

MANNKIND CORP
Form 10-Q
August 09, 2013
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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 June 30, 2013

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)

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Delaware
(State or other jurisdiction of
incorporation or organization)
28903 North Avenue Paine
Valencia, California
(Address of principal executive offices)

13-3607736
(I.R.S. Employer
Identification No.)
91355
(Zip Code)
(661) 775-5300
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of August 2, 2013, there were 301,774,215 shares of the registrant's common stock, \$.01 par value per share, outstanding.

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MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended June 30, 2013

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

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)**

| | June 30, 2013 | December 31, 2012 |
|---|---------------|-------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 28,529 | \$ 61,840 |
| State research and development credit exchange receivable current | 450 | 450 |
| Prepaid expenses and other current assets | 3,183 | 4,520 |
| Total current assets | 32,162 | 66,810 |
| Property and equipment net | 179,567 | 183,961 |
| State research and development credit exchange receivable net of current portion | 470 | 313 |
| Other assets | 230 | 230 |
| Total | \$ 212,429 | \$ 251,314 |
| LIABILITIES AND STOCKHOLDERS DEFICIT | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,419 | \$ 4,555 |
| Accrued expenses and other current liabilities | 26,984 | 25,777 |
| Senior convertible notes | 114,744 | 114,443 |
| Note payable to related party | 119,635 | |
| Total current liabilities | 266,782 | 144,775 |
| Senior convertible notes | 98,004 | 97,583 |
| Note payable to related party | | 119,635 |
| Total liabilities | 364,786 | 361,993 |
| Commitments and contingencies | | |
| Stockholders deficit: | | |
| Undesignated preferred stock, \$0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2013 and December 31, 2012 | | |
| Common stock, \$0.01 par value 550,000,000 shares authorized at June 30, 2013 and December 31, 2012; 300,869,683 and 286,035,082 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively | 3,012 | 2,860 |
| Additional paid-in capital | 2,036,640 | 1,991,379 |
| Accumulated other comprehensive loss | (8) | (6) |
| Deficit accumulated during the development stage | (2,192,001) | (2,104,912) |
| Total stockholders deficit | (152,357) | (110,679) |

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| | | |
|-------|------------|------------|
| Total | \$ 212,429 | \$ 251,314 |
|-------|------------|------------|

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)**

| | Three months ended June 30, | | Six months ended June 30, | | Cumulative period from February 14, 1991 (date of inception) to June 30, 2013 |
|---|--------------------------------|-------------|------------------------------|-------------|--|
| | 2013 | 2012 | 2013 | 2012 | |
| Revenue | \$ | \$ | \$ | \$ | \$ 3,166 |
| Operating expenses: | | | | | |
| Research and development | 27,052 | 26,638 | 53,450 | 50,794 | 1,521,023 |
| General and administrative | 14,533 | 17,416 | 24,572 | 27,193 | 450,276 |
| In-process research and development costs | | | | | 19,726 |
| Goodwill impairment | | | | | 151,428 |
| Total operating expenses | 41,585 | 44,054 | 78,022 | 77,987 | 2,142,453 |
| Loss from operations | (41,585) | (44,054) | (78,022) | (77,987) | (2,139,287) |
| Other income (expense) | 15 | 13,347 | 38 | 14,729 | (2,229) |
| Interest expense on note payable to related party | (1,689) | (3,028) | (3,378) | (6,076) | (42,203) |
| Interest expense on senior convertible notes | (2,866) | (2,844) | (5,729) | (5,419) | (45,662) |
| Interest income | 1 | 1 | 2 | 2 | 36,998 |
| Loss before benefit for income taxes | (46,124) | (36,578) | (87,089) | (74,751) | (2,192,383) |
| Income tax benefit | | | | | 382 |
| Net loss | (46,124) | (36,578) | (87,089) | (74,751) | (2,192,001) |
| 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 | \$ (46,124) | \$ (36,578) | \$ (87,089) | \$ (74,751) | \$ (2,215,213) |
| Net loss per share applicable to common stockholders basic and diluted | \$ (0.16) | \$ (0.23) | \$ (0.31) | \$ (0.49) | |
| Shares used to compute basic and diluted net loss per share applicable to common stockholders | 284,044 | 159,859 | 282,062 | 151,506 | |

See notes to condensed consolidated financial statements.

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MANKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

| | Three months ended June 30, | | Six months ended June 30, | | Cumulative period from February 14, 1991 (date of inception) to June 30, 2013 |
|---|--------------------------------|-------------|------------------------------|-------------|---|
| | 2013 | 2012 | 2013 | 2012 | |
| Net Loss | \$ (46,124) | \$ (36,578) | \$ (87,089) | \$ (74,751) | \$ (2,192,001) |
| Other comprehensive loss: | | | | | |
| Cumulative translation (loss) gain | | 6 | (2) | 5 | (8) |
| Unrealized gain (loss) on investments: | | | | | |
| Unrealized holding gain during the period | | | | | 48 |
| Less: reclassification adjustment for gains (losses) included in net loss | | | | 48 | (48) |
| Net unrealized gain on investments | | | | 48 | |
| Other comprehensive loss | | 6 | (2) | 53 | (8) |
| Comprehensive loss | \$ (46,124) | \$ (36,572) | \$ (87,091) | \$ (74,698) | \$ (2,192,009) |

