
Stock-based compensation expense	25,100	16,919	8,181	48%
General and administrative expenses	$ 66,840	$ 42,053	$ 24,787	59%

The increase in general and administrative expenses of $1.6 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 was primarily due to increased professional fees of $13.6 million associated with the closing of the Sanofi License Agreement offset by a decrease in stock compensation expense of $12.5 million resulting from a credit of $7.4 million for the settlement value of modified performance awards and an overall decrease in stock-based compensation expense of $5.1 million related to performance milestones that were substantially recorded in 2013 but were achieved and settled in 2014.

General and administrative expenses for the nine months ended September 30, 2014 increased by $24.8 million compared to the nine months ended September 30, 2013 primarily due to an $8.2 million increase in stock-based compensation resulting from the net effect of $12.6 million in increased stock-based compensation expense due to the modification and subsequent settlement value of performance awards, partially offset by an overall decrease in stock-based compensation of $4.4 million, increased professional fees of $13.6 million associated with the Sanofi License Agreement, and an increase of $1.5 million in professional fees related to financing transactions and associated filings.

General and administrative expenses overall will be higher in 2014 as compared to 2013 as a result of increased stock compensation expense due to milestone achievements and the modification and re-measurement of performance shares in the third quarter of 2014.

Other Income (Expense)

Other income increased by $7.9 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 and by $1.6 million for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013. The increase for the three months ended September 30, 2014 was due to $7.9 million of other income, net of expenses, associated with the sale of intellectual property in the third quarter. The increase for the nine months ended September 30, 2014 was due to income associated with the sale of intellectual property related to oncology in the third quarter, partially offset by the $6.4 million loss on the conversion of Deerfield debt into equity.

Interest Income and Expense

Interest expense increased by $0.1 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 and decreased by $1.1 million for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013. The decrease for the nine months ended September 30, 2014 was primarily due to a decrease of $3.0 million in interest expense on the Loan Arrangement with The Mann Group due to a lower carrying value in 2014, partially offset by incremental interest expense of $1.9 million resulting from the achievement and re-measurement of the first milestone under the Milestone Rights Purchase Agreement dated July 1, 2013, or the Milestone Agreement, by and between us and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL, referred to collectively as the Milestone Purchasers, in the third quarter.

Table of Contents

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 September 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 September 30, 2014, Deerfield had purchased all four tranches of 2019 notes in the aggregate principal amount of $160.0 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, prior to December 30, 2014, we may issue to Deerfield up to $90.0 million aggregate principal amount of Tranche B notes, subject to the satisfaction of certain conditions, $20.0 million of which had been issued as of September 30, 2014. As of September 30, 2014, the Tranche B notes bear interest at the rate of 8.75% 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 initially accrued interest at the rate of 9.75% per year on the outstanding principal amount, subject to reduction to 8.75% if we entered into a collaboration with a third party to commercialize AFREZZA. Pursuant to the terms of the amendment, the interest rate was subsequently reduced to 8.75% on September 23, 2014 following completion of the U.S. Federal Trade Commission s review of the transaction under the Hart-Scott-Rodino Act and the completion of documentation related to the $175.0 million secured loan facility being provided to MannKind. 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 $20.0 million of the Tranche 1 notes and the full $40.0 million of 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 connection with the execution of the Facility Agreement, on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures. The 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.

As of September 30, 2014, the first milestone triggering event was achieved following our entry into the Sanofi License Agreement. Subsequent to September 30, 2014, in connection with the milestone triggering event, we paid a

$5.0 million payment to Deerfield pursuant to the terms of the Milestone Agreement.

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 of 1933, as amended. 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.

On August 11, 2014, we and Sanofi executed the Sanofi License Agreement, which subsequently became effective on September 23, 2014. Pursuant to the Sanofi License Agreement, we received a $150.0 million up-front 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, we will manufacture AFREZZA at our manufacturing facility in Danbury, Connecticut to supply Sanofi s demand for the product.

