MANNKIND CORP
Form 10-Q
May 10, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended March 31, 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 May 3, 2013, there were 290,882,301 shares of the registrant s common stock, $.01 par value per share, outstanding.

Table of Contents

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended March 31, 2013

TABLE OF CONTENTS

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

Table of Contents

PART 1: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	March 31, 2013	December 31, 2012
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,005	$ 61,840
State research and development credit exchange receivable current	450	450
Prepaid expenses and other current assets	3,830	4,520
Total current assets	32,285	66,810
Property and equipment net	182,290	183,961
State research and development credit exchange receivable net of current portion	391	313
Other assets	230	230
Total	$ 215,196	$ 251,314
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 3,604	$ 4,555
Accrued expenses and other current liabilities	26,379	25,777
Senior convertible notes	114,593	114,443
Note payable to related party	119,635	
Total current liabilities	264,211	144,775
Senior convertible notes	97,791	97,583
Note payable to related party		119,635
Total liabilities	362,002	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 March 31, 2013 and December 31, 2012		
Common stock, $0.01 par value 550,000,000 shares authorized at March 31, 2013 and December 31, 2012; 289,375,250 and 286,035,082 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	2,894	2,860
Additional paid-in capital	1,996,185	1,991,379
Accumulated other comprehensive loss	(8)	(6)
Deficit accumulated during the development stage	(2,145,877)	(2,104,912)
Total stockholders deficit	(146,806)	(110,679)

Total	$ 215,196	$ 251,314

See notes to condensed consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended March 31,		Cumulative period from February 14, 1991 (date of inception) to March 31, 2013
	2013	2012	
	(In thousands, except per share data)		
Revenue	$	$	$ 3,166
Operating expenses:			
Research and development	26,398	24,156	1,493,971
General and administrative	10,039	9,777	435,743
In-process research and development costs			19,726
Goodwill impairment			151,428
Total operating expenses	36,437	33,933	2,100,868
Loss from operations	(36,437)	(33,933)	(2,097,702)
Other income (expense)	23	1,382	(2,244)
Interest expense on note payable to related party	(1,689)	(3,048)	(40,514)
Interest expense on senior convertible notes	(2,863)	(2,575)	(42,796)
Interest income	1	1	36,997
Loss before benefit for income taxes	(40,965)	(38,173)	(2,146,259)
Income tax benefit			(382)
Net loss	(40,965)	(38,173)	(2,145,877)
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	$ (40,965)	$ (38,173)	$ (2,169,089)
Net loss per share applicable to common stockholders basic and diluted	$ (0.15)	$ (0.27)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	280,058	143,154	

See notes to condensed consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended March 31,		Cumulative period from February 14, 1991 (date of inception) to March 31, 2013
	2013	2012	
	(In thousands)		
Net loss	$ (40,965)	$ (38,173)	$ (2,145,877)
Other comprehensive loss:			
Cumulative translation (loss) gain	(2)	1	(8)
Unrealized gain (loss) on investments:			
Unrealized holding gain (loss) during the period			48
Less: reclassification adjustment for gains (losses) included in net loss		(48)	(48)
Net unrealized (loss) gain on investments		(48)	
Comprehensive loss	$ (40,967)	$ (38,220)	$ (2,145,885)

See notes to condensed consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31,		Cumulative Period from February 14, 1991 (Date of Inception) to March 31, 2013
	2013	2012	
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (40,965)	$ (38,173)	$ (2,145,877)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and accretion	3,348	3,696	130,125
Stock-based compensation expense	5,189	2,878	143,107
Stock expense for shares issued pursuant to research agreement			3,018
(Gain) loss on sale, abandonment/disposal or impairment of property and equipment		(32)	24,253
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		(1,705)	1,237
Other, net	(2)	285	1,097
Changes in assets and liabilities:			
State research and development credit exchange receivable	(78)	(92)	(841)
Prepaid expenses and other current assets	690	365	(1,880)
Other assets			(230)
Accounts payable	(924)	(1,713)	3,494
Accrued expenses and other current liabilities	715	1,888	35,764
Other liabilities			(2)
Net cash used in operating activities	(32,027)	(32,486)	(1,628,288)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities			(796,779)
Sales and maturities of marketable securities			796,393
Purchase of property and equipment	(1,459)	(323)	(329,205)
Proceeds from sale of property and equipment		32	454
Net cash used in investing activities	(1,459)	(291)	(329,137)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net of issuance costs	78	80,598	1,397,834
Collection of Series C convertible preferred stock subscriptions receivable			50,000
Issuance of Series B convertible preferred stock for cash			15,000
Cash received for common stock to be issued			3,900
Repurchase of common stock			(1,028)
Put shares sold to majority stockholder			623