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)**

| | Six months ended June 30, | | Cumulative Period from February 14, 1991 (Date of Inception) to June 30, 2013 |
|---|------------------------------|-------------|---|
| | 2013 | 2012 | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss | \$ (87,089) | \$ (74,751) | \$ (2,192,001) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and accretion | 6,668 | 7,343 | 133,445 |
| Stock-based compensation expense | 15,362 | 5,951 | 153,280 |
| Stock expense for shares issued pursuant to research agreement | | | 3,018 |
| (Gain) loss on sale, abandonment/disposal or impairment of property and equipment | 686 | (73) | 24,939 |
| 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 | | 117 | 990 |
| Litigation settlement in stock | | | 6,494 |
| Fair value of forward purchase contract | | (12,011) | 1,237 |
| Other, net | (2) | (2,716) | 1,097 |
| Changes in assets and liabilities: | | | |
| State research and development credit exchange receivable | (157) | (185) | (920) |
| Prepaid expenses and other current assets | 1,337 | (15,731) | (1,233) |
| Other assets | | | (230) |
| Accounts payable | (974) | 1,244 | 3,444 |
| Accrued expenses and other current liabilities | 2,398 | 33,308 | 37,447 |
| Other liabilities | | | (2) |
| Net cash used in operating activities | (61,771) | (57,504) | (1,658,032) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchase of marketable securities | | | (796,779) |
| Sales and maturities of marketable securities | | | 796,393 |
| Purchase of property and equipment | (1,591) | (448) | (329,337) |
| Proceeds from sale of property and equipment | | 73 | 454 |
| Net cash used in investing activities | (1,591) | (375) | (329,269) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Issuance of common stock and warrants, net of issuance costs | 2,191 | 80,992 | 1,399,947 |
| 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) |

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| | | | |
|--|--------|--------|-----------|
| Put shares sold to majority stockholder | | | 623 |
| Exercise of warrants for common stock | 28,308 | | 28,308 |
| Borrowings under lines of credit | | | 4,220 |
| Proceeds from notes receivables | | | 1,742 |
| Borrowings on notes payable to related party | 6,250 | | 387,750 |
| Principal payments on notes payable to related party | | | (70,000) |
| Borrowings on notes payable | | | 3,460 |
| Principal payments on notes payable | | | (1,667) |
| Proceeds from senior convertible notes | | | 207,050 |
| Payment of employment taxes related to vested restricted stock units | (448) | (405) | (13,475) |
| Net cash provided by financing activities | 30,051 | 86,837 | 2,015,830 |

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| | Six months ended | | Cumulative Period |
|--|------------------|-----------|--|
| | 2013 | 2012 | from February 14, 1991 (Date of Inception) to June 30, 2013 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | \$ (33,311) | \$ 28,958 | \$ 28,529 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 61,840 | 2,681 | |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 28,529 | \$ 31,639 | \$ 28,529 |
| SUPPLEMENTAL CASH FLOWS DISCLOSURES: | | | |
| Cash paid for income taxes | \$ | \$ | \$ 26 |
| Interest paid in cash, net of amounts capitalized | 5,006 | 4,751 | 64,158 |
| 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 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 | 4,605 | 2,343 | 4,605 |
| Capitalization of interest on note payable to related party | | 11,876 | 14,219 |
| Cancellation of principal on note payable to related party | | 77,187 | 212,334 |
| Forward purchase contract contribution to APIC | | 1,080 | 29,317 |
| Reclassification of forward purchase contract to APIC | | 13,091 | 28,080 |
| 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**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 (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. These statements should be read in conjunction with the financial statements and notes thereto included in the *Company*'s latest audited annual financial statements. The audited statements for the year ended December 31, 2012 are included in the *Company*'s annual report on Form 10-K for the fiscal year ended December 31, 2012 filed with the *SEC* on March 18, 2013 (the *Annual Report*).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the six months ended June 30, 2013 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 trial expenses, valuation of forward purchase contracts, 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.

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 candidate, AFREZZA (insulin human [rDNA origin]) inhalation powder, is an ultra rapid-acting insulin therapy in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

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 trials for these products. Since its inception through June 30, 2013 the *Company* has reported accumulated net losses of \$2.2 billion, which include a goodwill impairment charge of \$151.4 million, and cumulative negative cash flow from operations of \$1.7 billion. On December 15, 2013, \$115.0 million of aggregate principal under the 3.75% Senior Convertible Notes (the *2013 notes*) will mature (see Note 10 *Senior convertible notes*), and on January 1, 2014, the *Company*'s borrowings under the amended and restated promissory note with The Mann Group will mature though The Mann Group's right to repayment under the promissory note is subject to a subordination agreement between The Mann Group and affiliates of Deerfield Management Company L.P. (*Deerfield*), pursuant to which The Mann Group has agreed not to accept repayment under the note until the *Company*'s borrowings under its debt facility with *Deerfield* are repaid. These factors raise substantial doubt about the *Company*'s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties. At June 30, 2013, the *Company*'s capital resources consisted of cash and cash equivalents of \$28.5 million and \$125.4 million of available borrowings through September 30, 2013 under the loan agreement with an entity controlled by the *Company*'s principal stockholder, The Mann Group, LLC (*The Mann Group*) (see Note 9 *Related-party arrangements*). Based upon the *Company*'s current expectations, management believes the *Company*'s existing capital resources, including the available borrowings under the loan arrangement with The Mann Group and proceeds received on July 1, 2013 from the first tranche of the debt facility as described below, will enable it to continue planned operations into the fourth quarter of 2013. As described below, the *Company* previously issued certain public offering warrants that expire in October 2013. If these warrants are exercised prior to their expiration, the *Company* would receive cash proceeds of \$64.6 million, which it believes, when combined with the cash resources and available borrowings discussed above, would provide sufficient capital resources to continue planned operations at least through the end of 2013. However, the *Company* cannot provide assurances that the warrants will be exercised, that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates.

