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, 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)

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

(661) 775-5300

(Registrant s telephone number, including area code)

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

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

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

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

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

As of November 4, 2013, there were 357,312,740 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, 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.

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PART 1: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share data)

	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 93,803	$ 61,840
State research and development credit exchange receivable current	298	450
Prepaid expenses and other current assets	5,228	4,520
Total current assets	99,329	66,810
Property and equipment net	177,829	183,961
State research and development credit exchange receivable net of current portion	223	313
Other assets	10,227	230
Total	$ 287,608	$ 251,314
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 7,786	$ 4,555
Accrued expenses and other current liabilities	21,553	25,777
Senior convertible notes	114,897	114,443
Facility financing obligation	72,933	
Total current liabilities	217,169	144,775
Senior convertible notes	98,220	97,583
Note payable to related party	119,635	119,635
Other liabilities	20,306	
Total liabilities	455,330	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 September 30, 2013 and December 31, 2012		
Common stock, $0.01 par value 550,000,000 shares authorized at September 30, 2013 and December 31, 2012; 309,993,285 and 286,035,082 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	3,100	2,860
Additional paid-in capital	2,072,006	1,991,379
Accumulated other comprehensive loss	(9)	(6)
Deficit accumulated during the development stage	(2,242,819)	(2,104,912)

Total stockholders deficit		(167,722)		(110,679)
Total	$	287,608	$	251,314

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three months ended September 30, 2013	Three months ended September 30, 2012	Nine months ended September 30, 2013	Nine months ended September 30, 2012	Cumulative period from February 14, 1991 (date of inception) to September 30, 2013
Revenue	$	$ 35	$	$ 35	$ 3,166
Operating expenses:					
Research and development	27,281	25,453	80,731	76,247	1,548,304
General and administrative	17,481	10,069	42,053	37,262	467,757
In-process research and development costs					19,726
Goodwill impairment					151,428
Total operating expenses	44,762	35,522	122,784	113,509	2,187,215
Loss from operations	(44,762)	(35,487)	(122,784)	(113,474)	(2,184,049)
Other income (expense)	10	(2,651)	48	12,078	(2,219)
Interest expense on note payable to related party	(1,745)	(2,245)	(5,123)	(8,321)	(43,948)
Interest expense on senior convertible notes and facility financing obligation	(4,323)	(2,859)	(10,052)	(8,278)	(49,985)
Interest income	2		4	2	37,000
Loss before benefit for income taxes	(50,818)	(43,242)	(137,907)	(117,993)	(2,243,201)
Income tax benefit		408		408	382
Net loss	(50,818)	(42,834)	(137,907)	(117,585)	(2,242,819)
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	$ (50,818)	$ (42,834)	$ (137,907)	$ (117,585)	$ (2,266,031)
Net loss per share applicable to common stockholders basic and diluted	$ (0.17)	$ (0.22)	$ (0.48)	$ (0.71)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	296,386	190,534	286,889	164,611	

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30, 2013
	2013	2012	2013	2012	
Net Loss	$ (50,818)	$ (42,834)	$ (137,907)	$ (117,585)	$ (2,242,819)
Other comprehensive loss:					
Cumulative translation (loss) gain	(1)	(1)	(3)	4	(9)
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	(1)	(1)	(3)	52	(9)
Comprehensive loss	$ (50,819)	$ (42,835)	$ (137,910)	$ (117,533)	$ (2,242,828)

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine months ended September 30, 2013	Nine months ended September 30, 2012	Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (137,907)	$ (117,585)	$ (2,242,819)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and accretion	10,109	10,929	136,886
Stock-based compensation expense	31,304	9,770	169,222
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	(3)	(4)	1,096
Changes in assets and liabilities:			
State research and development credit exchange receivable	242	(270)	(521)
Prepaid expenses and other current assets	(708)	(18,007)	(3,278)
Other assets			(230)
Accounts payable	(1,929)	(1,526)	2,489
Accrued expenses and other current liabilities	3,525	36,898	38,574
Other liabilities			(2)
Net cash used in operating activities	(94,681)	(91,762)	(1,690,942)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities			(796,779)
Sales and maturities of marketable securities			796,393
Purchase of property and equipment	(1,821)	(572)	(329,567)
Proceeds from sale of property and equipment		73	454
Net cash used in investing activities	(1,821)	(499)	(329,499)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net of issuance costs	2,488	80, 982	1,400,244
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
Exercise of warrants for common stock	49,170		49,170
Borrowings under lines of credit			4,220
Proceeds from notes receivables			1,742
Proceeds from issuance of facility financing obligation & milestone rights	79,500		79,500
Facility financing obligation & milestone rights issuance costs	(598)		(598)
Borrowings on notes payable to related party		11,250	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	(2,095)	(887)	(15,122)
Net cash provided by financing activities	128,465	91,345	2,114,244

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	Nine months ended September 30, 2013	Nine months ended September 30, 2012	Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2013
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 31,963	$ (916)	$ 93,803
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	61,840	2,681	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 93,803	$ 1,765	$ 93,803
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 26
Interest paid in cash, net of amounts capitalized	7,862	7,626	67,014
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	5,523	2,907	5,523
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.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (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 nine months ended September 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 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.

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 that recently completed two additional Phase 3 clinical studies for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. On August 14, 2013, the Company released the results of these Phase 3 clinical studies, both of which met their primary efficacy endpoints and safety objectives. On October 13, 2013, the Company submitted the results of these studies to the U.S. Food and Drug and Administration (FDA) as an amendment to its new drug application (NDA). The FDA subsequently acknowledged the resubmission and advised the Company that it considers the updated NDA to be a complete class 2 response to the Company s Completed Response Letter issued in January 2011, and assigned a user fee goal (PDUFA) date of April 15, 2014.

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, 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 aggregate principal under the Company s 3.75% Senior Convertible Notes due 2013 (the 2013 notes) will become due and payable (see Note 10 Senior convertible notes). 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 September 30, 2013, the Company s capital resources consisted of cash and cash equivalents of $93.8 million. In addition, the Company expects to sell $40.0 million principal amount of the Company s 9.75% Senior Convertible Notes due 2019 (the 2019 notes) to Deerfield (as defined below) under a facility agreement in the fourth quarter of 2013 (see Note 11 Facility financing agreement). The Company is required, with the funds made available by the purchase of these 2019 notes, to repay the 2013 notes. On September 30, 2013, the Company s ability to borrow additional amounts under a loan arrangement provided by the Company s principal stockholder, The Mann Group LLC (The Mann Group), terminated. In October 2013, however, the loan arrangement was amended to, among other things, extend the maturity date of the loan until January 5, 2020 and extend the date through which the Company can borrow under the loan arrangement to December 31, 2019 (see Note 13 Subsequent events). As of October 31, 2013, the Company had $30.1 million principal amount of available borrowings under the loan arrangement, although the Company anticipates using a portion of these available borrowings to capitalize into principal, upon mutual agreement of the parties, accrued interest as it becomes due and payable under the loan arrangement (see Note 9 Related-party arrangements and Note 13 Subsequent events). Subsequent to September 30, 2013, the Company received $45.0 million in cash proceeds from the exercise of certain public offering warrants prior to their expiration on October 29, 2013. Based upon the Company s current expectations, including the expectation that Deerfield will purchase $40.0 million principal amount of 2019 notes in the fourth quarter of 2013 in connection with the repayment of the 2013

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notes, management believes the Company s existing capital resources will enable it to continue planned operations into at least the first quarter of 2014. However, the Company cannot provide assurances that Deerfield will fund the third tranche under the Facility Agreement (as defined below), that the Company will be able to access capital through the ATM Agreements (as defined below) on favorable terms, or at all, or that the Company s plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates.

Capital resources potentially available to the Company include proceeds from the exercise of warrants issued in its February 2012 public offering, the ATM Agreements and issuance of additional 2019 notes to Deerfield, as more fully described below:

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 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. As of September 30, 2013, the Company had received $4.5 million in cash proceeds from the exercise of the February 2012 public offering warrants, with $47.3 million remaining unexercised.

On March 18, 2013, the Company entered into at-the-market issuance sales agreements (the ATM Agreements) with two sales agents, under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50.0 million under each ATM Agreement (provided that in no event may the Company issue and sell more than $50.0 million of shares of its common stock under both ATM Agreements in the aggregate) from time to time through either of the sales agents. Neither the Company nor either of the sales agents has any obligation to sell shares of the Company s 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). The Company has not yet issued any shares of its common stock under the ATM Agreements. There can be no assurance that the Company will be able to access capital through the ATM Agreements on a timely basis, or at all.

On July 1, 2013, the Company entered into a Facility Agreement (the Facility Agreement) with Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design International II, L.P. (collectively, Deerfield), providing for the sale of up to $160.0 million of 2019 notes to Deerfield in four equal tranches of $40.0 million principal amount. 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 (HS and together with Deerfield Private Design Fund, the Milestone Purchasers), pursuant to which, the Company sold the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures (the Milestone Rights see Note 11 Facility financing agreement).

On July 1, 2013, Deerfield purchased the first tranche of 2019 notes and the Milestone Rights for an aggregate of $40.0 million. The closing of the second tranche of 2019 notes, which was subject to achievement and reporting of certain results from the Company s two Phase 3 clinical studies of AFREZZA, occurred on September 5, 2013. There can be no assurance that the conditions required for the purchase of the third or fourth tranches of the 2019 notes will be met or met in a timeframe necessary to support the Company s 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 certain 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 September 30, 2013 and December 31, 2012, the Company held $93.8 million and $61.8 million, respectively, of cash and cash equivalents, consisting primarily of money market funds of $91.1 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).

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The following is a summary of the carrying values and estimated fair values of the 2013 notes, the Company s 5.75% Senior Convertible Notes due 2015 (the 2015 notes) and the 2019 notes (in millions).