Borrowings under lines of credit			4,220
Proceeds from notes receivables			1,742
Borrowings on notes payable to related party		6,250	387,750
Principal payments on notes payable to related party			(70,000)
Borrowings on notes payable			3,460
Principal payments on notes payable			(1,667)
Proceeds from senior convertible notes			207,050
Payment of employment taxes related to vested restricted stock units	(427)	(397)	(13,454)
Net cash provided by (used in) financing activities	(349)	86,451	1,985,430
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ (33,835)	$ 53,674	$ 28,005
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	61,840	2,681	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 28,005	$ 56,355	$ 28,005
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 26
Interest paid in cash, net of amounts capitalized	2,863	2,595	62,015
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	3,863	921	3,863
Capitalization of interest on note payable to related party			14,219
Cancellation of principal on note payable to related party			212,334
Forward purchase contract contribution to APIC			29,317
Reclassification of forward purchase contract to APIC			28,080

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

See notes to condensed consolidated financial statements.

Table of Contents

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 three months ended March 31, 2013 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets for impairment, accrued expenses, including clinical trial expenses, valuation of forward purchase contracts, valuation of stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets.

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

Basis of Presentation The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. It is costly to develop therapeutic products and conduct clinical trials for these products. Since its inception through March 31, 2013 the Company has reported accumulated net losses of $2.1 billion, which include a goodwill impairment charge of $151.4 million, and cumulative negative cash flow from operations of $1.6 billion. At March 31, 2013, the Company s capital resources consisted of cash and cash equivalents of $28.0 million and $125.4 million of available borrowings through September 30, 2013 under the loan agreement with an entity controlled by the Company s principal stockholder, The Mann Group, LLC (The Mann Group) (see Note 9 Related-party arrangements).

In October 2012, we sold in an underwritten public offering common stock and warrants resulting in net proceeds of $86.3 million and concurrently issued common stock and warrants to The Mann Group in exchange for cancellation of indebtedness under the amended and restated promissory note with The Mann Group (see Note 7 Common and preferred stock and Note 9 Related-party arrangements). To the extent that the trading price of our common stock exceeds the exercise price of the warrants on or about the expiration date of the public offering warrants and The Mann Group Warrants issued in October 2012, the warrant holders may potentially exercise such warrants during the fourth quarter of 2013. If the October 2012 public offering warrants are fully exercised, an additional $89.7 million in gross proceeds may become available. There can be no assurances that the trading price of our common stock will be greater than the exercise price of the warrants on or about the expiration date of the warrants due to a variety of factors, including the factors described under Risks Related to Our Common Stock in Item IA of Part II of this quarterly report on Form 10-Q, and there can be no assurances that the warrants will ever be exercised or that we will receive any proceeds from the exercise of the warrants.

On March 18, 2013, we entered into at-the-market issuance sales agreements (the ATM Agreements) with two sales agents, under which we may issue and sell shares of our common stock having an aggregate offering price of up to $50.0 million under each ATM Agreement (provided that in no event may we issue and sell more than $50.0 million of shares of our common stock under both ATM Agreements in the aggregate) from

time to time through either of the sales agents. Neither we nor either of the sales agents has any obligation to sell shares of our common stock under the ATM Agreements. Any sales of common stock made under the ATM Agreements will be made in at the market offerings as defined in Rule 415 of the Securities Act of 1933, as amended. We have not yet issued any shares of our common stock under the ATM Agreements.

Table of Contents

Based upon the Company s current expectations, management believes the Company s existing capital resources, including the available borrowings under the loan arrangement with The Mann Group and the proceeds that may be raised under the ATM agreements, will enable it to continue planned operations through at least the third quarter of 2013. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital, 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 the sale of equity or debt securities, a strategic business collaboration with a pharmaceutical company, the establishment of other funding facilities, licensing arrangements, asset sales or other means. On December 15, 2013, $115.0 million of aggregate principal under the 3.75% Senior Convertible Notes (the 2013 notes) will mature (see Note 10 Senior convertible notes) , and on January 1, 2014, the Company s borrowings under the amended and restated promissory note with The Mann Group will mature. 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.