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Capital resources potentially available to the Company include proceeds from the exercise of warrants, at-the-market agreements and issuance of additional 2019 notes as follows:

In October 2012, we sold in an underwritten public offering common stock and warrants resulting in net proceeds of \$86.3 million and concurrently issued common stock and warrants to The Mann Group in exchange for cancellation of indebtedness under the amended and restated promissory note with The Mann Group (see Note 7 Common and preferred stock and Note 9 Related-party arrangements). To the extent that the trading price of our common stock exceeds the exercise price of the warrants on or about the expiration date of the public offering warrants and The Mann Group Warrants issued in October 2012, the warrant holders may potentially exercise all warrants prior to their expiration in the fourth quarter of 2013 making available \$89.7 million in gross proceeds from the exercise of public offering warrants and The Mann Group warrant exercise could be settled in exchange for cancellation of indebtedness of \$78.0 million. As of June 30, 2013, we have received \$25.1 million in proceeds from the exercise of the public offering warrants with \$64.6 million remaining unexercised. The Mann Group warrants remained unexercised as of June 30, 2013. There can be no assurances that the trading price of our common stock will be greater than the exercise price of the warrants on or about the expiration date of the warrants due to a variety of factors. There can be no assurances that the remaining warrants will be exercised or that we will receive any additional proceeds from the exercise of the warrants.

On March 18, 2013, we entered into at-the-market issuance sales agreements (the ATM Agreements) with two sales agents, under which we may issue and sell shares of our common stock having an aggregate offering price of up to \$50.0 million under each ATM Agreement (provided that in no event may we issue and sell more than \$50.0 million of shares of our common stock under both ATM Agreements in the aggregate) from time to time through either of the sales agents. Neither we nor either of the sales agents has any obligation to sell shares of our common stock under the ATM Agreements. Any sales of 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 (the Securities Act). We have not yet 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 July 1, 2013, we entered into a facility agreement (the Facility Agreement) with Deerfield, pursuant to which Deerfield has purchased \$40.0 million aggregate principal amount of 9.75% senior secured convertible notes due 2019 (the 2019 notes) and has committed to purchasing up to an additional \$120.0 million aggregate principal amount of 2019 notes upon the satisfaction of certain conditions (see Note 12 Subsequent Event). There can be no assurance that the conditions required for the additional \$120 million of borrowings will be met or met in a timeframe necessary to support our liquidity needs.

The Company will need to raise additional capital through the resources identified above or, through the sale of equity or debt securities, a strategic business collaboration with a pharmaceutical company, the establishment of other funding facilities, licensing arrangements, assets sales or other means, in order to continue the development and commercialization of AFREZZA and other product candidates and to support its other ongoing activities. However, the Company cannot provide assurances that such additional capital will be available through any such sources or other sources.

Fair Value of Financial Instruments The carrying amounts of financial instruments, which include cash equivalents and accounts payable, approximate their fair values due to their relatively short maturities. The fair value of the note payable to related party cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment.

Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of June 30, 2013 and December 31, 2012, the Company held \$28.5 million and \$61.8 million, respectively of cash and cash equivalents, consisting primarily of money market funds of \$25.9 million and \$60.8 million, respectively, and the remaining in non-interest bearing checking accounts. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

The following is a summary of the carrying values and estimated fair values of the 2013 notes and the Company's senior convertible notes due in 2015 (the 2015 notes) (in millions).

| | June 30, 2013 | | December 31, 2012 | |
|----------------|----------------|----------------------|-------------------|----------------------|
| | Carrying value | Estimated fair value | Carrying value | Estimated fair value |
| Notes due 2013 | \$ 114.7 | \$ 113.3 | \$ 114.4 | \$ 81.9 |
| Notes due 2015 | \$ 98.0 | \$ 109.9 | \$ 97.6 | \$ 63.2 |

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The estimated fair value of the 2013 notes was calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy). 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 (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.

The Company concluded its Common Stock Purchase Agreement with The Mann Group entered into in February 2012 (The Mann Group Common Stock Purchase Agreement) (see Note 7 Common and preferred stock) represented a contingent forward purchase contract that met the definition of a derivative instrument in accordance with ASC 815 *Derivatives and Hedging* (ASC 815). Of the 31,250,000 shares issuable pursuant to The Mann Group Common Stock Purchase Agreement, the portion of the derivative instrument representing 14.7 million shares were recorded as equity (Equity Portion) as they met the criteria for equity classification under ASC 815-40 *Derivatives and Hedging, Contracts in an Entity's Own Stock*. The remaining 16.5 million shares (Non-Equity Portion) required classification outside of equity as the Company did not have sufficient available shares at the time of issuance. The Company revalued the Non-Equity Portion of the forward purchase contract at each reporting date and recorded a fair value adjustment within Other income (expense). The estimated fair value of The Mann Group Common Stock Purchase Agreement was based on a forward