	September 30, 2013		December 31, 2012	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2013 notes	$ 114.9	$ 114.8	$ 114.4	$ 81.9
2015 notes	$ 98.2	$ 106.0	$ 97.6	$ 63.2
2019 notes	$ 72.9	$ 75.7		

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. As there is no current observable market for the 2019 notes, the Company determined the estimated fair value using a bond valuation model based on a discounted cash flow methodology. The bond valuation model combined expected cash flows associated with principal repayment and interest based on the contractual terms of the debt agreement discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy).

As discussed in Note 11 Facility financing agreement, in connection with the Facility Agreement, the Company issued 2019 notes and Milestone Rights and recorded a commitment asset on July 1, 2013. The estimated fair value of the 2019 notes was calculated using a bond valuation model based on a discounted cash flow methodology. The bond valuation model combined expected cash flows associated with principal repayment and interest based on the contractual terms of the debt agreement discounted to present value using a selected market discount rate of 12% (Level 3 in the fair value hierarchy). The estimated fair value of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (17.5%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. The fair value of the commitment asset was estimated using the income approach by estimating the fair value of the future tranches using a market debt rate (12%) commensurate with the risk of the future tranches and the fair value of the cash expected to be received by the Company and assessing the probability of the commitments being funded in the future based on the operational hurdles required for funding being met (Level 3 in the fair value hierarchy). At September 30, 2013, the carrying value of the Milestone Rights and commitment asset approximates their respective estimated fair values.

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 purchase contract valuation (Level 3 in the fair value hierarchy). The fair value of the forward purchase contract was 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 nine months ended September 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 (the date at which the Company had sufficient available shares) 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.

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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 September 30, 2012 Forward Purchase Contract		Nine months ended September 30, 2012 Forward Purchase Contract	
Beginning Balance	$		$	
Issuance				1,080
Adjustments to fair value included in other income				12,011
Transfers to additional paid-in-capital				(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.

2. Accrued expenses and other current liabilities

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

	September 30, 2013		December 31, 2012	
Salary and related expenses	$	9,414	$	10,074
Research and clinical study costs		3,155		5,995
Accrued interest		3,265		4,533
Construction in progress		226		3,878
Other		5,493		1,297
Accrued expenses and other current liabilities	$	21,553	$	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 nine months ended September 30, 2013 and 2012 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2013	**2012**	**2013**	**2012**
Stock-based compensation	$ 15,943	$ 3,820	$ 31,304	$ 9,770

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On March 7, 2013, the Company s board of directors 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, with vesting terms subject to the achievement of specified regulatory and business development milestones related to AFREZZA. 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.

The Company issued stock awards to employees during the three months ended September 30, 2013 with a four-year vesting schedule. The grant date fair value of the 732,350 restricted stock units and 1,106,000 stock options issued was $5.89 and $4.14, respectively.

As of September 30, 2013, there was $27.1 million and $21.4 million of unrecognized compensation cost related to restricted stock units and options, respectively, which are expected to be recognized over the remaining weighted average vesting period of 1.5 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, 2013, there was $107,000 and $3.7 million of unrecognized expenses related to performance restricted stock units and options, respectively, for milestones not considered probable of achievement.

4. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned to Bank of America, N.A. under a share lending arrangement (see Note 7 Common and preferred stock). As of September 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 and conversion of the facility financing obligation, that are not included in the diluted net loss per share calculation consisted of an aggregate of 133,944,425 shares and 63,833,521 shares as of September 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 tax credit available for exchange. Current estimated amounts receivable under the program were $298,000 and $450,000 at September 30, 2013 and December 31, 2012, respectively. Long-term estimated amounts receivable under the program were $223,000 and $313,000 at September 30, 2013 and December 31, 2012, respectively.

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6. Property and equipment

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

	Estimated Useful Life (Years)	September 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	82,283	81,382
Furniture, fixtures and office equipment	5-10	5,164	5,239
Computer equipment and software	3	11,935	11,840
Leasehold improvements		17	17
Construction in progress		13,876	12,266
		287,741	285,210
Less accumulated depreciation and amortization		(109,912)	(101,249)
Property and equipment net		$ 177,829	$ 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 nine months ended September 30, 2013 and 2012 was as follows (in thousands):

	Three months ended September 30, 2013	Three months ended September 30, 2012	Nine months ended September 30, 2013	Nine months ended September 30, 2012
Depreciation and amortization expense	$ 2,874	$ 3,237	$ 8,820	$ 9,898

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, 2013 and December 31, 2012, 309,993,285 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 September 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 $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.

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 offering were approximately $80.6 million, excluding any future proceeds from the exercise of the warrants. The warrants are exercisable at $2.40 per share and expire in February 2016. Concurrently 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 loan arrangement (see Note 9 Related-party arrangements). For the nine months ended September 30, 2013, the Company received $4.5 million in proceeds from the exercise of the February 2012 public offering warrants, with $47.3 million remaining unexercised.

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 warrants issued in this offering were exercisable until October 29, 2013 at an exercise price of $2.60 per share. As of September 30, 2013, we had received $44.7 million in proceeds from the exercise of a portion of such warrants with $45.0 million of warrants remaining unexercised. Concurrently 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 shares of common stock at an exercise price of $2.60 per share (The Mann Group Warrants), which were issued in December 2012 in exchange for cancellation of principal indebtedness of $107.4 million under the Company s revolving loan arrangement with The Mann Group (see Note 9 Related-party arrangements). In October 2013, the Company received an additional $45.0 million in cash proceeds from the exercise of the October 2012 public offering warrants and $78.0 million of consideration in the form of cancelled principal indebtedness under the Company s loan arrangement with The Mann Group as payment for the aggregate exercise price of The Mann Group Warrants (see Note 13 Subsequent events).

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.

Contingencies The Company is obligated under a registration rights agreement entered into with Deerfield (the Registration Rights Agreement), pursuant to which the Company agreed to register for sale, the shares of common stock issuable upon conversion of the 2019 notes (the Conversion Shares) within a specified time period following the issuance of each tranche of 2019 notes.

The Company entered into a Milestone Agreement with Deerfield pursuant to which, the Company sold the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures (see Note 11 Facility financing agreement).

9. Related-party arrangements

In October 2007, the Company entered into a $350.0 million revolving loan arrangement with Alfred E. Mann, its principal stockholder. In February 2009, as a result of the Company s principal stockholder being subject to the licensing requirement under the California Finance Lenders Law, the promissory note underlying the loan arrangement was revised to reflect the lender as 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. In October 2012, the promissory note was amended to adjust the annual interest rate on all outstanding principal to the one-year LIBOR on December 31, 2012 plus 5%. As a result of these amendments, effective January 1, 2013, the borrowing rate for all borrowings under the promissory note with The Mann Group was set at 5.84%. On October 31, 2013, the promissory note was further 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, provide that repayments or cancellations of principal under the loan arrangement will not be available for reborrowing, and to cancel $78.0 million of principal indebtedness under the loan arrangement as payment for the aggregate exercise price of The Mann Group Warrants. Under guidance of ASC 470-10-45, the note payable to related party is excluded from current liabilities due to the amendment on October 31, 2013 and presented as a non-current liability as of September 30, 2013. In addition, the Company and The Mann Group agreed to capitalize into principal $7.9 million of accrued interest that became due and payable upon cancellation of the $78.0 million of principal indebtedness. As such, the Company included the accrued interest at September 30, 2013 in Other liabilities in the accompanying condensed consolidated balance sheet.

As of September 30, 2013, the total principal amount outstanding under the loan arrangement was $119.6 million. As of October 31, 2013, the Company had $30.1 million principal amount of available borrowings under the loan arrangement. 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 (less approximately $105.0 million aggregate principal amount that was cancelled in connection with two common stock purchase agreements a Common Stock Purchase Agreement between the Company and The Mann Group dated August 2010 and the Mann Group Common Stock Purchase Agreement - and subject to the subordination agreement entered into by The Man Group with Deerfield). 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.

In the event of a default, 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. There are no warrants associated with the loan arrangement. In connection with the Facility Agreement with Deerfield, The Mann Group entered into a subordination agreement with Deerfield, pursuant to which it agreed to subordinate its right to payments under the loan arrangement and not accept repayment until the 2019 notes have been repaid in full.

In February 2012, concurrently with an 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 $77.2 million of principal indebtedness under the revolving loan arrangement.

In October 2012, concurrently 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 December 2012 in exchange for cancellation of principal indebtedness of $107.4 million under the revolving loan arrangement. Additionally, in accordance with the terms of the loan arrangement, 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, second, and third quarters of 2013, there were no borrowings under or amendments to The Mann Group loan arrangement. The Mann Group exercised the warrants at a price of $2.60 per share in October 2013 in exchange for the cancellation of $78.0 million of principal indebtedness under the Company s loan arrangement with The Mann Group.

The restricted shares sold to The Mann Group in both the June and December 2012 transactions, and the restricted shares issued to The Mann Group upon the exercise of The Mann Group Warrants in October 2013, 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.