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

Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of March 31, 2013 and December 31, 2012, the Company held $28.0 million and $61.8 million, respectively of cash and cash equivalents, consisting primarily of money market funds of $25.7 million and $60.8 million, respectively, and the remaining in non-interest bearing checking accounts. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

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

	March 31, 2013		December 31, 2012	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
Notes due 2013	$ 114.6	$ 102.2	$ 114.4	$ 81.9
Notes due 2015	$ 97.8	$ 83.8	$ 97.6	$ 63.2

The Company concluded that The Mann Group Common Stock Purchase Agreement entered into in February 2012 (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 2013 notes was calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy). The estimated fair value of the 2015 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company s stock price, and non-observable, such as the Company s longer-term historical volatility (Level 3 in the fair value hierarchy). As there is no current observable market for the 2015 notes, the Company determined the estimated fair value using a convertible bond valuation model within a lattice framework. The convertible bond valuation model combined expected cash outflows with market-based assumptions regarding risk-adjusted yields, stock price volatility and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible.

The estimated fair value of The Mann Group Common Stock Purchase Agreement entered into in February 2012 was based on a forward purchase contract valuation (Level 3 in the fair value hierarchy). The fair value of the forward purchase contract is highly sensitive to the discount applied for lack of marketability and the stock price, and changes in this discount and/or the stock price caused the value of the forward purchase contract to change significantly. The Company recognized the change in fair value of $(336,000) in Other income (expense) for the three months ended March 31, 2012. The Company revalued the Non-Equity Portion using a forward contract valuation formula, in which the forward contract was estimated to be equal to the valuation date stock price minus the strike price discounted to the valuation date using a

risk-free rate of 0.08% at issuance and 0.06% at March 31, 2012. As the shares which would be received upon settlement were unregistered, the Company applied a discount for lack of marketability of 2.57% at issuance and 1.64% at March 31, 2012 based on quantitative put models, adjusted to take into account qualitative factors, including the fact that the Company s stock was publicly traded and the fact that there was no contractual restriction on the unregistered shares being registered.

Table of Contents

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 March 31, 2013	Three months ended March 31, 2012
Beginning balance	$	$
Issuance		1,080
Unrealized gain/(loss) included in other income (expense)		(336)
Ending balance	$	$ 744

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.

2. Accrued expenses and other current liabilities

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

	March 31, 2013	December 31, 2012
Salary and related expenses	$ 5,852	$ 10,074
Research and clinical trial costs	9,187	5,995
Accrued interest	5,863	4,533
Construction in progress	3,753	3,878
Other	1,724	1,297
Accrued expenses and other current liabilities	$ 26,379	$ 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 months ended March 31, 2013 and 2012 was as follows (in thousands):

	Three months ended March 31,	
	2013	2012
Stock-based compensation	$ 5,189	$ 2,878

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

development milestones related to AFREZZA. The performance-based restricted stock units had a grant date fair value of $2.81 per unit.

As of March 31, 2013, there was $13.6 million and $22.7 million of unrecognized compensation cost related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 1.6 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 March 31, 2013, there was $107,000 and $3.7 million of unrecognized expenses related to performance options and restricted stock units, respectively, for milestones not considered probable of achievement.

Table of Contents

4. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned to Bank of America, N.A. under a share lending arrangement (see Note 7 Common and preferred stock). As of March 31, 2013, 9,000,000 shares of the Company s common stock, which were loaned to Bank of America, N.A. pursuant to the terms of a share lending agreement as described in Note 7, were issued and are outstanding, and holders of the borrowed shares have all the rights of a holder of the Company s common stock. However, because the share borrower must return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof), the borrowed shares are not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying condensed consolidated statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 133,500,568 shares and 54,310,177 shares as of March 31, 2013 and March 31, 2012, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement as of March 31, 2013 and 2012.

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 $450,000 at March 31, 2013 and December 31, 2012. Long-term estimated amounts receivable under the program were $391,000 and $313,000 at March 31, 2013 and December 31, 2012, respectively.