Table of Contents

In addition, an affiliate of Sanofi has provided 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 permit the incurrence of additional debt under the Sanofi Loan Facility. Advances under the Sanofi Loan Facility will bear interest at a rate of 8.5% per year and will be payable-in-kind and compounded quarterly. We will be required to make mandatory prepayments on any outstanding loans under the Sanofi Loan Facility from our share of any profits under the Sanofi License Agreement. We have not yet incurred any indebtedness under the Sanofi Loan Facility.

During the nine months ended September 30, 2014, our operations provided $39.8 million of cash, and we had a net loss of $161.9 million, which included $62.3 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. By comparison, during the nine months ended September 30, 2013, we used $94.7 million of cash for our operations and had a net loss of $137.9 million, which included $41.4 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. The operating cash outflow decreased by $134.5 million primarily due to the $150.0 million deferred up-front payment recorded from the up-front fee associated with the Sanofi License Agreement being partially offset by the $15.0 million deposit to Amphastar as prepayment for 2015 quantities of insulin as part of the Supply Agreement. Going forward, we expect our operating cash flow to be negative at least until we achieve commercialization of AFREZZA.

We used $9.9 million of cash for investing activities during the nine months ended September 30, 2014, compared to $1.8 million for the nine months ended September 30, 2013. The $8.1 million increase was primarily due to $19.1 million in purchases of machinery and equipment for the preparation for commercialization of AFREZZA, offset by $9.3 million proceeds from the sale of intellectual property.

Our financing activities provided $71.7 million of cash for the nine months ended September 30, 2014, compared to $128.5 million for the nine months ended September 30, 2013. Cash provided by financing activities during the nine months ended September 30, 2014 was comprised of $40.0 million in proceeds received from the issuance of the fourth tranche of 2019 notes to Deerfield, $20.0 million from the sale of Tranche B notes to Deerfield, $27.8 million from warrant exercises, and $10.1 million from the exercise of stock options, which were partially offset by $26.8 million paid for employment taxes related to vested restricted stock units. For the nine months ended September 30, 2013, cash provided by financing activities was primarily comprised of $79.5 million from the sale of the first two tranches under the Facility Agreement with Deerfield and $49.2 million in warrant exercises.

As of September 30, 2014, we had $172.5 million in cash and cash equivalents. Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements for at least the next 12 months. We may need to raise additional capital in the future, 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, if needed, 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.

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. 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, if needed, 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 could be substantial doubt about our ability to continue as a going concern.

Table of Contents

Contractual Obligations and Commitments

As of September 30, 2014, in addition to the obligations and commitments disclosed in Management s Discussion and Analysis of Financial Condition and Results of Operation contained in our Annual Report, we incurred additional contractual obligations pursuant to our issuance of $20.0 million aggregate principal amount of Tranche B notes in accordance with the provisions of the Facility Agreement, as amended, to Deerfield on May 6, 2014; the issuance of the fourth tranche of $40.0 million aggregate principal amount of 2019 notes to Deerfield on July 28, 2014; the entry into our supply agreement with Amphastar France Pharmaceuticals S.A.S., or 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; the entry into the Sanofi License Agreement, under which we are responsible for 35% of worldwide losses with respect to AFREZZA; and additional contractual obligations pursuant to the Sanofi Loan Facility.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Due to the fixed interest rates of our debt, we 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 nine months ended September 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 the 2015 notes, at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75% and debt related to the Tranche B notes at a fixed interest rate of 8.75%. In addition, any advances under the Sanofi Loan Facility will bear interest at a rate of 8.5%.

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

If a change in interest rates equal to 10% of the interest rates on September 30, 2014 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts.

Foreign Currency Exchange Risk

We will incur significant expenses, including for insulin supply purchases, outside the United States based on contractual obligations denominated in the euro. At the end of each reporting period, these liabilities are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We have not entered into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks, but may enter into foreign currency hedging transactions in the future. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If a minimum quarterly supply purchase under our supply agreement with Amphastar and if a movement of 10% in the U.S. dollar to euro exchange rate were to have occurred on

September 30, 2014, this movement would not have had a material effect on our results of operations or financial condition.