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10. Senior convertible notes

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

	September 30, 2013	December 31, 2012
2013 notes		
Principal amount	$ 115,000	$ 115,000
Unaccreted debt issuance expense	(103)	(557)
Net carrying amount	114,897	114,443
2015 notes		
Principal amount	$ 100,000	$ 100,000
Unaccreted debt issuance expense	(1,780)	(2,417)
Net carrying amount	98,220	97,583
Senior convertible notes	$ 213,117	$ 212,026

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 $0.7 million and $2.2 million as of September 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 principal amount, which is equal to a conversion price of approximately $6.80 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the 2015 notes converted in connection with a fundamental change by increasing the conversion rate on such 2015 notes, which amount, if any, will be based on the Company s common stock price and the effective date of the fundamental change, and (2) each holder of 2015 notes will have the option to require the Company to repurchase all or any portion of such holder s 2015 notes at a repurchase price of 100% of the principal amount of the 2015 notes to be repurchased plus accrued and unpaid interest, if any. The Company may elect to redeem some or all of the 2015 notes if the closing stock price has equaled 150% of the conversion price for at least 20 of the 30 consecutive trading days ending on the trading day before the Company s redemption notice. The redemption price will equal 100% of the principal amount of the 2015 notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, plus a make-whole payment equal to the sum of the present values of the remaining scheduled interest payments through and including August 15, 2015 (other than interest accrued up to, but excluding, the redemption date). The Company will be obligated to make the make-whole payment on all the 2015 notes called for redemption and converted during the period from the date the Company mailed the notice of redemption to and including the redemption date. The Company may elect to make the make-whole payment in cash or shares of its common stock, subject to certain limitations. Under the terms of the 2015 Note Indenture, the conversion option must be physically 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 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 $1.3 million and $0.2 million as of September 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. The Company intends to use a portion of the net proceeds from the third tranche of 2019 notes

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expected to be sold under the Facility Agreement to repay the 2013 notes. 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 must be physically 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 2013 notes and 2015 notes contain provisions that upon an acceleration of certain indebtedness, which would include the 2019 notes described in Note 11, that the holders may elect to accelerate the Company s repayment obligations under the notes if such acceleration is not cured, waived, rescinded or annulled. There can be no assurance that the holders would not choose to exercise these rights in the event such events were to occur.

The Company incurred approximately $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 nine months ended September 30, 2013 were as follows (in thousands).

	Three months ended September 30,		Nine months ended September 30,	
	2013	**2012**	**2013**	**2012**
Accretion expense	$ 369	$ 348	$ 1,091	$ 1,031

11. Facility financing agreement

The components of the facility financing agreement recorded as of September 30, 2013 consist of the following (in thousands):

	September 30, 2013
2019 notes	
Principal amount	$ 80,000
Debt discount-net of amortization	(6,798)
Unaccreted debt issuance expense	(269)
Net carrying amount of facility financing obligation	$ 72,933
Milestone rights	
Principal amount	$ 16,276
Debt discount-net of amortization	(51)
Unaccreted debt issuance expense	(61)
Less current portion of milestone rights included in other current liabilities	(3,150)

Net carrying amount included in other liabilities	$	13,013
Commitment Asset		
Initial commitment asset fair value	$	13,393
Less Tranche 2 portion of commitment asset		(3,656)
Commitment asset value included in other assets	$	9,737

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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. The 2019 notes accrue interest at a rate of 9.75% per annum until maturity in 2019 or their earlier repayment, repurchase, or conversion. A portion of the principal amount of the 2019 notes may be converted into shares of the Company s common stock (the Conversion Shares) at the noteholder s option. The conversion price will be determined by the volume weighted average price of the Company s common stock during the 20 trading days immediately preceding the conversion date. The number of Conversion Shares that may be issued upon conversion of all 2019 notes will be limited to an aggregate of 12.0 million shares or such lesser number of shares as may be determined pursuant to the conversion limitations contained in the 2019 notes if the conversion price at which the 2019 notes are actually converted from time to time is greater than $3.33.

Deerfield purchased the first tranche of 2019 notes (the Tranche 1 Notes) and Milestone Rights (as defined below) in the aggregate principal amount of $40.0 million. The closing of the second tranche of 2019 notes (the Tranche 2 Notes), which was subject to achievement and reporting of certain results from the Company s two Phase 3 clinical studies of AFREZZA, occurred on September 5, 2013. Deerfield s obligation to purchase the third tranche of 2019 notes is subject to the repayment of the 2013 notes with the funds made available by the purchase of these 2019 notes. Deerfield s obligation to purchase the fourth tranche of 2019 notes is subject to receipt of marketing approval of AFREZZA by the FDA and the prior satisfaction of the conditions for the third tranche closing. In addition to the foregoing conditions, Deerfield s obligation to purchase 2019 notes at any of the two remaining closings is subject to, at each closing, the Conversion Shares issuable upon conversion of all previously sold 2019 notes being freely tradable pursuant to an effective registration statement filed with the SEC or pursuant to Rule 144 under the Securities Act.

The Company is required to repay 25% of the original 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; provided that the entire outstanding principal amount of all 2019 notes will become due and payable no later than December 31, 2019. The Company had the right to prepay the outstanding principal amount of the Tranche 1 Notes at a price equal to 110% of the outstanding principal thereof plus all accrued and unpaid interest as of the date of prepayment if the conditions for the Tranche 2 Notes had not been satisfied. The Company is required to repay any outstanding 2019 notes in full if the Company completes a major transaction (as defined), which includes, but is not limited to, certain mergers and other change of control transactions involving the Company.

The Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires the Company s cash and cash equivalents, which includes available borrowings on the related party note, on the last day of each fiscal quarter to not be less than $25.0 million. As discussed in Note 1 Basis of Presentation, the Company will need to raise additional capital to support its current operating plans. Due to the uncertainties related to maintaining sufficient resources to comply with the aforementioned covenant, the 2019 notes have been classified as current liabilities in the accompanying balance sheet as of September 30, 2013. In the event of non-compliance, there can be no assurances that the holders of the 2019 notes will not exercise remedies available to them, which may include, among other things, the issuance of a notice of acceleration.

In connection with the issuance of the Tranche 1 Notes and Milestone Rights on July 1, 2013, the Company recorded $52.9 million in value received, which consisted of $39.5 million in cash from the issuance of the Tranche 1 Notes plus a commitment asset (as described further below) with a fair value equal to $13.4 million. In exchange, the Company issued to Deerfield the Tranche 1 Notes and Milestone Rights with estimated fair values equal to $37.1 million and $16.3 million, respectively. The Tranche 1 Notes, the Milestone Rights and the commitment asset were initially recorded at fair value.

The Tranche 1 Notes are classified as short-term debt and are subsequently accounted for at amortized cost. The effective interest rate on the Tranche 1 Notes is 12.19% and a debt discount of approximately $3.3 million recognized on the Tranche 1 Notes is being amortized to interest expense over the term of the Tranche 1 Notes using the effective interest method.

In accordance with the Facility Agreement, the Company reimbursed Deerfield $500,000 for a portion of documented expenses for attorneys, accountants and other professional advisors, and other out-of-pocket expenses Deerfield incurred in connection with the transaction. These costs were allocated between the 2019 notes and the Milestone Rights based upon their relative fair value resulting in $448,737 being allocated to the 2019 notes and included within the debt discount with the remainder being allocated to the Milestone Rights. In addition, the Company incurred a total of $597,529 in debt issuance costs, of which $536,266 was allocated to the 2019 notes and the remainder to the Milestone Rights using the relative fair value allocation method. A portion of the debt issuance costs, or $259,800, related to the third and fourth tranches of 2019 notes are included in other assets.

The commitment asset represents the right to receive additional funding under the second, third and fourth tranches of the Facility Agreement. The fair value of the commitment asset was estimated using the income approach by estimating the fair value of the future tranches using a market debt rate commensurate with the risk of the future tranches and the fair value of the cash expected to be received by the Company and assessing the probability of the commitments being funded in the future. The commitment asset will not be subsequently remeasured but it will be monitored for impairment until future tranches of 2019 notes are drawn. Upon the drawing of additional tranches of 2019 notes, the portion of the commitment asset related to such tranche will be derecognized resulting in a debt discount being recorded on the additional tranches of 2019 notes issued. If the additional funding under the third and fourth tranches ceases to be probable of occurring, the commitment asset will be impaired and will be written off as an expense in the Statement of Operations.

Upon the issuance of the Tranche 2 Notes, the portion of the commitment asset attributed to the Tranche 2 Notes was derecognized and recorded as a debt discount to the Tranche 2 Notes. Therefore, the Tranche 2 Notes were recorded as short-term debt for the $40.0 million received, less a $3.7 million debt discount. The effective interest rate on the Tranche 2 Notes is 12.45% and the debt discount is being amortized over the term of the Tranche 2 Notes using the effective interest method.

The Company identified and evaluated a number of embedded features in the Facility Agreement to determine if they represented embedded derivatives requiring bifurcation and separate accounting pursuant to ASC 815, *Derivatives and Hedging*. There were two embedded features that required bifurcation and separate accounting and the Company determined that they should be bundled together as a single, compound embedded derivative, bifurcated from the host contract, and accounted for at fair value, with changes in fair value being recorded in the Statement of Operations. Management determined that the value of these embedded derivatives at July 1, 2013 and at September 30, 2013 was insignificant.

Milestone Agreement

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

The Milestone Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to AFREZZA. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement and terminate if the Company exercises its right to prepay the Tranche 1 Notes.

The Milestone Rights were initially recorded as a short-term liability equal to $3.2 million included in Accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet and a long term liability equal to $13.1 million included in Other liabilities. In determining the fair value of the Milestone Rights, the 13 individual milestone payments were adjusted for both (i) the expected timing and (ii) the probability of achieving the milestones, and then discounted to present value using a discount rate of 17.5%. Once the initial valuation of each specified milestone payment was determined, the individual milestone payments were then aggregated to arrive at a total fair value of $16.3 million. The discount rate was based on the estimated cost of equity which was derived using the capital asset pricing model. In addition, a 5% risk premium was added to the computation of the cost of equity to adjust for non-systemic risk factors, such as the Company s lack of product diversification and history of financial losses, which were not captured in other model inputs.