6. Property and equipment

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

	Estimated Useful Life (Years)	March 31, 2013	December 31, 2012
Land		$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	114,245	114,245
Machinery and equipment	3-15	81,396	81,382
Furniture, fixtures and office equipment	5-10	5,239	5,239
Computer equipment and software	3	11,876	11,840
Leasehold improvements		17	17
Construction in progress		13,535	12,266
		286,529	285,210
Less accumulated depreciation and amortization		(104,239)	(101,249)
Property and equipment net		$ 182,290	$ 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 months ended March 31, 2013 and 2012 was as follows (in thousands):

	Three months ended March 31,	
	2013	2012
Depreciation and amortization expense	$ 2,990	$ 3,357

Table of Contents

7. Common and preferred stock

The Company is authorized to issue 550,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company s board of directors. No other class of capital stock is authorized. As of March 31, 2013 and December 31, 2012, 289,375,250 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 March 31, 2013 and December 31, 2012 are 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of the $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 (see Note 10 Senior convertible notes). Bank of America is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company on or about the 45th business day following the date as of which the entire principal amount of the notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America s option. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of $0.01 per share from Bank of America for the use of borrowed shares.

In February 2012, the Company sold in an underwritten public offering 35,937,500 units worth $86.3 million, including the full exercise of an over-allotment option granted to the underwriters, 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. Concurrent with this public offering, pursuant to The Mann Group Common Stock Purchase Agreement entered into in February 2012, The Mann Group agreed to purchase $77.2 million worth of restricted shares or 31,250,000 restricted shares of common stock, which were issued in June 2012 in exchange for cancellation of principal indebtedness of $77.2 million under the revolving amended and restated loan arrangement (see Note 9 Related-party arrangements).

In October 2012, the Company sold in an underwritten public offering 46,000,000 units worth $92.0 million, including the full exercise of an over-allotment option granted to the underwriters, 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 are exercisable at $2.60 per share and expire in the fourth quarter of 2013. Concurrent with this public offering, 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 shares of common stock, which were issued in October 2012 in exchange for cancellation of principal indebtedness of $107.4 million under the revolving amended and restated loan arrangement (see Note 9 Related-party arrangements). The Mann Group warrants are exercisable at $2.60 per share and expire in the fourth quarter of 2013.

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 entered into in February 2012, 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 entered into in October 2012, 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.

Table of Contents

9. Related-party arrangements

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. In February 2009, the promissory note underlying the loan arrangement was revised as a result of the Company s principal stockholder being subject to the licensing requirement under the California Finance Lenders Law. Accordingly, the lender was changed to The Mann Group. Until January 1, 2013, interest on outstanding principal amounts accrued at a fixed rate equal to the one-year LIBOR as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum. The promissory note underlying the loan arrangement was amended at various dates during 2012. The most recent amendment occurred in October 2012 to extend the maturity date to January 1, 2014, extend the date through which the Company can borrow under the promissory note to September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one-year LIBOR on December 31, 2012 plus 5%, effective beginning on January 1, 2013. The borrowing rate was 4.5% at March 31, 2013 and December 31, 2012.

As of March 31, 2013, the total principal amount outstanding under the credit facility was $119.6 million, and the amount available for future borrowings was $125.4 million. Interest is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized at any time upon mutual agreement of both parties. The Mann Group can require the Company to prepay up to $200.0 million in advances that have been outstanding for at least 12 months. If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice (or the number of days to maturity of the note if less than 90 days) to prepay such advances (see discussion regarding letter agreement below).

In August 2010, the Company entered into a letter agreement confirming a previous commitment by The Mann Group to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group s option, and the interest rate will increase to the one-year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under the loan arrangement are unsecured. The loan arrangement contains no financial covenants. There are no warrants associated with the loan arrangement.

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

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

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

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

Table of Contents

10. Senior convertible notes

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

	March 31 2013	December 31 2012
2013 notes		
Principal amount	$ 115,000	$ 115,000
Unaccreted debt issuance expense	(407)	(557)
Net carrying amount	114,593	114,443
2015 notes		
Principal amount	$ 100,000	$ 100,000
Unaccreted debt issuance expense	(2,209)	(2,417)
Net carrying amount	97,791	97,583
Senior convertible notes	$ 212,384	$ 212,026

On August 18, 2010, the Company completed a Rule 144A offering of $100.0 million aggregate principal amount of the 2015 notes. The 2015 notes are governed by the terms of an indenture dated as of August 24, 2010 (the 2015 Note Indenture). The 2015 notes bear interest at the rate of 5.75% per year on the principal amount, payable in cash semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2011. In connection with the 2015 notes, the Company had accrued interest of $735,000 and $2.2 million as of March 31, 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 can be net-share settled and the maximum number of shares that could be required to be delivered under the contract, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the contract period under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2015 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the contract period under existing commitments.