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purchase contract valuation (Level 3 in the fair value hierarchy). The fair value of the forward purchase contract is highly sensitive to the discount applied for lack of marketability and the stock price, and changes in this discount and/or the stock price caused the value of the forward purchase contract to change significantly. The Company recognized the change in fair value of \$(336,000) in Other income (expense) for the three months ended March 31, 2012. The Company revalued the Non-Equity Portion using a forward contract valuation formula, in which the forward contract was estimated to be equal to the valuation date stock price minus the strike price discounted to the valuation date using a risk-free rate of 0.08% at issuance and 0.06% at March 31, 2012. As the shares which would be received upon settlement were unregistered, the Company applied a discount for lack of marketability of 2.57% at issuance and 1.64% at March 31, 2012 based on quantitative put models, adjusted to take into account qualitative factors, including the fact that the Company's stock was publicly traded and the fact that there was no contractual restriction on the unregistered shares being registered. As of and for the six months ended June 30, 2012, the Company recognized the change in fair value of \$12.0 million in Other income. The Company revalued the Non-Equity Portion using a forward contract valuation formula, in which the forward contract is estimated to be equal to the valuation date stock price of \$2.40 at issuance and \$1.69 at May 17, 2012 minus the strike price discounted to the valuation date using a risk-free rate of 0.08% at issuance and 0.18% at May 17, 2012. As the shares which would be received upon settlement are currently unregistered, the Company applied a discount for lack of marketability of 10.27% at issuance and 1.67% at May 17, 2012 based on quantitative put models, adjusted to take into account qualitative factors, including the fact that the Company's stock is publicly traded and the fact that there is no contractual restriction on the unregistered shares being registered.

The following roll-forward provides a summary of changes in fair value of the Company's Level 3 forward purchase contract (in thousands):

| | Three months ended June 30, 2012 Forward Purchase Contract | Six months ended June 30, 2012 Forward Purchase Contract |
|--|---|---|
| Beginning Balance | \$ 744 | \$ |
| Issuance | | 1,080 |
| Adjustments to fair value included in other income | 12,347 | 12,011 |
| Transfers to additional paid-in-capital | (13,091) | (13,091) |
| Ending Balance | \$ | \$ |

Recently Issued Accounting Standards In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income (Topic 220) Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. These amendments do not change the current requirements for reporting net income or other comprehensive income in the financial statements. These amendments provide for additional disclosure requirements for amounts reclassified out of accumulated other comprehensive income. These amendments are effective prospectively for interim and annual periods beginning after December 15, 2012. Early adoption is permitted. Effective January 1, 2013, the Company adopted the new requirements as set forth in ASU 2013-02 in the disclosure of comprehensive income on the Company's consolidated financial statements. The adoption of the new requirements did not have a significant impact on the Company's consolidated financial statements.

In July, 2013, the FASB 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 Company is evaluating the impact, if any, of the adoption of ASU 2013-11 will have on the Company's consolidated financial statements.

Table of Contents**2. Accrued expenses and other current liabilities**

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

| | June 30, 2013 | December 31, 2012 |
|--|------------------|----------------------|
| Salary and related expenses | \$ 8,146 | \$ 10,074 |
| Research and clinical trial costs | 6,558 | 5,995 |
| Accrued interest | 7,911 | 4,533 |
| Construction in progress | 2,661 | 3,878 |
| Other | 1,708 | 1,297 |
| Accrued expenses and other current liabilities | \$ 26,984 | \$ 25,777 |

3. Accounting for stock-based compensation

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2013 and 2012 was as follows (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|--------------------------|--------------------------------|----------|------------------------------|----------|
| | 2013 | 2012 | 2013 | 2012 |
| Stock-based compensation | \$ 10,172 | \$ 3,072 | \$ 15,362 | \$ 5,951 |

On March 7, 2013, the Board approved a management proposal designed to encourage employee retention, as recommended for approval by the Compensation Committee. The Company granted 5,846,000 performance-based restricted stock units to employees, including executive officers of the Company other than our Chief Executive Officer, with vesting terms subject to the achievement of specified regulatory and business development milestones related to AFREZZA. The performance-based restricted stock units had a grant date fair value of \$2.81 per unit.

On May 23, 2013, the Company's stockholders approved the 2013 Equity Incentive Plan (the "Plan"). The Plan is the successor to and continuation of the previous active stock-based compensation plans - 2004 Equity Incentive Plan and the 2004 Non-Employee Directors' Stock Option Plan. The Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, other stock awards, and performance awards that may be settled in cash, stock, or other property. All of the Company's employees, non-employee directors and consultants are eligible to participate in the Plan and may receive all types of awards; provided that incentive stock options may be granted under the Plan only to employees (including officers) and employees of the Company's affiliates.

On May 23, 2013, the Compensation Committee approved a management proposal designed to encourage employee retention. The proposal involved the grant of 5,598,100 performance-based stock options and 1,687,900 performance-based restricted stock units to employees, including executive officers of the Company. These grants have vesting terms subject to the achievement of certain performance milestones. The performance-based options and performance-based restricted stock units had a grant date per share fair value of \$3.05 and \$6.85, respectively.

As of June 30, 2013, there was \$24.3 million and \$31.5 million of unrecognized compensation cost related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 0.8 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period. As of June 30, 2013, there was \$107,000 and \$3.7 million of unrecognized expenses related to performance options and restricted stock units, respectively, for milestones not considered probable of achievement.