The Milestone Rights did not meet the definition of a derivative under ASC 815; therefore the Company analogized to the accounting guidance contained in ASC 470-10-35-4, which addresses indexed debt. As each milestone is achieved, the portion of the initial liability pertaining to the specified milestone will be remeasured to equal the amount of the milestone payment. The change in the balance of the liability that occurs upon remeasurement will be recorded as interest expense in the Statement of Operations. Once the milestone payment is made for a specific milestone event, the remeasured liability pertaining to that specific milestone event will be extinguished. The resulting effect is that the payment required to be made upon the occurrence of the milestone event is allocated between a reduction of the initial liability pertaining to that milestone and an expense representing a return on that portion of the liability paid to the Milestone Purchasers for the achievement of that milestone.

The Company identified and evaluated a number of embedded features in the Milestone Rights to determine if they represented embedded derivatives requiring bifurcation and separate accounting pursuant to ASC 815, *Derivatives and Hedging*. There were no features in the Milestone Rights that required bifurcation and separate accounting

Security Agreement

In connection with the Facility Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the Security Agreement) with Deerfield and HS (collectively, the Purchasers), pursuant to which the Company and MannKind LLC each granted the Purchasers a security interest in substantially all of their respective assets, including respective intellectual property, accounts, receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Security Agreement includes customary covenants by the Company and MannKind LLC, remedies of the Purchasers and representations and warranties by the Company and MannKind LLC. The security interests granted by us and MannKind LLC will terminate upon repayment of the 2019 notes in full. Our obligations under the Facility Agreement and the Milestone Agreement are also secured by certain mortgages on the Company s facilities in Danbury, Connecticut and Valencia, California.

Registration Rights Agreement

In connection with the Facility Agreement and the sale of the 2019 notes pursuant thereto, the Company entered into a Registration Rights Agreement with Deerfield (the Registration Rights Agreement), pursuant to which the Company agreed to register for sale, the Conversion Shares within a specified time period following the issuance of each tranche of 2019 notes.

Pursuant to the Registration Rights Agreement, the number of aggregate shares of Common Stock included in the initial mandatory registration statement is 12.0 million shares (subject to adjustment in the event of a stock split, stock combination, reclassification, payment of stock dividends, recapitalization, or other similar transactions).

In the event the Company is unable to meet certain requirements of the Registration Rights Agreement specifically related to the filing of the registration statement within specified periods, using its best efforts to obtain effectiveness of the registration statement, or maintaining the effectiveness of the registration statement, the Company will be required to pay additional damages to Deerfield. The additional damages are calculated as 1% of Deerfield s original principal amount of the relevant tranche of 2019 notes and shall accrue until the earlier of (i) the date on which the registration failure has been cured and (ii) the date on which the Conversion Shares may be disposed of by Deerfield.

In accordance with the accounting guidance contained in ASC 825-20, the contingent obligation to make future payments, or otherwise transfer consideration, under a registration payment arrangement should be recognized and measured in accordance with ASC 450-20. ASC 450-20 requires an accrual to be recorded for a contingent payment if it is both probable of occurring and the amount of the payment can be reasonably estimated. As of September 30, 2013, the Company determined that it is not probable that it will be obligated to pay additional damages to Deerfield pursuant to the Registration Rights Agreement, and therefore no accrual for such contingent payment has been recorded.

Accretion of debt issuance cost and debt discount in connection with the Deerfield financing during the three and nine months ended September 30, 2013 are as follows (in thousands).

	Three months ended September 30, 2013	Nine months ended September 30, 2013
Accretion expense- debt issuance cost	$ 8	$ 8
Accretion expense- debt discount	$ 190	$ 190

12. Income taxes

As required by ASC 740 *Income Taxes* (ASC 740), management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. 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 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.

13. Subsequent events

In October 2013, the Company received an additional $45.0 million in cash proceeds from the exercise of the October 2012 public offering warrants and $78.0 million of consideration from The Mann Group in the form of cancelled principal indebtedness under the Company s loan arrangement with The Mann Group as payment for the aggregate exercise price of The Mann Group Warrants.

On October 31, 2013, the Company s loan arrangement with The Mann Group 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, provide that repayments or cancellations of principal under the loan arrangement will not be available for reborrowing, and to cancel $78.0 million of principal indebtedness under the loan arrangement as payment for the aggregate exercise price of The Mann Group Warrants. In addition, the Company and The Mann Group agreed to capitalize into principal $7.9 million of accrued interest that became due and payable upon cancellation of the $78.0 million of principal indebtedness.

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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 recently completed two additional Phase 3 clinical studies in adults with type 1 or type 2 diabetes.

On August 14, 2013, we released the results of these Phase 3 clinical studies, both of which met their primary efficacy endpoints and safety objectives. On October 13, 2013, we submitted the results of these studies to the FDA as an amendment to our NDA. The FDA subsequently acknowledged the resubmission and advised us that it considers the updated NDA to be a complete class 2 response to our Completed Response Letter issued in January 2011, and assigned a user fee goal date of April 15, 2014. However, the data collected from these clinical studies may not be sufficient to support 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 September 30, 2013, we have incurred a cumulative net loss of $2.2 billion and an accumulated stockholders deficit of $167.7 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 The Mann Group and a Facility Agreement with Deerfield. 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 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 studies and the regulatory approval process, our potential inability to enter into sales and marketing collaborations or to commercialize AFREZZA in a timely manner, the 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 studies 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 study 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 study 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

The following are recent critical accounting policies since our Annual Report:

Milestone rights

On July 1 2013, in conjunction with the execution of the Facility Agreement, we issued Milestone Rights to Deerfield whereby we agreed to provide Deerfield with pre-specified Milestone Payments upon the achievement of 13 specific Milestone Events related to the commercial release and future cumulative net sales of AFREZZA®. We analyzed the Milestone Rights under the provisions of ASC 815 *Derivatives and Hedging* and determined that the agreement does not meet the definition of a freestanding derivative. Since we have not elected to apply the fair value option to the Milestone Rights Purchase Agreement, we have initially recorded the Milestone Rights at their estimated fair value and accounted for the Milestone Rights as a liability by applying the indexed debt guidance contained in paragraphs ASC 470-10-25-3 and 35-4.

The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate. The expected timing and probability of achieving the milestones was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate was selected based on an estimation of required rate of returns for similar investment opportunities using available market data.

The Milestone Rights liability will be remeasured as the pre-specified Milestone Events are achieved. Specifically, as each Milestone Event is achieved, the portion of the initially recorded Milestone Rights liability, which pertains to the Milestone Event being achieved, will be remeasured to the amount of the pre-specified Milestone Payment. The resulting change in the balance of the Milestone Rights liability due to such remeasurement will be recorded in the Company s Income Statement as interest expense. Furthermore, the Milestone Rights liability will be reduced upon the Milestone Payment being paid. As a result, the required Milestone Payment is effectively allocated between a reduction of the initially recorded Milestone Rights liability and an expense representing a return on a portion of the Milestone Rights liability paid to the investor for the achievement of a Milestone Event.

Commitment asset

In connection with issuance of the first tranche of the 2019 notes and the Milestone Rights, the Company recorded a commitment asset on July 1, 2013. The initial value of the commitment asset was calculated using the income approach by estimating the fair value of the future tranches using a market debt rate commensurate with the risk of the future tranches and the fair value of the cash expected to be received by us and assessing the probability of the commitments being funded in the future based on the operational hurdles required for funding being met. The commitment asset attributable to each tranche of 2019 notes to be issued under the Facility Agreement will be derecognized and recorded as a debt discount on the 2019 notes when issued. The debt discount will be amortized using the effective interest rate method over the life of the 2019 notes. Prior to derecognition occurring, we will monitor the commitment asset on an ongoing basis to determine whether an impairment indicator is present that would result in a full or partial write down of the commitment asset as a result of events that may lead to the subsequent tranches of 2019 notes not being issued.

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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 nine months ended September 30, 2013 and 2012

Revenue

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

Research and Development Expenses

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

	Three months ended September 30,			
	2013	**2012**	**$ Change**	**% Change**
Clinical	$ 8,249	$ 12,248	$ (3,999)	(33%)
Manufacturing	10,240	9,735	505	5%
Research	1,601	1,721	(120)	(7%)
Research and development tax credit	(51)	(85)	34	(40%)
Stock-based compensation expense	7,242	1,834	5,408	295%
Research and development expenses	$ 27,281	$ 25,453	$ 1,828	7%

	Nine months ended September 30,			
	2013	**2012**	**$ Change**	**% Change**
Clinical	$ 32,509	$ 36,454	$ (3,945)	(11%)
Manufacturing	29,354	29,727	(373)	(1%)
Research	4,690	5,843	(1,153)	(20%)
Research and development tax credit	(207)	(270)	63	(23%)
Stock-based compensation expense	14,385	4,493	9,892	220%

Research and development expenses	$ 80,731	$ 76,247	$ 4,484	6%

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The increase in overall research and development expenses for the three months ended September 30, 2013, compared to the three months ended September 30, 2012, was primarily due to an increase in stock-based compensation expense of $5.4 million in connection with performance-based grants to all employees, including our executive officers, in the first and second quarters of 2013, offset by $4.0 million in decreased clinical study related expenses upon the completion of two Phase 3 studies in May 2013 and June 2013.

The increase in overall research and development expenses for the nine months ended September 30, 2013, compared to the nine months ended September 30, 2012, was primarily due to an increase in stock-based compensation expense of $9.9 million in connection with performance-based grants to all employees, including our executive officers, in the first and second quarters of 2013, offset by $3.9 million in decreased clinical study related expenses from the completion of two Phase 3 studies in May 2013 and June 2013, and reduced research expenses resulting from the positive effect of our cost cutting measures and lower manufacturing expenses associated with the completion of the two Phase 3 studies in May 2013 and June 2013.

We anticipate that our overall research and development expense will increase in 2013 as compared to 2012 as a result of the increased stock compensation expenses partly offset by lower research and development costs due to the completion of the two Phase 3 clinical studies.