The Company incurred approximately $4.2 million in issuance costs which are recorded as an offset to the 2015 notes in the accompanying condensed consolidated balance sheets. These costs are being amortized to interest expense using the effective interest method over the term of the 2015 notes.

On December 12, 2006, the Company completed an offering of $115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013 (the 2013 notes), including $15.0 million aggregate principal amount of the 2013 notes sold pursuant to the underwriters over-allotment option that was exercised in full. The 2013 notes are governed by the terms of an indenture dated as of November 1, 2006 and a First Supplemental Indenture, dated as of December 12, 2006 (the 2013 Note Indenture). The 2013 notes bear interest at the rate of 3.75% per year on the principal amount, payable in cash semi-annually in arrears on June 15 and December 15 of each year, beginning June 15, 2007. In connection with the 2013 notes, the Company had accrued interest of $1.3

Table of Contents

million and $192,000 as of March 31, 2013 and December 31, 2012, respectively. The 2013 notes are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company s secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other liabilities of the Company. The maturity date of the 2013 notes is December 15, 2013, and payment is due in full on that date for unconverted securities. Holders of the 2013 notes may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding principal into shares of the Company s common stock at an initial conversion rate of 44.5002 shares per $1,000 principal amount, which is equal to a conversion price of approximately $22.47 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the 2013 notes converted in connection with a fundamental change by increasing the conversion rate on such Notes, which amount, if any, will be based on the Company s common stock price and the effective date of the fundamental change, and (2) each holder of 2013 notes will have the option to require the Company to repurchase all or any portion of such holder s Notes at a repurchase price of 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any. Under the terms of the 2013 Note Indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the contract, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the contract period under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2013 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the contract period under existing commitments.

The Company incurred approximately $3.7 million in issuance costs which are recorded as an offset to the 2013 notes in the accompanying condensed consolidated balance sheets. These costs are being amortized to interest expense using the effective interest method over the term of the 2013 notes.

Accretion of debt issuance expense in connection with the offerings of the 2015 notes and the 2013 notes during the three months ended March 31, 2013 and 2012 were $358,000 and $339,000, respectively.

11. Income taxes

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

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

Table of Contents

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

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this quarterly report on Form 10-Q. These interim condensed consolidated financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes for the year ended December 31, 2012 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

OVERVIEW

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

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

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of March 31, 2013, we have incurred a cumulative net loss of $2.1 billion and an accumulated stockholders deficit of $146.8 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under a loan arrangement provided by our principal stockholder. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding in the future, there will be substantial doubt about our ability to continue as a going concern.

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

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

- continue the clinical development of AFREZZA and new inhalation systems for the treatment of diabetes;
- seek regulatory approval to sell AFREZZA in the United States and other markets;
- seek development and commercialization collaborations for AFREZZA; and
- develop additional applications of our proprietary Technosphere platform technology for the pulmonary delivery of other drugs.

Our business is subject to significant risks, including but not limited to the risks inherent in our ongoing clinical trials and the regulatory approval process, our potential inability to enter into sales and marketing collaborations or to commercialize AFREZZA in a timely manner, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

Table of Contents

RESEARCH AND DEVELOPMENT EXPENSES

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

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

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

GENERAL AND ADMINISTRATIVE EXPENSES

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

CRITICAL ACCOUNTING POLICIES

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

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

RESULTS OF OPERATIONS

Three months ended March 31, 2013 and 2012

Revenue

We did not recognize any revenue for the three months ended March 31, 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 months ended March 31, 2013 and 2012 (dollars in thousands):

	Three months ended March 31,			
	2013	2012	$ Change	% Change
Clinical	$ 13,282	$ 10,879	$ 2,403	22%
Manufacturing	9,390	10,093	(703)	(7%)
Research	1,316	1,940	(624)	(32%)
Research and development tax credit	(78)	(92)	14	(15%)
Stock-based compensation expense	2,488	1,336	1,152	86%
Research and development expenses	$ 26,398	$ 24,156	$ 2,242	9%

Table of Contents

The increase in overall research and development expenses for the three months ended March 31, 2013, compared to the three months ended March 31, 2012, was primarily due to a $2.6 million increase in clinical trial related expenses in connection with studies 171 and 175 subsequent to the completion of enrollment of these studies in October 2012, partially offset by $0.6 million decrease in facilities related costs and depreciation.