4. Net loss per common share

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Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned to Bank of America, N.A. under a share lending arrangement (see Note 7 – Common and preferred stock). As of June 30, 2013, 9,000,000 shares of the Company's common stock, which were loaned to Bank of America, N.A. pursuant to the terms of a share lending agreement as described in Note 7, were issued and are outstanding, and holders of the borrowed shares have all the rights of a holder of the Company's common stock. However, because the share borrower must return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof), the borrowed shares are not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying condensed consolidated statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 129,432,728 shares and 61,741,900 shares as of June 30, 2013 and 2012, 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

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tax credit available for exchange. Current estimated amounts receivable under the program were \$450,000 at June 30, 2013 and December 31, 2012. Long-term estimated amounts receivable under the program were \$470,000 and \$313,000 at June 30, 2013 and December 31, 2012, respectively.

6. Property and equipment

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

| | Estimated Useful Life (Years) | June 30, 2013 | December 31, 2012 |
|--|--|------------------|----------------------|
| Land | | \$ 5,273 | \$ 5,273 |
| Buildings | 39-40 | 54,948 | 54,948 |
| Building improvements | 5-40 | 114,245 | 114,245 |
| Machinery and equipment | 3-15 | 81,368 | 81,382 |
| Furniture, fixtures and office equipment | 5-10 | 5,164 | 5,239 |
| Computer equipment and software | 3 | 11,834 | 11,840 |
| Leasehold improvements | | 17 | 17 |
| Construction in progress | | 13,757 | 12,266 |
| | | 286,606 | 285,210 |
| Less accumulated depreciation and amortization | | (107,039) | (101,249) |
| Property and equipment net | | \$ 179,567 | \$ 183,961 |

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

Depreciation and amortization expense related to property and equipment for the three and six months ended June 30, 2013 and 2012 was as follows (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|---------------------------------------|--------------------------------|----------|------------------------------|----------|
| | 2013 | 2012 | 2013 | 2012 |
| Depreciation and amortization expense | \$ 2,956 | \$ 3,304 | \$ 5,946 | \$ 6,661 |

7. Common and preferred stock

The Company is authorized to issue 550,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value \$0.01 per share, issuable in one or more series designated by the Company's board of directors. No other class of capital stock is authorized. As of June 30, 2013 and December 31, 2012, 300,869,683 and 286,035,082 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding. Included in the common stock outstanding as of June 30, 2013 and December 31, 2012 are 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of the \$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 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.

In February 2012, the Company sold in an underwritten public offering 35,937,500 units at an aggregate price to the public of \$86.3 million, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock. Net proceeds from this

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offering were approximately \$80.6 million, excluding any future proceeds from the exercise of warrants. The warrants are exercisable at \$2.40 per share and expire in February 2016. Concurrent with this public offering, pursuant to The Mann Group Common Stock Purchase Agreement entered into in February 2012, The Mann Group agreed to purchase \$77.2 million worth of restricted shares or 31,250,000 restricted shares of common stock at an aggregate purchase price of \$77.2 million, which were issued in June 2012 in exchange for cancellation of principal indebtedness of \$77.2 million under the revolving amended and restated loan arrangement (see Note 9 Related-party arrangements).

In October 2012, the Company sold in an underwritten public offering 46,000,000 units at an aggregate price to the public of \$92.0 million, with each unit consisting of one share of common stock and a warrant to purchase 0.75 of a share of common stock. Net proceeds from this offering were approximately \$86.3 million, excluding any future proceeds from the exercise of warrants. The

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warrants are exercisable at \$2.60 per share and expire in the fourth quarter of 2013. As of June 30, 2013, we have received \$25.1 million in proceeds from the exercise of a portion of such warrants with \$64.6 million remaining unexercised. Concurrent with this public offering, pursuant to a Common Stock and Warrant Purchase Agreement with The Mann Group entered into in October 2012 (the "Mann Group Common Stock and Warrant Purchase Agreement"), The Mann Group agreed to purchase for an aggregate purchase price of \$107.4 million, 40,000,000 restricted shares of common stock and warrants to purchase 30,000,000 restricted shares of common stock, which were issued in October 2012 in exchange for cancellation of principal indebtedness of \$107.4 million under the revolving amended and restated loan arrangement (see Note 9 Related-party arrangements). The Mann Group warrants are exercisable at \$2.60 per share and expire in the fourth quarter of 2013. As of June 30, 2013, The Mann Group warrants remained unexercised.

In connection with both the February and October 2012 public offerings, the Company performed an analysis of the warrants to determine their appropriate classification and concluded that in both instances the warrants should be classified within equity. In connection with The Mann Group Common Stock Purchase Agreement the Company concluded that this agreement represented a contingent forward contract that met the definition of a derivative instrument in accordance with ASC 815 *Derivatives and Hedging*, and that a portion of the restricted common stock issued should be classified as equity and the remaining portion should be classified as assets or liabilities accounted for at fair value. In connection with The Mann Group Common Stock and Warrant Purchase Agreement, the Company concluded that this agreement represented a contingent forward contract and that the restricted common stock and warrants issued to The Mann Group should be classified as assets or liabilities accounted for at fair value. Both the February and October forward contracts settled during 2012.

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.