General and Administrative Expenses

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

	Three months ended September 30,			
	2013	2012	$ Change	% Change
Salaries and employee related expenses	$ 4,028	$ 3,825	$ 203	5%
Professional fees and other general expenses	4,752	3,357	1,395	42%
Charge for litigation settlement		901	(901)	(100%)
Stock-based compensation expense	8,701	1,986	6,715	338%
General and administrative expenses	$ 17,481	$ 10,069	$ 7,412	74%

	Nine months ended September 30,			
	2013	2012	$ Change	% Change
Salaries and employee related expenses	$ 11,763	$ 11,691	$ 72	1%
Professional fees and other general expenses	13,371	11,646	1,725	15%
Charge for litigation settlement		8,648	(8,648)	(100%)
Stock-based compensation expense	16,919	5,277	11,642	221%
General and administrative expenses	$ 42,053	$ 37,262	$ 4,791	13%

General and administrative expenses for the three months ended September 30, 2013 increased compared to the three months ended September 30, 2012 primarily due to an increase in stock-based compensation expense of $6.7 million in connection with performance-based grants to all employees, including our executive officers, in the first and second quarters of 2013 and professional legal fees.

General and administrative expenses for the nine months ended September 30, 2013 increased compared to the nine months ended September 30, 2012 primarily due to an increase in stock-based compensation expense of $11.6 million in connection with performance-based grants to all employees, including our executive officers, in the first and second quarters of 2013 and professional legal fees, offset by the $8.6 million litigation settlement charge recorded in 2012.

We expect general and administrative expenses overall to be higher in 2013 as compared to 2012 due to increased stock compensation expense.

Other Income (Expense)

Other income for the three months ended September 30, 2012 was $2.7 million due to a fair value adjustment recorded related to warrants. Other expense for the nine months ended September 30, 2012 was $12.0 million and comprised primarily of the $12.0 million adjustment to the fair value of the forward purchase contract with The Mann Group in the second quarter of 2012.

Interest Expense

Interest expense for the three months ended September 30, 2013 increased compared to the same period in the prior year primarily due to interest related to the 2019 notes issued in the third quarter of 2013. Interest expense for the nine months ended September 30, 2013 decreased compared to the same period in the prior year primarily due to the cancellation of principal on the related party loan offset by an increase in interest related to the 2019 notes.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under our loan arrangement with our principal stockholder.

In October 2007, we entered into a $350.0 million loan arrangement with Alfred E. Mann, our principal stockholder. In February 2009, as a result of our principal stockholder being subject to the licensing requirement under the California Finance Lenders Law, the promissory note underlying the loan arrangement was revised to reflect the lender as The Mann Group, an entity controlled by our principal stockholder. 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. We amended the promissory note underlying the loan arrangement at various dates during 2012. In October 2012, we amended the loan arrangement to adjust the annual interest rate on all outstanding principal to the one-year LIBOR on December 31, 2012 plus 5%. As a result of these amendments, effective January 1, 2013, the borrowing rate for all borrowings under the promissory note with The Mann Group was set at 5.84%. In October 2013, the promissory note was further amended to, among other things, extend the maturity date of the loan to January 5, 2020, extend the date through which we 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, provide that repayments or cancellations of principal under the loan arrangement will not be available for reborrowing, and to cancel $78.0 million of principal indebtedness under the loan arrangement as payment for the aggregate exercise price of The Mann Group Warrants. As of October 31, 2013, there was $30.1 million principal amount of available borrowings under the loan arrangement.

As of September 30, 2013, the total principal amount outstanding under the loan arrangement with The Mann Group was $119.6 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 we 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 us to prepay up to $200.0 million in advances (less approximately $105.0 million aggregate principal amount that was cancelled in connection with two common stock purchase agreements a Common Stock Purchase Agreement between us and The Mann Group dated August 2010 and the Mann Group Common Stock Purchase Agreement subject to the subordination agreement entered into by The Mann Group with Deerfield). If The Mann Group exercises this right, we 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.

In the event of a default, 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. There are no warrants associated with the loan arrangement.

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). As of September 30, 2013, we received $44.7 million in proceeds from the exercise of a portion of the public offering warrants with $45.0 million remaining unexercised. The Mann Group Warrants also remained unexercised as of September 30, 2013. In October 2013, we received an additional $45.0 million in cash proceeds from the exercise of the October 2012 public offering warrants and $78.0 million of consideration from The Mann Group in the form of cancelled principal indebtedness under our loan arrangement with The Mann Group as payment for the aggregate exercise price of The Mann Group Warrants.

On March 18, 2013, we entered into 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. 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 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. In connection with the Facility Agreement, on July 1, 2013, we also entered into the Milestone Agreement with the Milestone Purchasers, pursuant to which, we 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.

Deerfield purchased the first tranche of 2019 notes and the Milestone Rights in the aggregate principal amount of $40.0 million. The closing of the second $40.0 million principal amount tranche of 2019 notes, which was subject to achievement and reporting of certain results from our two Phase 3 clinical studies of AFREZZA, occurred on September 5, 2013. There can be no assurance that the conditions required for the purchase of the third and fourth tranches of 2019 notes will be met or met in a timeframe necessary to support our liquidity needs.

During the nine months ended September 30, 2013, we used $94.7 million of cash for our operations and had a net loss of $137.9 million, which included $41.4 million of non-cash charges primarily consisting of depreciation and accretion and stock-based compensation. By comparison, during the nine months ended September 30, 2012, we used $91.8 million of cash for our operations and had a net loss of $117.6 million, which included $20.7 million of non-cash charges primarily consisting of depreciation and accretion and stock-based compensation. Cash used for our operations increased by $2.9 million primarily due to the payment of accrued clinical study expenses and other accrued expenses in 2013. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

We used $1.8 million of cash for investing activities during the nine months ended September 30, 2013, compared to $0.5 million of cash used for the nine months ended September 30, 2012. Cash used for investing activities for the nine months ended September 30, 2013 compared to the same period in the prior year increased $1.3 million, primarily due to purchases of machinery and equipment to expand the manufacturing lines in preparation for a future approval of AFREZZA.

Our financing activities resulted in positive cash flow of $128.5 million during the nine months ended September 30, 2013, compared to positive cash flow of $91.3 million for the same period in 2012. For the nine months ended September 30, 2012, cash provided by financing activities was primarily from $81.0 million related to the February 2012 issuance of common stock and warrants through the sale of 35,937,500 units, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock as well as the exercise of stock options. Additionally, we generated cash of $11.3 million from related party borrowings. For the nine months ended September 30, 2013, cash provided by financing activities was primarily from $79.5 million from the first two tranches of the Facility Agreement with Deerfield and $49.2 million in warrant exercises.

At September 30, 2013, our capital resources consisted of cash and cash equivalents of $93.8 million. In addition, we expect to sell $40.0 million principal amount of 2019 notes to Deerfield under the Facility Agreement in the fourth quarter of 2013 in connection with the requirement to repay the 2013 notes with the funds made available by the purchase of these notes. As of October 31, 2013, we had $30.1 million principal amount of available borrowings under the loan arrangement with The Mann Group, although we anticipate using a portion of these available borrowings to capitalize into principal accrued interest as it becomes due and payable under the loan arrangement. In connection with the Facility Agreement with Deerfield, The Mann Group entered into a subordination agreement with Deerfield, pursuant to which it agreed to subordinate its right to payments under the loan arrangement and not accept repayment until the 2019 notes have been repaid in full.

Based on our current expectations, including the expectation that Deerfield will purchase $40.0 million principal amount of 2019 notes in the fourth quarter of 2013, a portion of which will be used to repay the $115.0 million in 2013 notes, we believe our existing capital resources will enable us to continue planned operations into at least the first quarter of 2014. However, we cannot provide assurances that Deerfield will fund the third tranche under the Facility Agreement, that we will be able to access capital through the ATM Agreements on favorable terms, or at all, or that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

As discussed above, on July 1, 2013, we entered into the Facility Agreement with Deerfield. Under the Facility Agreement, Deerfield s obligation to purchase the third tranche of 2019 notes is subject to our repayment of the 2013 notes and Deerfield s obligation to purchase the fourth tranche of 2019 notes is subject to our receipt of approval of AFREZZA by the FDA and the prior satisfaction of the conditions for the third tranche closing. In addition to the foregoing conditions, Deerfield s obligation to purchase 2019 notes at either of the two remaining closings is subject to, at each closing, the Conversion Shares 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. We are 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 2019 notes accrue interest at a rate of 9.75% per annum until maturity or their earlier repayment, repurchase, or conversion. A portion of the principal amount of the 2019 notes may be converted into shares of our common stock at Deerfield s option. The conversion price will be determined by the volume weighted average price of our 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

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may be issued upon conversion; and if the conversion price is between these dollar amounts, no more than $40.0 million worth of common stock may be issued upon conversion. The Facility Agreement includes customary representations, warranties and covenants, including a financial covenant which requires the Company s cash and cash equivalents, which includes available borrowings on the related party note, on the last day of each fiscal quarter not be less than $25.0 million, by the Company, including restrictions on the incurrence of additional indebtedness. In connection with the Facility Agreement, we also entered into the Milestone Agreement with the Milestone Purchasers, pursuant to which, we sold the Milestone Purchasers the Milestone Rights, which entitle them to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures.