ITEM 4. CONTROLS AND PROCEDURES

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

Table of Contents

Management determined that, as of September 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 products. We have expended significant time, money and effort in the development of our only approved product, AFREZZA. We anticipate that in the near term, our ability to generate revenues will depend on the successful commercialization of AFREZZA in the United States, which we have not yet begun to commercialize. On August 11, 2014, we executed the Sanofi License Agreement, which became effective on September 23, 2014. Pursuant to the Sanofi License Agreement, Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. We will manufacture AFREZZA at our 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. Our product candidates are generally in early clinical or preclinical development. 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.

Table of Contents

We are dependent on our collaboration with Sanofi to further develop and to commercialize AFREZZA worldwide. This collaboration may place the development and commercialization largely outside our control, and poor performance under or failure to maintain the collaboration agreement between us and Sanofi could have a material and adverse impact on our business.*

We have entered into the Sanofi License Agreement to provide for the future development and commercialization of AFREZZA. We cannot be certain that our collaboration with Sanofi will continue for as long as there is a potential market for AFREZZA. Both we and Sanofi have certain rights to terminate the collaboration agreement, in certain circumstances, including a right by Sanofi to terminate the agreement upon specified prior written notice. If the agreement is terminated prior to the end of the commercial life of AFREZZA, we may not be able to find another collaborator for the development and commercialization of AFREZZA, and even if we elected to pursue further development and commercialization of AFREZZA on our own, we might not be able to do so successfully and would experience substantially increased capital requirements that we might not be able to fund. Our dependence on Sanofi and the Sanofi License Agreement will subject us to a number of risks, including:

Sanofi may not perform as expected and we may not be able to control the amount and timing of resources that Sanofi may devote to the development or commercialization of AFREZZA;

we and Sanofi could disagree as to development plans and Sanofi may delay clinical trials or stop a clinical trial;

there may be disputes between us and Sanofi, including disagreements regarding the Sanofi License Agreement, that may result in (a) the delay of (or prevent entirely) the achievement of regulatory and commercial objectives that would result in milestone payments, (b) the delay or termination of the development or commercialization of AFREZZA, and/or (c) costly litigation or arbitration that diverts our management s attention and resources;

Sanofi may not comply with applicable regulatory guidelines with respect to the development or commercialization of AFREZZA, which could adversely impact the development of or sales of AFREZZA and could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;

Sanofi may not provide us with timely and accurate information regarding sales activities and supply forecasts, which could adversely impact our ability to comply with our manufacturing and supply obligations under our supply agreement with Sanofi and our and Sanofi s ability to launch and commercialize AFREZZA;

Sanofi may experience financial difficulties;

business combinations or significant changes in Sanofi s business strategy may also adversely affect Sanofi s ability to perform its obligations under the Sanofi License Agreement;

Sanofi may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and

notwithstanding the non-competition requirements in the Sanofi License Agreement, Sanofi could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Any failure of Sanofi to adequately perform its obligations under the Sanofi License Agreement or the termination of such agreement could have a material and adverse impact on 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.*

Although we had a positive cash flow from operations during the nine months ended September 30, 2014, due to the $150.0 million up-front payment received from Sanofi, we expect negative cash flows from operations for the full year. We have never been profitable or generated positive cash flow from cumulative operations to date and, as of September 30, 2014, we had incurred a cumulative net loss of $2.5 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 September 30, 2014, we had stockholders deficit of $40.7 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.

Table of Contents

In the future we may need to raise additional capital to fund our operations.*

In the future, 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 September 30, 2014, we had stockholders deficit of $40.7 million, which may raise concerns about our solvency and affect our ability to raise additional capital. The extent of our additional funding requirements will depend on a number of factors, including:

- the 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;
- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facilities;
- our obligation to make milestone payments pursuant to the milestone rights issued to the Milestone Purchasers pursuant to 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;
- the 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.

Table of Contents

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. 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, if needed, on favorable terms, or at all. If we need but cannot raise adequate additional capital in the future 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 may be 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, may incur additional indebtedness under the Sanofi Loan Facility and may be unable to make required payments of interest and principal as they become due.*

As of September 30, 2014, we had $180.0 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;
- $60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum and maturing between 2016 and December 31, 2019; and
- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum and maturing between 2017 and December 31, 2019.