9. Related-party arrangements

In October 2007, the Company entered into a \$350.0 million loan arrangement with its principal stockholder. In February 2009, the promissory note underlying the loan arrangement was revised as a result of the Company's principal stockholder being subject to the licensing requirement under the California Finance Lenders Law. Accordingly, the lender was changed to The Mann Group. Until January 1, 2013, interest on outstanding principal amounts accrued at a fixed rate equal to the one-year LIBOR as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum. The promissory note underlying the loan arrangement was amended at various dates during 2012. The most recent amendment occurred in October 2012 to extend the maturity date to January 1, 2014, extend the date through which the Company can borrow under the promissory note to September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one-year LIBOR on December 31, 2012 plus 5%. Effective January 1, 2013, the borrowing rate for all borrowings under the promissory note with The Mann Group was set at 5.84%.

As of June 30, 2013, the total principal amount outstanding under the credit facility was \$119.6 million, and the amount available for future borrowings was \$125.4 million. Interest 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 at any time upon mutual agreement of both parties. 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. 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 (see discussion regarding letter agreement below).

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In August 2010, the Company entered into a letter agreement confirming a previous commitment by The Mann Group 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 the event of a default, all unpaid principal and interest either becomes immediately

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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. There are no warrants associated with the loan arrangement.

In February 2012, concurrent with an the underwritten public offering (see Note 7 Common and preferred stock), pursuant to The Mann Group Common Stock Purchase Agreement, The Mann Group agreed to purchase \$77.2 million worth of restricted shares or 31,250,000 restricted shares of common stock, which were issued in June 2012 in exchange for cancellation of principal indebtedness of \$77.2 million under the revolving amended and restated loan arrangement.

In October 2012, concurrent with an underwritten public offering (see Note 7 Common and preferred stock), pursuant to The Mann Group Common Stock and Warrant Purchase Agreement, The Mann Group agreed to purchase for an aggregate purchase price of \$107.4 million, 40,000,000 restricted shares of common stock and warrants to purchase 30,000,000 restricted shares of common stock, which were issued in October 2012 in exchange for cancellation of principal indebtedness of \$107.4 million under the revolving amended and restated loan arrangement. The Mann Group warrants are exercisable at \$2.60 per share and expire in October 2013.

The restricted shares sold to The Mann Group in both the June and October 2012 transactions may not be sold, pledged, assigned or transferred unless (i) the shares have been registered with the Securities and Exchange Commission (SEC) or (ii) the restricted shares are exempt from SEC registration requirements and the company has obtained an opinion from the company's counsel that the shares may be sold lawfully without registration.

The cancelled principal amount became available for reborrowing. Additionally, in accordance with the terms of the note, the Company elected to capitalize the accrued and unpaid interest on the cancelled principal amount that became due upon the closing (see Note 7 Common and preferred stock). During the first and second quarters of 2013, there were no borrowings under or amendments to The Mann Group loan arrangement.

10. Senior convertible notes

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

| | June 30 2013 | December 31 2012 |
|----------------------------------|-------------------|---------------------|
| 2013 notes | | |
| Principal amount | \$ 115,000 | \$ 115,000 |
| Unaccreted debt issuance expense | (256) | (557) |
| Net carrying amount | 114,744 | 114,443 |
| 2015 notes | | |
| Principal amount | \$ 100,000 | \$ 100,000 |
| Unaccreted debt issuance expense | (1,996) | (2,417) |
| Net carrying amount | 98,004 | 97,583 |
| Senior convertible notes | \$ 212,748 | \$ 212,026 |

On August 18, 2010, the Company completed a Rule 144A offering of \$100.0 million aggregate principal amount of the 2015 notes. The 2015 notes are governed by the terms of an indenture dated as of August 24, 2010 (the 2015 Note Indenture). The 2015 notes bear interest at the rate of 5.75% per year on the principal amount, payable in cash semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2011. In connection with the 2015 notes, the Company had accrued interest of \$2.2 million as of June 30, 2013 and December 31, 2012, respectively. The 2015 notes are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company's secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other liabilities of the Company's subsidiaries. The maturity date of the 2015 notes is August 15, 2015 and payment is due in full on that date for unconverted securities. Holders of the 2015 notes may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding principal into shares of the Company's common stock at an initial conversion rate of 147.0859 shares per \$1,000

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principal amount, which is equal to a conversion price of approximately \$6.80 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the 2015 notes converted in connection with a fundamental change by increasing the conversion rate on such 2015 notes, which amount, if any, will be based on the Company's common stock price and the effective date of the fundamental change, and (2) each holder of 2015 notes will have the option to require the Company to repurchase all or any portion of such holder's 2015 notes at a repurchase price of 100% of the principal amount of the 2015 notes to be repurchased plus accrued and unpaid interest, if any. The Company may elect to redeem some or all of the 2015 notes if the closing stock price has equaled 150% of the conversion price for at least 20 of the 30 consecutive trading days ending on the trading day before the Company's redemption notice. The redemption price will equal 100% of the principal amount of the 2015 notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, plus a make-whole payment equal to the sum of the present values of the remaining scheduled interest payments through and including August 15, 2015

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(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 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 amortized to interest expense using the effective interest method over the term of the 2015 notes.

