

MANKIND CORP  
Form 10-Q  
November 10, 2014  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**Form 10-Q**

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

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

**28903 North Avenue Paine**

**Valencia, California**  
**(Address of principal executive offices)**

**(661) 775-5300**

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

**91355**  
**(Zip Code)**

**(Registrant's telephone number, including area code)**

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

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

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

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

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

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

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**MANNKIND CORPORATION**

**Form 10-Q**

**For the Quarterly Period Ended September 30, 2014**

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AFREZZA<sup>®</sup>, MedTone<sup>®</sup> and Technosphere<sup>®</sup> 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****MANKIND CORPORATION AND SUBSIDIARIES****(A Development Stage Company)****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)****(In thousands, except share data)**

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
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)
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Total	\$ 386,818	\$ 258,646
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See notes to condensed consolidated financial statements.

Table of Contents**MANKIND CORPORATION AND SUBSIDIARIES****(A Development Stage Company)****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)****(In thousands, except per share data)**

	<b>Three months ended</b>		<b>Nine months ended</b>		<b>Cumulative period</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>from</b>
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>	<b>February 14,</b>
					<b>1991 (date of</b>
					<b>inception) to</b>
					<b>September 30, 2014</b>
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)

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Net loss applicable to common stockholders	\$ (36,520)	\$ (50,818)	\$ (161,941)	\$ (137,907)	\$ (2,481,555)
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Net loss per share applicable to common stockholders basic and diluted	\$ (0.09)	\$ (0.17)	\$ (0.42)	\$ (0.48)	
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Shares used to compute basic and diluted net loss per share applicable to common stockholders	394,163	296,386	381,332	286,889	
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See notes to condensed consolidated financial statements.



Table of Contents**MANKIND CORPORATION AND SUBSIDIARIES****(A Development Stage Company)****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****(Unaudited)****(In thousands)**

	Three months ended		Nine months ended		Cumulative period
	September 30,		September 30,		from February 14,
	2014	2013	2014	2013	1991 (date of
					inception) to
					September 30, 2014
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**MANKIND CORPORATION AND SUBSIDIARIES****(A Development Stage Company)****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(In thousands)**

	<b>Nine months ended</b>		<b>Cumulative Period</b>
	<b>September 30,</b>	<b>September 30,</b>	<b>from February 14,</b>
	<b>2014</b>	<b>2013</b>	<b>1991 (Date of</b>
			<b>Inception) to</b>
			<b>September 30, 2014</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
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

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Net cash provided by (used in) operating activities	39,830	(94,681)	(1,685,163)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
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)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
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)

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	<b>Cumulative Period</b>		
	<b>from February 14,</b>		
	<b>1991 (Date of</b>		
	<b>Inception) to</b>		
	<b>September 30, 2014</b>		
	<b>Nine months ended</b>		
	<b>September 30,</b>		
	<b>2014      2013</b>		
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
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>\$ 101,675</b>	<b>\$ 31,963</b>	<b>\$ 172,465</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>70,790</b>	<b>61,840</b>	
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 172,465</b>	<b>\$ 93,803</b>	<b>\$ 172,465</b>
<b>SUPPLEMENTAL CASH FLOWS DISCLOSURES:</b>			
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.

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**MANKIND 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).

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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



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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):

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
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):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
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):

	<b>Estimated Useful Life (Years)</b>	<b>September 30, 2014</b>	<b>December 31, 2013</b>
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):

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

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**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.



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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):

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
<b>2015 notes</b>		
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

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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):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
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):

	<b>September 30, 2014</b>
<b>Facility financing obligation</b>	
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

<b>Adjustment to debt discount related to modification of the 2019 notes</b>		
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
<b>Commitment Asset</b>		
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

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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):

	<b>Three months ended</b>	
	<b>September 30,</b>	<b>Nine months ended</b>
	<b>2014</b>	<b>September 30, 2014</b>
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 not