In relation to the research and development expenses categories, total clinical expenses increased $2.6 million in connection with studies 171 and 175, partially offset by $0.2 million in decreased employee related expenses resulting from the positive effect of our cost cutting measures on operating expenses. Manufacturing expenses decreased by $0.7 million primarily due to a $0.6 million decrease in facilities related costs and depreciation. Research expenses decreased by $0.6 million primarily due to $0.2 million in reduced employee related expenses resulting from the positive effect of our cost cutting measures on operating expenses and $0.2 million in reduced outside services and insulin purchases. Stock-based compensation expense increase primarily due to stock awards granted during the first quarter of 2013 (see Note 3 Accounting for stock-based compensation).

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

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the three months ended March 31, 2013 and 2012 (dollars in thousands):

	Three months ended March 31,			
	2013	2012	$ Change	% Change
Salaries, employee related and other general expenses	$ 7,338	$ 8,235	$ (897)	(11%)
Stock-based compensation expense	2,701	1,542	1,159	75%
General and administrative expenses	$ 10,039	$ 9,777	$ 262	3%

General and administrative expenses for the three months ended March 31, 2013 increased compared to the three months ended March 31, 2012 primarily due to $1.2 million increase in stock-based compensation expense related to stock awards granted during the first quarter of 2013 (see Note 3 Accounting for stock-based compensation), offset by a $0.7 million decrease in legal expenses due primarily to the settlement of certain litigation during 2012.

We expect general and administrative expenses overall to be lower in 2013 as compared to 2012 due to reduced legal expenses and the effect of our cost cutting measures on operating expenses.

Other Income (Expense)

Other income decreased from $1.4 million for the three months ended March 31, 2012 to $23,000 for the three months ended March 31, 2013. The decrease was primarily due to a $2.0 million benefit recorded during the three months ended March 31, 2012 on a forward purchase contract in other income, offset by a change in fair value of $336,000 recognized during the three months ended March 31, 2012 and by our common stock investment determined to be permanently impaired at a realized loss of $117,000.

Interest Expense

Interest expense for the three months ended March 31, 2013 decreased compared to the same period in the prior year primarily due to a reduced principal amount outstanding under our loan arrangement with our principal stockholder resulting from the issuance of common stock and warrants in exchange for the cancellation of principal indebtedness and the conversion of accrued and unpaid interest to principal during 2012.

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 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 LLC, 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. The most recent amendment occurred in October 2012 to extend the maturity date to January 1, 2014, extend the date through which we can borrow under the promissory note to September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one-year LIBOR on December 31, 2012 plus 5%, effective beginning on January 1, 2013. The borrowing rate was 4.5% at March 31, 2013.

As of March 31, 2013, the total principal amount outstanding under the credit facility was $119.6 million, and the amount available for future borrowings was $125.4 million. Interest is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as 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 that have been outstanding for at least 12 months. 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 (see discussion regarding letter agreement below).

Table of Contents

In August 2010, we entered into a letter agreement confirming a previous commitment by The Mann Group to not require us to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require us to use its working capital resources. 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). To the extent that the trading price of our common stock exceeds the exercise price of the warrants on or about the expiration date of the public offering warrants and The Mann Group Warrants issued in October 2012, the warrant holders may potentially exercise such warrants during the fourth quarter of 2013. If the October 2012 public offering warrants are fully exercised, an additional $89.7 million in gross proceeds may become available. There can be no assurances that the trading price of our common stock will be greater than the exercise price of the warrants on or about the expiration date of the warrants due to a variety of factors, including the factors described under Risks Related to Our Common Stock in Item IA of Part II of this quarterly report on Form 10-Q, and there can be no assurances that the warrants will ever be exercised or that we will receive any proceeds from the exercise of the warrants.

On March 18, 2013, we entered into at-the-market issuance sales agreements (the ATM Agreements) with two sales agents, under which we may issue and sell shares of our common stock having an aggregate offering price of up to $50.0 million under each ATM Agreement (provided that in no event may we issue and sell more than $50.0 million of shares of our common stock under both ATM Agreements in the aggregate) from time to time through either of the sales agents. Neither we nor either of the sales agents has any obligation to sell shares of our common stock under the ATM Agreements. Any sales of common stock made under the ATM Agreements will be made in at the market offerings as defined in Rule 415 of the Securities Act of 1933, as amended. We have not yet issued any shares of our common stock under the ATM Agreements.