On December 12, 2006, the Company completed an offering of \$115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013 (the 2013 notes), including \$15.0 million aggregate principal amount of the 2013 notes sold pursuant to the underwriters over-allotment option that was exercised in full. The 2013 notes are governed by the terms of an indenture dated as of November 1, 2006 and a First Supplemental Indenture, dated as of December 12, 2006 (the 2013 Note Indenture). The 2013 notes bear interest at the rate of 3.75% per year on the principal amount, payable in cash semi-annually in arrears on June 15 and December 15 of each year, beginning June 15, 2007. In connection with the 2013 notes, the Company had accrued interest of \$192,000 as of June 30, 2013 and December 31, 2012, respectively. The 2013 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. The maturity date of the 2013 notes is December 15, 2013, and payment is due in full on that date for unconverted securities. Holders of the 2013 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 44.5002 shares per \$1,000 principal amount, which is equal to a conversion price of approximately \$22.47 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 2013 notes converted in connection with a fundamental change by increasing the conversion rate on such 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 2013 notes will have the option to require the Company to repurchase all or any portion of such holder's Notes at a repurchase price of 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any. Under the terms of the 2013 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 existing commitments. Applying the Company's sequencing policy, the Company performed an analysis at the time of the offering of the 2013 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 \$3.7 million in issuance costs which are recorded as an offset to the 2013 notes in the accompanying condensed consolidated balance sheets. These costs are being amortized to interest expense using the effective interest method over the term of the 2013 notes.

Accretion of debt issuance expense in connection with the offerings of the 2015 notes and the 2013 notes during the three and six months ended June 30, 2013 and 2012 were as follows (in thousands).

| | Three months ended June 30, | | Six months ended June 30, | |
|-------------------|--------------------------------|--------|------------------------------|--------|
| | 2013 | 2012 | 2013 | 2012 |
| Accretion expense | \$ 364 | \$ 343 | \$ 722 | \$ 682 |

11. Income taxes

As required by ASC 740 *Income Taxes* (ASC 740), management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of operating losses. Accordingly, the net

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deferred tax assets have been 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.

Table of Contents**12. Subsequent event**

On July 1, 2013, the Company entered into the Facility Agreement with Deerfield. Under the Facility Agreement, Deerfield committed to purchase up to \$160.0 million aggregate principal amount of 2019 notes in four \$40.0 million tranches. The closing of the first tranche of \$40.0 million aggregate principal amount of 2019 notes (the purchase price for which was \$21.1 million as a result of the original issue discount) occurred on the date of the Facility Agreement. Deerfield's obligation to purchase the second tranche of 2019 notes is subject to the Company's achievement and reporting of certain Phase 3 results relating to the Company's clinical studies of AFREZZA. Deerfield's obligation to purchase the third tranche of 2019 notes is subject to the Company's repayment of its 2013 notes and the prior satisfaction of the conditions for the second tranche closing. Deerfield's obligation to purchase the fourth tranche of 2019 notes is subject to the Company's receipt of approval of AFREZZA by the U.S. Food and Drug Administration, or the FDA, and the prior satisfaction of the conditions for the second and third tranche closings. In addition to the foregoing conditions, Deerfield's obligation to purchase 2019 notes at any of the three remaining closings is subject to, at each closing, the shares issuable upon conversion of all previously sold 2019 notes being freely tradable pursuant to an effective registration statement filed with the Securities and Exchange Commission or pursuant to Rule 144 under the Securities Act. The Company is required to repay 25% of the outstanding principal amount of the 2019 notes sold in each tranche on the third, fourth, fifth and sixth anniversaries of the applicable issue dates of such 2019 notes, and the entire outstanding principal amount of all 2019 notes will become due and payable no later than December 31, 2019. The outstanding amount of 2019 notes will accrue interest at a rate of 9.75% per year commencing on September 30, 2013, payable in cash quarterly in arrears on the last business day of December, March, June and September of each year. A portion of the principal amount of the 2019 notes may be converted into shares of the Company's common stock at Deerfield's option after a specified period following the release of data from the aforementioned clinical trials. The conversion price will be determined by the volume weighted average price of the common stock during the 20 trading days immediately preceding the conversion date. If the conversion price exceeds \$6.67, no more than six million shares may be issued upon conversion; if the conversion price is less than \$3.33, no more than 12 million shares may be issued upon conversion; and if the conversion price is between these dollar amounts, no more than \$40 million worth of common stock may be issued upon conversion. In connection with the Facility Agreement, the Company also entered into a Milestone Rights Purchase Agreement (the Milestone Agreement) with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (the Milestone Purchasers), pursuant to which, in exchange for a payment of \$18.9 million, the Company sold the Milestone Purchasers 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.

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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. These 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 notes for the year ended December 31, 2012 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

OVERVIEW

We are a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes. Our lead product candidate, AFREZZA (insulin human [rDNA origin]) inhalation powder, is an ultra rapid-acting insulin that is in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

In the second quarter of 2013, we completed two Phase 3 clinical studies conducted at sites in the United States, Eastern Europe and South America. We expect to submit the results of these studies to the FDA as an amendment to our new drug application, or NDA, during the fourth quarter of 2013. However, the data collected from these clinical trials may not reach statistical significance or may not otherwise be sufficient to support an amendment to our NDA, or FDA approval. Moreover, there can be no assurance that we will satisfy all of the FDA's requirements with these two clinical studies or that the FDA will ultimately find our proposed approach to these clinical studies acceptable. The FDA could also request that we conduct additional clinical studies in order to provide sufficient data for approval of AFREZZA.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of June 30, 2013, we have incurred a cumulative net loss of \$2.2 billion and an accumulated stockholders' deficit of \$152.4 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under a loan arrangement provided by our principal stockholder. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding in the future, there will continue to be substantial doubt about our ability to continue as a going concern.