The $115.0 million aggregate principal amount of 2013 notes mature in December 2013, and our cash and cash equivalents as of September 30, 2013 are insufficient to repay these notes. However, subsequent to September 30, 2013, we received $45.0 million in cash proceeds from the exercise of certain public offering warrants prior to their expiration in October 2013 and we expect to receive an additional $40.0 million (less an original issue discount) upon issuance of the third tranche of the 2019 notes concurrently with the repayment of the 2013 notes, which will be sufficient to cover the total amounts due at maturity in respect of the 2013 notes. Going forward, however, we will need to raise additional capital, either through the sale of equity or debt securities, the entry into a strategic business collaboration with a pharmaceutical or biotechnology company, the establishment of other funding facilities, licensing arrangements, asset sales or other means in order to repay our obligations under the loan arrangement with The Mann Group, the 2015 notes, the 2019 notes, and to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. There can be no assurance that we will be able to raise additional capital on favorable terms by the applicable repayment dates, or at all.

In addition, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2013 notes and the 2015 notes, or in respect of the 2019 notes, a major transaction as defined under the Facility Agreement, each holder of the applicable notes will have the option to require us to repurchase all or any portion of such holder s notes at a repurchase price of 100% of the principal amount of such notes to be repurchased plus accrued and unpaid interest, if any. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the noteholders initiating bankruptcy proceedings or causing us to cease operations altogether. This raises substantial doubt about our ability to continue as a going concern.

In addition to repayment of the 2013 notes, we intend to use our capital resources to continue the development and, if approved, the commercialization of AFREZZA. We are expending a portion of our capital to scale up our manufacturing capabilities in our Danbury facilities. We also intend to use our capital resources for general corporate purposes.

We intend to pursue potential 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 potential strategic business collaborations for AFREZZA, to date, we have not reached an agreement on such collaborations 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.

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

If planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financing or entering a business collaboration, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

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Off-Balance Sheet Arrangements

As of September 30, 2013, we did not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds and investment-grade corporate, government and municipal debt. None of these investments is entered into for trading purposes. As of September 30, 2013, our cash was deposited in and invested through highly rated financial institutions in North America and consisted 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. Pursuant to an amendment to the promissory note underlying our loan arrangement with The Mann Group in October 2012, as of January 1, 2013 the interest rate on all outstanding principal amounts under our credit facility with The Mann Group was adjusted 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 October 31, 2013, we had $30.1 million principal amount of available borrowings under the loan arrangement.

ITEM 4. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

We performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of September 30, 2013. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting during the fiscal quarter ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

Item 1A. ***Risk Factors***

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

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RISKS RELATED TO OUR BUSINESS

We depend heavily on the successful development and commercialization of our lead product candidate, AFREZZA, which is not yet approved.*

To date, we have not commercialized any product candidates. We have expended significant time, money and effort in the development of our lead product candidate, AFREZZA, which has not yet received regulatory approval and which may not be approved by the FDA in a timely manner, or at all. Our other product candidates are generally in early clinical or preclinical development. We anticipate that in the near term, our ability to generate revenues will depend on the successful development and commercialization of AFREZZA.

On August 14, 2013, we released the results of two Phase 3 clinical studies of AFREZZA, both of which met their primary efficacy endpoints and safety objectives. On October 13, 2013, we submitted the results of these studies to the FDA as an amendment to our new drug application, or NDA. However, the data collected from these clinical studies may not be sufficient to support 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. There can be no assurance that we will obtain approval of the NDA in a timely manner or at all.

We must receive the necessary approvals from the FDA before AFREZZA can be marketed and sold in the United States and must receive the necessary approvals from similar foreign regulatory agencies before AFREZZA can be marketed outside of the United States. Even if we were to receive regulatory approval, we ultimately may be unable to gain market acceptance of AFREZZA for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and lack of coverage or adequate reimbursement. If we fail to commercialize AFREZZA, our business, financial condition and results of operations will be materially and adversely affected.

We have sought to develop our product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all.

A significant portion of the research that we have conducted involves new and unproven compounds and technologies, including AFREZZA and our Technosphere platform technology. Even if our research programs identify candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to successfully complete the development and commercialization of AFREZZA or develop or expand our other product candidates, or are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

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

We are a development stage company with no commercial products. All of our product candidates are still being developed, and all but AFREZZA are still in the early stages of development. Our product candidates will require significant additional development, clinical studies, regulatory clearances and additional investment before they can be commercialized. We cannot be certain when AFREZZA may be approved or if it will be approved.

We have never been profitable or generated positive cash flow from operations and, as of September 30, 2013, we had incurred a cumulative net loss of $2.2 billion. The cumulative net loss has resulted principally from costs incurred in our research and development programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to further develop and commercialize our product candidates, including costs and expenses to complete clinical studies, seek regulatory approvals and market our product candidates, including AFREZZA. This cumulative net loss may increase significantly as we continue development and clinical study efforts. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders equity. As of September 30, 2013, we had a stockholders deficit of $167.7 million. Our ability to achieve and sustain positive cash flow from operations and profitability primarily depends upon obtaining regulatory approvals for and successfully commercializing AFREZZA, either alone or with third parties. We do not currently have the required approvals to market any of our product candidates, and we may not receive them. We may not generate positive cash flow from operations or be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

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We will be required to raise additional capital to fund our operations, and our inability to do so could raise substantial doubt about our ability to continue as a going concern.*

Based on our current expectations, including the expectation that Deerfield will purchase $40.0 million principal amount of 2019 notes in the fourth quarter of 2013, a portion of which will be used to repay the $115.0 million in 2013 notes, we believe that our existing capital resources will enable us to continue planned operations into at least the first quarter of 2014. However, we cannot assure you that Deerfield will fund the third tranche under the Facility Agreement, that we will be able to access capital through the ATM Agreements on a timely basis, or at all, or that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. We will need to raise additional funds, through the sale of equity or debt securities, the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales, by amending the loan arrangement with The Mann Group to allow us to make additional borrowings, or other means, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. It may be difficult for us to raise additional funds on favorable terms, or at all. As of September 30, 2013, we had a stockholders deficit of $167.7 million which may raise concerns about our solvency and affect our ability to raise additional capital. The amount of additional funds we need will depend on a number of factors, including:

- the election of any or all of the holders of the 2013 notes, or of any or all of the holders of the 2015 notes, to require us to repay or repurchase such notes if and when required;
- our ability to refinance existing indebtedness, including indebtedness under the 2013 notes or 2015 notes which mature in December 2013 and August 2015, respectively;
- the satisfaction of the conditions to holding additional closings of the sale and purchase of 2019 notes under the Facility Agreement, or failing the satisfaction of such conditions, whether Deerfield chooses to waive satisfaction of such conditions and purchase additional 2019 notes;
- the extent to which the 2013 notes, 2015 notes and the 2019 notes are converted into shares of our common stock;
- rate of progress and costs of our clinical studies and research and development activities, including costs of procuring clinical materials and operating our manufacturing facilities;
- our obligation to make milestone payments under the Milestone Rights issued to the Milestone Purchasers;
- our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;
- the costs of preparing applications for regulatory approvals for our product candidates, including AFREZZA;
- actions taken by the FDA and other regulatory authorities affecting our product candidates and competitive products;
- our degree of success in commercializing AFREZZA assuming receipt of required regulatory approvals;

- the emergence of competing technologies and products and other market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal expenses;
- the costs associated with litigation; and
- the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

We have raised capital in the past primarily through the sale of equity and debt securities. We may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities including asset based borrowings. There can be no assurances, however, that we will be able to raise additional capital through such an offering on acceptable terms, or at all. Issuances of additional debt or equity securities, or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and may dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

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

We do not anticipate generating operating cash flow before AFREZZA is commercialized, which we expect will require us to reach an agreement with a commercialization partner, and therefore cannot provide assurances that changed or unexpected circumstances, including, among other things, delays in obtaining regulatory approval and in identifying and reaching agreements with a commercialization partner, will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we may be required to raise additional capital. There can be no assurances that we will be able to raise additional capital on acceptable terms, or at all. If planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financings or entering into a strategic business collaboration with a pharmaceutical or biotechnology company, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will be continued substantial doubt about our ability to continue as a going concern.

We have a substantial amount of convertible debt and may be unable to make required payments of interest and principal as they become due.*

As of September 30, 2013, we had $295.0 million of outstanding convertible debt, consisting of:

- $115.0 million principal amount of 2013 notes bearing interest at 3.75% per annum and maturing on December 15, 2013;

- $100.0 million principal amount of 2015 notes bearing interest at 5.75% per annum and maturing on August 15, 2015; and

- $80.0 million principal amount of 2019 notes bearing interest at 9.75% per annum and maturing between 2016 and December 31, 2019.

In addition, pursuant to the Facility Agreement, we may issue up to $80.0 million principal amount of additional 2019 notes upon the satisfaction of certain conditions. As of September 30, 2013, we did not have sufficient cash and cash equivalents to repay the 2013 notes, which notes by their terms will become due in December 2013. In addition, as of September 30, 2013, the effective conversion price of the 2013 notes was approximately $22.47 per share, subject to adjustment, which is substantially above the closing price of our common stock on November 2, 2013. Our intention is to repay the 2013 notes upon maturity with existing capital resources plus the funds made available by the purchase of 2019 notes, but if we are unable to do so we will need to refinance our 2013 notes before such notes mature, or raise additional funds to repay such notes, and there can be no assurance that we will be able to do so on favorable terms by the applicable repayment dates, or at all. In addition, there can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2015 notes or 2019 notes when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2013 notes and the 2015 notes, or a major transaction as defined in the Facility Agreement (in respect of the 2019 notes), each holder of the applicable notes will have the option to require us to repurchase all or any portion of such holder s notes at a repurchase price of 100% of the principal amount of such notes to be repurchased plus accrued and unpaid interest, if any. The 2013 notes bear interest at the rate of 3.75% per year on the outstanding principal amount, payable in cash semi-annually in arrears on June 15 and December 15 of each year, the 2015 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year, and the 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount 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. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2013 notes, 2015 notes or 2019 notes or if we fail to repay or repurchase the 2013 notes, 2015 notes or 2019 notes when required, we will be in default under the applicable indenture(s) or other applicable instrument for such note(s), and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the noteholders initiating bankruptcy proceedings or causing us to cease operations altogether.