During the three months ended March 31, 2013, we used $32.0 million of cash for our operations and had a net loss of $41.0 million, which included $8.5 million of non-cash charges primarily consisting of depreciation and accretion and stock-based compensation. By comparison, during the three months ended March 31, 2012, we used $32.5 million of cash for our operations and had a net loss of $38.2 million, which included $5.2 million of non-cash charges primarily consisting of depreciation and accretion and stock-based compensation. Cash used for our operations decreased by $0.5 million. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

We used $1.5 million of cash for investing activities during the three months ended March 31, 2013, compared to $0.3 million of cash used for the three months ended March 31, 2012. Cash used for investing activities for the three months ended March 31, 2013 compared to the same period in the prior year increased $1.2 million, primarily due to a $1.1 million increase in purchases of machinery and equipment to expand the manufacturing lines in preparation for a future approval AFREZZA.

Our financing activities resulted in negative cash flow of $0.3 million during the three months ended March 31, 2013, compared to positive cash flow of $86.5 million for the same period in 2012. For the three months ended March 31, 2012, cash provided by financing activities was primarily from $80.6 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 $6.3 million from related party borrowings.

At March 31, 2013, our capital resources consisted of cash and cash equivalents of $28.0 million and $125.4 million of available borrowings under the loan agreement with an entity controlled by the Company s principal stockholder, The Mann Group. Based on our current expectations, we believe our existing cash resources, including the available borrowings under the loan arrangement with The Mann Group and the proceeds that may be raised under the ATM agreements, will enable us to continue planned operations through at least the third quarter of 2013. The $115.0 million aggregate principal amount of 2013 notes mature in December 2013, and our cash and cash equivalents as of March 31, 2013 will be insufficient to repay these notes. Accordingly, 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, and/or refinance our indebtedness under the 2013 notes, in order 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 do so on favorable terms by the applicable repayment date, 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, each holder of 2013 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.

Table of Contents

We intend to use our capital resources to continue the development and commercialization of AFREZZA, if approved. 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 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.

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.

Off-Balance Sheet Arrangements

As of March 31, 2013, we did not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates impacting our short-term investment portfolio as well as the interest rate on the promissory note underlying our revolving credit facility with The Mann Group. The interest rate on amounts borrowed under our credit facility with The Mann Group for the year ended December 31, 2012 was 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. Pursuant to an amendment to the promissory note 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%. As of March 31, 2013, the total principal amount outstanding under the credit facility was $119.6 million. In addition, all borrowings under the credit facility for periods on and after January 1, 2013 bear interest at the one-year LIBOR on December 31, 2012 plus 5%. Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds and investment-grade corporate, government and municipal debt. None of these investments is entered into for trading purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. We continue to utilize our $350.0 million revolving credit facility with The Mann Group to fund operations. As of March 31, 2013, the amount available for borrowing under our revolving credit facility with The Mann Group was $125.4 million. If a 10% change in interest rates were to have occurred on March 31, 2013, this change would not have had a material effect on the value of our short-term investment portfolio.

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.

Table of Contents

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 March 31, 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 March 31, 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 on Form 10-K. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

RISKS RELATED TO OUR BUSINESS

We depend heavily on the successful 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.

In January 2011, the FDA issued a Complete Response letter and requested that we conduct additional clinical studies of AFREZZA using our next-generation inhaler, Dreamboat. Over the next eight months, we participated in a number of written and verbal exchanges with the FDA in order to clarify the FDA s requirements for approval of AFREZZA, culminating in an in-person meeting in August 2011 in which we confirmed with the FDA the designs of the two requested studies. There can be no assurance that we will satisfy all of the FDA s requirements with our current clinical studies. The FDA could also again request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. 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

Table of Contents

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 trials, 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 March 31, 2013, we had incurred a cumulative net loss of $2.1 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 trials, seek regulatory approvals and market our product candidates, including AFREZZA. This cumulative net loss may increase significantly as we continue development and clinical trial 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 March 31, 2013, we had a stockholders deficit of $146.8 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.