We intend to pursue collaboration opportunities with large pharmaceutical companies in the United States, Europe and elsewhere to provide the operational and financial resources to develop, commercialize, market and sell AFREZZA. Although we have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA, to date, we have not reached an agreement on a collaboration with any of these companies. We cannot predict when, if ever, we may conclude an agreement with a partner. There can be no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms, if at all.

We do not expect to record sales of any product prior to regulatory approval and commercialization of AFREZZA. We currently do not have the required approvals to market any of our 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 any of our product candidates. We expect to make substantial expenditures and to incur additional operating losses for at least the next several years as we:

continue the clinical development of AFREZZA and new inhalation systems for the treatment of diabetes;

seek regulatory approval to sell AFREZZA in the United States and other markets;

seek development and commercialization collaborations for AFREZZA; and

develop additional applications of our proprietary Technosphere platform 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 ongoing clinical trials and the regulatory approval process, our potential inability to enter into sales and marketing collaborations or to commercialize AFREZZA in a timely manner, the

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results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

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RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of laboratory equipment. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash.

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

Clinical development timelines, likelihood of success and total costs vary widely. We are focused primarily on advancing AFREZZA through regulatory filings. 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, we are unable to estimate with any certainty the costs that we will incur in the continued development of our product candidates for commercialization. The costs required to complete the development of AFREZZA will be largely dependent on the cost and efficiency of our clinical trial operations and discussions with the FDA regarding its requirements.

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

There have been no material changes to our critical accounting policies as described in Item 7 of our Annual Report.

Recently Issued Accounting Standards In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income (Topic 220) Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. These amendments do not change the current requirements for reporting net income or other comprehensive income in the financial statements. These amendments provide for additional disclosure requirements for amounts reclassified out of accumulated other comprehensive income. These amendments are effective prospectively for interim and annual periods beginning after December 15, 2012. Early adoption is permitted. Effective January 1, 2013, we adopted the new requirements as set forth in ASU No. 2013-02 in the disclosure of comprehensive income in our consolidated financial statements. The adoption of the new requirements did not have a significant impact on our consolidated financial statements.

In July, 2013, the FASB 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. We are evaluating the impact, if any, of the adoption of ASU 2013-11 will have on our consolidated financial statements.

RESULTS OF OPERATIONS

Three and six months ended June 30, 2013 and 2012

Revenue

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We did not recognize any revenue for the six months ended June 30, 2013 and 2012. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFREZZA.

Table of Contents**Research and Development Expenses**

The following table provides a comparison of the research and development expense categories for the three and six months ended June 30, 2013 and 2012 (dollars in thousands):

| | Three months ended | | | |
|-------------------------------------|--------------------|-----------|------------|----------|
| | June 30, | | | |
| | 2013 | 2012 | \$ Change | % Change |
| Clinical | \$ 10,978 | \$ 13,327 | \$ (2,349) | (18%) |
| Manufacturing | 9,724 | 9,899 | (175) | (2%) |
| Research | 1,773 | 2,182 | (409) | (19%) |
| Research and development tax credit | (78) | (93) | 15 | (16%) |
| Stock-based compensation expense | 4,655 | 1,323 | 3,332 | 252% |
| Research and development expenses | \$ 27,052 | \$ 26,638 | \$ 414 | 2% |

| | Six months ended | | | |
|-------------------------------------|------------------|-----------|-----------|----------|
| | June 30, | | | |
| | 2013 | 2012 | \$ Change | % Change |
| Clinical | \$ 24,260 | \$ 24,206 | \$ 54 | 0% |
| Manufacturing | 19,114 | 19,992 | (878) | (4%) |
| Research | 3,089 | 4,122 | (1,033) | (25%) |
| Research and development tax credit | (156) | (185) | 29 | (16%) |
| Stock-based compensation expense | 7,143 | 2,659 | 4,484 | 169% |
| Research and development expenses | \$ 53,450 | \$ 50,794 | \$ 2,656 | 5% |

The decrease in research and development expenses for the three months ended June 30, 2013, compared to the three months ended June 30, 2012, was primarily due to \$2.3 million in decreased clinical trial related expenses upon the completion of studies 171 and 175 in May 2013 and June 2013, respectively, and reduced research expenses resulting from the positive effect of our cost cutting measures offset by an increase in stock-based compensation expense for stock awards granted during the second quarter of 2013 (see Note 3 Accounting for stock-based compensation).

The increase in overall research and development expenses for the six months ended June 30, 2013, compared to the six months ended June 30, 2012, was primarily due to a \$4.5 million increase in stock-based compensation expense in connection with the May 2013 performance-based grants to employees, including executive officers of the Company, offset by \$1.0 million in decreased research expenses resulting from the positive effect of our cost cutting measures and lower manufacturing expenses associated with the completion of studies 171 and 175 in the second quarter of 2013.

We anticipate that our overall research and development expense will decrease in 2013 as compared to 2012 with the completion of our clinical trials and as we prepare our resubmission for regulatory approval of AFREZZA.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the three and six months ended June 30, 2013 and 2012 (dollars in thousands):

| | Three months ended | | | |
|--|--------------------|----------|-----------|----------|
| | June 30, | | | |
| | 2013 | 2012 | \$ Change | % Change |
| Salaries and employee related expenses | \$ 4,298 | \$ 3,952 | \$ 346 | 9% |

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| | | | | |
|--|-------|-------|-----|-----|
| Professional fees and other general expenses | 4,718 | 3,968 | 750 | 19% |
|--|-------|-------|-----|-----|