Our agreements with Deerfield relating to our 2019 notes and the milestone purchase rights contain covenants that we may not be able to meet and place restrictions on our operating and financial flexibility.*

Our indebtedness under the 2019 notes, including any future indebtedness we incur as the result of our sale of additional 2019 notes, is secured by substantially all of our assets, including our intellectual property, accounts receivables, equipment, general intangibles, inventory (including the insulin inventory) and investment property, and all of the proceeds and products of the foregoing. Our obligations under the Facility Agreement, the 2019 notes and the Milestone Agreement are also secured by certain mortgages on our facilities in Danbury, Connecticut and Valencia, California.

The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the 2019 notes; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents, including amounts available to us under our revolving loan arrangement with The Mann Group, falling below $25.0 million as of the last day of any fiscal quarter; our failure to timely deliver any shares issuable upon conversion of the 2019 notes; and our failure to cause the shares issuable upon conversion of the 2019 notes to be freely tradable within certain agreed upon timeframes. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the 2019 notes may declare all or any portion of the 2019 notes to be immediately due and payable. The Milestone Agreement includes customary representations and warranties and covenants by us, including restrictions on transfers of intellectual property related to AFREZZA. The milestones are subject to acceleration in the event we transfer our intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement.

There can be no assurance that we will be able to satisfy the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the 2019 notes would demand repayment of the outstanding balance of the 2019 notes or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our indebtedness, including our indebtedness under the 2013 notes and the 2015 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of our 2013 notes, 2015 notes and 2019 notes may accelerate all of our repayment obligations, and, with respect to the 2019 notes, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations.

If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding debt would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation.

Deterioration of the general global economic conditions may have an adverse impact on our loan facility with The Mann Group.*

In the recent past, financial markets in the United States, Europe and Asia have experienced a period of unprecedented turmoil and upheaval characterized by extreme volatility and declines in security prices, severely diminished liquidity and credit availability, inability to access capital markets, the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government and other governments. We cannot predict the impact of the deterioration, if any, of the general stock market and global economy on the financial condition of The Mann Group. If The Mann Group has insufficient assets or if we are otherwise unable to draw on The Mann Group loan facility, our business and financial condition may be adversely affected.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business will be harmed and the market price of our common stock could decline.*

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

- the rate of progress, costs and results of our clinical study and research and development activities;

our ability to identify and enroll patients who meet clinical study eligibility criteria;

- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including insulin and other materials for AFREZZA;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent to which our clinical studies compete for clinical sites and eligible subjects with clinical studies sponsored by other companies;
- our ability to enter into sales and marketing collaborations for AFREZZA; and
- other actions by regulators.

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

We face substantial competition in the development of our product candidates and may not be able to compete successfully, and our product candidates may be rendered obsolete by rapid technological change.

A number of established pharmaceutical companies have or are developing technologies for the treatment of diabetes. We also face substantial competition for the development of our other product candidates.

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, production, and sales and marketing resources than we do and have a greater depth and number of experienced managers. As a result, our competitors may be better equipped than we are to develop, manufacture, market and sell competing products. In addition, gaining favorable reimbursement is critical to the success of AFREZZA. Many of our competitors have existing infrastructure and relationships with managed care organizations and reimbursement authorities which can be used to their advantage.

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

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

If we fail to enter into a strategic collaboration with respect to AFREZZA, we may not be able to execute on our business model.

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 will 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 we are not able to enter into a collaboration on terms that are favorable to us, we may be unable to undertake and fund product development, clinical studies, manufacturing and/or marketing activities at our own expense, which would delay or otherwise impede the commercialization of AFREZZA. Our product candidates are intended to be used by a large number of healthcare professionals who will require substantial education and support. For example, a broad base of physicians, including primary care physicians and endocrinologists, treat patients with diabetes. A large sales force would be required in order to educate these physicians about the benefits and advantages of AFREZZA and to provide adequate support for them. With respect to the commercialization of AFREZZA, if approved, if we fail to enter into collaborations, we would be required to establish our own direct sales, marketing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and would delay our ability to commercialize AFREZZA. Because we lack experience in selling pharmaceutical products to the diabetes market, we would be at a disadvantage compared to our potential competitors, many of whom have substantially more resources and experience than we do. For example, several other companies selling products to treat diabetes have existing sales forces in excess of 1,500 sales representatives. We, acting alone, would not initially be able to field a sales force as large as our competitors or provide the same degree of marketing support. Also, we would not be able to match our competitors spending levels for pre-launch marketing preparation, including medical education. We cannot assure you that we will succeed in entering into acceptable collaborations, that any such collaboration will be successful or, if not, that we will successfully develop our own sales, marketing and distribution capabilities.

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We will face similar challenges as we seek to develop our other product candidates. Our current strategy for developing, manufacturing and commercializing our other product candidates includes evaluating the potential for collaborating with pharmaceutical and biotechnology companies at some point in the drug development process and for these collaborators to undertake the advanced clinical development and commercialization of our product candidates. It may be difficult for us to find third parties that are willing to enter into collaborations on economic terms that are favorable to us, or at all. Failure to enter into a collaboration with respect to any other product candidate could substantially increase our requirements for capital and force us to substantially reduce our development efforts.

If we enter into collaborative agreements with respect to AFREZZA and if our third-party collaborators do not perform satisfactorily or if our collaborations fail, development or commercialization of AFREZZA may be delayed and our business could be harmed.

We may enter into license agreements, partnerships or other collaborative arrangements to support the financing, development and marketing of AFREZZA. We may also license technology from others to enhance or supplement our technologies. These various collaborators may enter into arrangements that would make them potential competitors. These various collaborators also may breach their agreements with us and delay our progress or fail to perform under their agreements, which could harm our business.

If we enter into collaborative arrangements, we will have less control over the timing, planning and other aspects of our clinical studies, and the sale and marketing of AFREZZA and our other product candidates. We cannot offer assurances that we will be able to enter into satisfactory arrangements with third parties as contemplated or that any of our existing or future collaborations will be successful.

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

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

- safety and efficacy results for AFREZZA obtained in our nonclinical and previous clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing AFREZZA;

- the analysis of data collected from clinical studies of AFREZZA or our other product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;

- after reviewing preclinical and/or clinical data, we or any potential collaborators may abandon projects that we previously believed were promising; and

- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical studies or in much larger populations may not be consistent with the clinical results. If use of AFREZZA results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell AFREZZA, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical studies, which may be time-consuming and expensive and may not produce favorable results.

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

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

could decline.

For AFREZZA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA s current Good Manufacturing Practices, or cGMP for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with Quality System Regulations, or QSRs. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory

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requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the development or manufacturing of AFREZZA may be delayed. Any such events could delay market introduction and subsequent sales of AFREZZA and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

We have never manufactured AFREZZA or any other product candidates in commercial quantities, and if we fail to develop an effective manufacturing capability for our product candidates or to engage third-party manufacturers with this capability, we may be unable to commercialize these products.

We use our Danbury, Connecticut facility to formulate AFREZZA inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We will utilize a contract packager to do the final kitting and cartoning of foil pouched blisters containing cartridges, as well as inhalers and the package insert. Although the Danbury facility has been qualified and undergone an inspection by the FDA in connection with our original NDA submission that sought approval of AFREZZA using our MedTone inhaler, we anticipate that our facility will need to undergo further inspection related to our ability to fill and package cartridges for our next-generation Dreamboat inhaler before we can be approved to distribute AFREZZA commercially. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend clinical studies, regulatory submissions or required approvals of our product candidates, could entail higher costs and may result in our being unable to effectively commercialize our products. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of any product on a timely basis, and at commercially reasonable prices and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for such products and we would lose potential revenues.

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

AFREZZA and our other product candidates are new and unproven. Even if any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of AFREZZA and our other product candidates will depend on many factors, including the:

- claims for which FDA approval can be obtained, including superiority claims;
- effectiveness of our or our third party collaborator(s) efforts to educate physicians about the benefits and advantages of AFREZZA or our other products and to provide adequate support for them, and the perceived advantages and disadvantages of competitive products;
- willingness of the healthcare community and patients to adopt new technologies;
- ability to manufacture the product in sufficient quantities with acceptable quality and cost;

- perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits compared to competing products or therapies;
- convenience and ease of administration relative to existing treatment methods;
- coverage and pricing and reimbursement relative to other treatment therapeutics and methods; and
- marketing and distribution support.

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

If third-party payors do not cover any products for which we receive regulatory approval or adequately reimburse consumers for any such products, our products might not be used or purchased, which would adversely affect our revenues.

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

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

If we are unable to obtain coverage of, and adequate payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

Healthcare legislation may make it more difficult to receive revenues, even if we have products that are approved.*

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of drug-device combination products;

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- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payments or transfers of value made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required as of August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services, or CMS, to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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

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

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

the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

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- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

If product liability claims are brought against us, we may incur significant liabilities and suffer damage to our reputation.

The testing, manufacturing, marketing and sale of AFREZZA and our other product candidates expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical studies volunteers and loss of revenues. We currently carry worldwide liability insurance in the amount of $10.0 million. In addition, we carry local policies per study in each country in which we conduct clinical studies that require us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales in the future if AFREZZA is approved. However, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will be able to obtain sufficient coverage at an acceptable cost, if at all. If losses from such claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product liability claim our business and results of operations would be harmed and the market price of our common stock may decline.

If we lose any key employees or scientific advisors, our operations and our ability to execute our business strategy could be materially harmed.