Prior to December 30, 2014, we may request that Deerfield purchase up to $70.0 million principal amount of additional Tranche B notes under the Facility Agreement. In addition, an affiliate of Sanofi has provided the Sanofi Loan Facility to us, the proceeds of which will 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 8.75% 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. 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, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2015 notes, 2019 notes, Tranche B notes, or the loans under the Sanofi Loan Facility when required, we will be in default under the indenture or other applicable instrument for such note(s) or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

Table of Contents

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

Our 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 a certain mortgage on our facility in Danbury, Connecticut. Our obligations under the Sanofi Loan Facility are secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which we purchase or have purchased such insulin, and a second priority security interest in our assets that secure our obligations under the Facility Agreement.

The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the 2019 notes or the Tranche B notes; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents, including amounts available to us under 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. Similarly, the Sanofi Loan Facility includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens and make certain changes to our organizational documents. Events of default under the Sanofi Loan Facility include: our failure to make timely payments due under the Sanofi Loan Facility; inaccuracies in our representations and warranties to the noteholder; our failure to comply with any of our covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of our breach of the Sanofi License Agreement; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, the noteholder may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including our failure to timely make payments due under the Sanofi Loan Facility; our failure to comply with the negative covenants under the Sanofi Loan Facility limiting our ability to incur additional indebtedness or grant certain liens; our insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of our breach of the non-compete provisions of the Sanofi License Agreement; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect)

occur and are continuing, the noteholder may accelerate all of our repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor.

There can be no assurance that we will be able to comply with the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the 2019 notes or Tranche B notes or the lender under the Sanofi Loan Facility would demand repayment of the outstanding balance of the 2019 notes, the Tranche B notes or the loans under the Sanofi Loan Facility as 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 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.

Table of Contents

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 may be required to reduce expenses by delaying, reducing or curtailing our development of product candidates. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development goals in the timeframes we 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.

Table of Contents

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. Our primary supplier of insulin is Amphastar. 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 support commercialization of this product.*

We use our Danbury, Connecticut facility to formulate AFREZZA inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We 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. 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 support commercialization of 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.

Table of Contents

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

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

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

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

to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing 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.

Table of Contents

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

Table of Contents

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 or our marketing partner 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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); and

two pharmacokinetic-pharmacodynamic studies, one to characterize dose-response and one to characterize within-subject variability.

Table of Contents

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.*

We depend on suppliers for insulin and other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements 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. Amphastar is our primary supplier of insulin. If we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier s ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and commercialization of AFREZZA.

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

Table of Contents

RISKS RELATED TO INTELLECTUAL PROPERTY

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

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

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for our AFREZZA inhalation powder expired in 2012 and 2014. Other patents providing protection for AFREZZA 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.

Table of Contents

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.

Table of Contents

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock 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, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;

the availability of critical materials used in developing and manufacturing AFREZZA or other product candidates;

developments or disputes concerning our 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;

Table of Contents

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 September 30, 2014, our Chairman and Chief Executive Officer, Alfred E. Mann beneficially owned 37.8% 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 nine 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 November 3, 2014, we had 405,699,862 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.

Table of Contents

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

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).

Table of Contents

Exhibit Number	Description of Document
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).
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).
4.14	Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P.
4.15	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind Corporation and Aventisub LLC (incorporated by reference to Exhibit 99.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).

Table of Contents

Exhibit

Number	Description of Document
4.16	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind Corporation, MannKind LLC and Aventisub LLC (incorporated by reference to Exhibit 99.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
10.1	License and Collaboration Agreement, dated as of August 11, 2014, by and among MannKind Corporation, Technosphere International C.V., MannKind Netherlands B.V. and Sanofi-Aventis Deutschland GmbH.
10.2	Supply Agreement, dated as of August 11, 2014, by and between MannKind Corporation and Sanofi-Aventis Deutschland GmbH.
10.3	Supply Agreement, dated as of July 31, 2014, by and between MannKind Corporation and Amphastar France Pharmaceuticals S.A.S.
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.

Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

Table of Contents

SIGNATURE

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

Dated: November 10, 2014

MANNKIND CORPORATION

By: /s/ MATTHEW J. PFEFFER
Matthew J. Pfeffer
Corporate Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)