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 upon our current expectations, we believe that our existing capital resources including the available borrowings under our loan arrangement with The Mann Group and the proceeds that may be raised under the ATM agreements will enable us to continue planned operations through at least the third quarter of 2013. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. We 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 or other means, or an increase in the borrowings available under the loan arrangement with The Mann Group, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. However, it may be difficult for us to raise additional funds through these planned measures. As of March 31, 2013, we had a stockholders deficit of $146.8 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 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;
- rate of progress and costs of our clinical trials and research and development activities, including costs of procuring clinical materials and operating our manufacturing facilities;
- 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;

Table of Contents

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.

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 interest payments in the future or to refinance or repay this debt before it becomes due.*

In December 2006, we completed the sale of $115.0 million aggregate principal amount of 2013 notes, which mature in December 2013, and in August 2010, we completed the sale of $100.0 million aggregate principal amount of 2015 notes, which mature in August 2015. As of May 3, 2013, all $115.0 million principal amount of the 2013 notes remained outstanding, and all $100.0 million principal amount of the 2015 notes remained outstanding. As of March 31, 2013, we did not have sufficient cash and cash equivalents to repay the 2013 notes or the 2015 notes. In addition, as of March 31, 2013, the effective conversion prices of the 2013 notes and 2015 notes were approximately $22.47 per share and $6.80 per share, respectively, subject to adjustment, which are substantially above the closing price of our common stock on May 3, 2013. We may therefore need to refinance our 2013 notes and/or 2015 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, 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, each holder of 2013 notes or 2015 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, and 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

Table of Contents

and August 15 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 or 2015 notes or repay or repurchase the 2013 notes or 2015 notes when required, we will be in default under the applicable indenture(s) 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.

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 trials 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 trial and research and development activities, which will be impacted by the level of proficiency and experience of our clinical staff;
- our ability to identify and enroll patients who meet clinical trial 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 of scheduling conflicts with participating clinicians and clinical institutions;
- the receipt of approvals by our competitors and by us from the FDA and other regulatory agencies;
- 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.

Table of Contents

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 trials, 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.

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 trials, 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 trials or following long-term use, and we may as a result be forced to stop developing AFREZZA;

Table of Contents

- the data collected from clinical trials of AFREZZA or our other product candidates may not reach statistical significance or otherwise be sufficient to support FDA or other regulatory approval;

- after reviewing test results, 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 trials 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 trials, 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 trials or marketing of AFREZZA at any time. Any suspension or termination of our clinical trials 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 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 trials, 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.

Table of Contents

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

AFREZZA and our other product candidates 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.

Table of Contents

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

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 to be required beginning 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

Table of Contents

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;

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

Table of Contents

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 trial 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 trial in each country in which we conduct clinical trials 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.

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

Table of Contents

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.

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 rigorous nonclinical and clinical testing and we must obtain regulatory approvals, which could be costly and time-consuming and 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;

Table of Contents

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 trials 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 trials 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 trials 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 trials 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 trial 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.

Table of Contents

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 trials. 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 trials, 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 trials. 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 trials 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 trials 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 trials involving insulin therapies, we could encounter delays in the timing of our clinical trials, 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.

Table of Contents

There are also a number of clinical trials 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 trials 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 and 2031. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023 and 2031, 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 in the United States. 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 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.

32

Table of Contents

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

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

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

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

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

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

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

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

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

33

Table of Contents

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

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

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

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

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.

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

- the progress and results of our clinical trials;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us or our competitors concerning clinical trial 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 against us or any of our executive officers and directors, including the legal proceedings described under Item 3 of this Annual Report;

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 or 2015 notes into shares of our common stock; and

Table of Contents

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

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

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

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

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

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

At March 31, 2013, Mr. Mann beneficially owned 42.5% 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 March 31, 2013, we had 289,375,250 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 and October 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.

Table of Contents

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

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 Warrant to Purchase Common Stock issued October 23, 2012.
4.10(11)	Form of Warrant to Purchase Common Stock issued December 21, 2012.
10.1(11)	At-The-Market Issuance Sales Agreement, dated March 18, 2013, by and between MannKind and MLV & Co. LLC.
10.2(11)	At-The-Market Issuance Sales Agreement, dated March 18, 2013, by and between MannKind and Brinson Patrick Securities Corporation.
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.

(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.

37

Table of Contents

(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 October 19, 2012.

Table of Contents

SIGNATURE

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

Dated: May 10, 2013

MANNKIND CORPORATION

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

(Principal Financial and Accounting Officer)