We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all. In addition, in order to commercialize our product candidates successfully, we may be required to expand our work force, particularly in the areas of manufacturing, and, if we are unable to enter into collaborations with third parties to commercialize AFREZZA or any other approved products, sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel on acceptable terms, if at all.

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

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

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

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

If our internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

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

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

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

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

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

Our research and development work involves the controlled storage and use of hazardous materials, including chemical and biological materials. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to $1.0 million per occurrence and $2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further $4.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition.

When we purchased the facilities located in Danbury, Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection. During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of $1.625 million. It has conducted at its expense all work and will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business and results of operations may be harmed.

RISKS RELATED TO REGULATORY APPROVALS

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

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

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

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

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

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We are not aware of any precedent for the successful commercialization of products based on our technology. In January 2006, the FDA approved the first pulmonary insulin product, Exubera. This approval has had an impact on, and notwithstanding the voluntary withdrawal of the product from the market by its manufacturer could still impact, the development and registration of AFREZZA in different ways. For example, Exubera may be used as a reference for safety and efficacy evaluations of AFREZZA, and the approval standards set for Exubera may be applied to other products that follow, including AFREZZA.

The FDA is regulating AFREZZA as a combination product because of the complex nature of the system that includes the combination of a new drug (AFREZZA) and a new medical device (the inhaler used to administer the insulin). The review of our NDA for AFREZZA involves several separate review groups of the FDA including: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health, which reviews medical devices. The Metabolic and Endocrine Drug Products Division is the lead group and obtains consulting reviews from the other two FDA groups. We can make no assurances at this time about what impact FDA review by multiple groups will have on the approvability of our product or that we will obtain approval of the NDA in a timely manner or at all.

Also, questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by the FDA in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products. FDA review of AFREZZA as a combination product may lengthen the product development and regulatory approval process, increase our development costs and delay or prevent the commercialization of AFREZZA. Other product candidates that we may develop could face similar obstacles and costs.

We have only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely approvals from the FDA or foreign regulatory agencies, if at all.

We will not be able to commercialize AFREZZA or any other product candidates unless we have obtained regulatory approval. Until we prepared and submitted our NDA for AFREZZA, we had no experience as a company in late-stage regulatory filings, such as preparing and submitting NDAs, which may place us at risk of delays, overspending and human resources inefficiencies. Any delay in obtaining, or inability to obtain, regulatory approval could harm our business.

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies. In addition, if we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and a reformulation of our products, additional clinical studies, changes in labeling of, or indications of use for, our products and/or additional marketing applications may be required. If we encounter any of the foregoing problems, our business and results of operations will be harmed and the market price of our common stock may decline.

Even if we obtain regulatory approval for our product candidates, such approval may be limited and we will be subject to stringent, ongoing government regulation.

Even if regulatory authorities approve any of our product candidates, they could approve less than the full scope of uses or labeling that we seek or otherwise require special warnings or other restrictions on use or marketing or could require potentially costly post-marketing follow-up clinical studies. Regulatory authorities may limit the segments of the diabetes population to which we or others may market AFREZZA or limit the target population for our other product candidates. There are no assurances that any advantages of AFREZZA will be agreed to by the FDA or otherwise included in product labeling or advertising and, as a result, AFREZZA may not have our expected competitive advantages when compared to other insulin products.

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

We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as cGMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. If our facilities, or the facilities of our manufacturers or suppliers, cannot pass a preapproval plant inspection, the FDA will not approve the marketing of our product candidates. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (*e.g.*, recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business and results of operations.

Our suppliers will be subject to FDA inspection before the agency approves an NDA for AFREZZA.

When we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier s ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of AFREZZA. We also depend on suppliers for other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements including QSR, and is subject to inspection by the FDA. There can be no assurance, in the conduct of an inspection of any of our suppliers, that the agency would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

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

At present, there are a number of clinical studies being conducted by us and other pharmaceutical companies involving insulin delivery systems. If we discover that AFREZZA is associated with a significantly increased frequency of adverse events, or if other pharmaceutical companies announce that they observed frequent adverse events in their studies involving insulin therapies, we could encounter delays in the timing of our clinical studies, difficulties in obtaining approval of AFREZZA or be subject to class warnings in the label for AFREZZA, if approved. In addition, the public perception of AFREZZA might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company s products or product candidates.

There are also a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical studies could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business and results of operations and cause the market price of our common stock to decline.

RISKS RELATED TO INTELLECTUAL PROPERTY

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

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

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for our AFREZZA inhalation powder expired in 2012. Other patents providing similar protection have terms extending into 2020, 2030 and 2031. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 and 2032, and we have method of treatment claims that extend into 2026 and 2029. As and when these different patents expire, AFREZZA could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations or other review in the United States. In some instances we may seek re-examination or reissuance of our own patents. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted, subjected to post-grant challenge, and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO is continuing to develop regulations and procedures to govern administration of the Leahy-Smith Act, and while all of the substantive changes to patent law associated with the Leahy-Smith Act have become effective, many changes have only recently become effective. Moreover there will be a transitional period of many years during which some applications may be eligible for prosecution under the previous rules. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

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

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

Interference proceedings brought by the USPTO, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Additionally, the Leahy-Smith Act has greatly expanded the options for post-grant review of patents that can be brought by third parties. Litigation, post-grant review, or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation, post-grant review, or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock may decline.

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If our technologies conflict with the proprietary rights of others, we may incur substantial costs as a result of litigation or other proceedings and we could face substantial monetary damages and be precluded from commercializing our products, which would materially harm our business.

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

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

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

Moreover, certain components of AFREZZA may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B), or a 337 action, with the International Trade Commission, or the ITC. A 337 action can be expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party s patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100% of the value of the patented products. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms, or at all, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Although we own a number of domestic and foreign patents and patent applications relating to AFREZZA, we have identified certain third-party patents having claims relating to pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of AFREZZA. If a court were to determine that AFREZZA was infringing any of these patent rights, we would have to establish with the court that these patents were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business would be harmed and our profitability could be materially adversely impacted.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock may decline.

In addition, patent litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business and results of operations and cause the market price of our common stock to decline.

We may not obtain trademark registrations for our potential trade names.*

We have not selected trade names for some of our product candidates; therefore, we have not filed trademark registrations for all of our potential trade names for our product candidates in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere, or once registered that, prior to our being able to enter a particular market, they will not be cancelled for non-use. Nor can we give assurances, that the use of any of our trademarks will confer a competitive advantage in the marketplace.

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Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.*

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

- the progress and results of our clinical studies;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing AFREZZA or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- announcements by us concerning our financial condition or operating performance;
- changes in securities analysts estimates of our financial condition or operating performance;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors;

- the existence of, and the issuance of shares of our common stock pursuant to, the share lending agreement and the short sales of our common stock effected in connection with the sale of our 2015 notes;

- the conversion of any of our 2013 notes, 2015 notes or 2019 notes into shares of our common stock; and

- discussion of AFREZZA, our other product candidates, competitors products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.

Any of these risks, as well as other factors, could cause the market price of our common stock to decline.

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

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

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

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

At November 4, 2013, our Chairman and Chief Executive Officer, Alfred E. Mann beneficially owned 42.8% of our outstanding shares of capital stock. By virtue of his holdings, Mr. Mann may be able to continue to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

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

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

As of November 4, 2013, we had 357,312,740 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. Likewise the issuance of additional shares of our common stock upon the conversion of some or all of our senior convertible notes, or upon the exercise of some or all of the warrants we issued in February 2012, could adversely affect the trading price of our common stock. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We are incorporated in Delaware. Certain anti-takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our anti-takeover provisions include provisions such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of your investment in our common stock.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(3)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.4(4)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.5(10)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.6(5)	Amended and Restated Bylaws.
4.1(6)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated November 1, 2006.
4.2(7)	First Supplemental Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated December 12, 2006.
4.3(7)	Form of 3.75% Senior Convertible Note due 2013.
4.4(11)	Form of common stock certificate.
4.5(1)	Registration Rights Agreement, dated October 15, 1998, by and among CTL ImmunoTherapies Corp., Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended.
4.6(8)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010.
4.7(8)	Form of 5.75% Senior Convertible Note due 2015.
4.8(9)	Form of Warrant to Purchase Common Stock issued February 8, 2012.
4.9(12)	Form of 9.75% Senior Secured Convertible Promissory Note due 2019.
4.10(12)	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL.
4.11(12)	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL.
4.12(12)	Registration Rights Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P.
10.1(13)	Acknowledgment and Agreement, dated as of October 31, 2013, by and between MannKind and The Mann Group LLC.
31.1	Certification of the Chief Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

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(1) Incorporated by reference to MannKind s registration statement on Form S-1 (File No. 333-115020), filed with the SEC on April 30, 2004, as amended.
(2) Incorporated by reference to MannKind s quarterly report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2007.
(3) Incorporated by reference to MannKind s quarterly report on Form 10-Q (File No. 000-50865), filed with the SEC on August 2, 2010.
(4) Incorporated by reference to MannKind s quarterly report on Form 10-Q (File No. 000-50865), filed with the SEC on August 4, 2011.
(5) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007.
(6) Incorporated by reference to MannKind s registration statement on Form S-3 (File No. 333-138373), filed with the SEC on November 2, 2006.
(7) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on December 12, 2006.
(8) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on August 24, 2010.
(9) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on February 6, 2012.
(10) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on December 24, 2012.
(11) Incorporated by reference to MannKind s annual report on Form 10-K (File No. 000-50865), filed with the SEC on March 18, 2013.
(12) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013.
(13) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on November 4, 2013.

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SIGNATURE

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

Dated: November 12, 2013	MANNKIND CORPORATION
	By: /s/ MATTHEW J. PFEFFER
	Matthew J. Pfeffer
	Corporate Vice President and Chief Financial Officer
	(Principal Financial and Accounting Officer)