MANNKIND CORP
Form 10-Q
August 09, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2012

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 August 6, 2012, there were 199,384,118 shares of the registrant s common stock, $.01 par value per share, outstanding.

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MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended June 30, 2012

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

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PART 1: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands except share data)

	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,639	$ 2,681
Available for sale securities and certificate of deposit	350	515
Prepaid expenses and other current assets	18,356	2,625
Total current assets	50,345	5,821
Property and equipment net	189,159	193,029
State research and development credit exchange receivable	658	473
Other assets	230	230
Total	$ 240,392	$ 199,553
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 5,817	$ 4,624
Accrued expenses and other current liabilities	49,624	20,736
Total current liabilities	55,441	25,360
Senior convertible notes	211,184	210,642
Note payable to related party	218,142	277,203
Total liabilities	484,767	513,205
Commitments and contingencies		
Stockholders deficit:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2012 and December 31, 2011		
Common stock, $0.01 par value 350,000,000 and 250,000,000 shares authorized at June 30, 2012 and December 31, 2011, respectively; 199,300,833 and 131,522,945 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	1,993	1,315
Additional paid-in capital	1,763,939	1,620,535
Accumulated other comprehensive income (loss)	(9)	44
Deficit accumulated during the development stage	(2,010,298)	(1,935,546)
Total stockholders deficit	(244,375)	(313,652)
Total	$ 240,392	$ 199,553

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three months ended June 30, 2012	Three months ended June 30, 2011	Six months ended June 30, 2012	Six months ended June 30, 2011	Cumulative period from February 14, 1991 (date of inception) to June 30, 2012
Revenue	$	$	$	$ 50	$ 3,131
Operating expenses:					
Research and development	26,638	30,296	50,794	56,585	1,416,845
General and administrative	17,416	8,890	27,193	20,652	407,424
In-process research and development costs					19,726
Goodwill impairment					151,428
Total operating expenses	44,054	39,186	77,987	77,237	1,995,423
Loss from operations	(44,054)	(39,186)	(77,987)	(77,187)	(1,992,292)
Other income	13,347	47	14,729	1,397	13,653
Interest expense on note payable to related party	(3,028)	(2,509)	(6,076)	(4,985)	(34,410)
Interest expense on senior convertible notes	(2,844)	(2,834)	(5,419)	(5,247)	(34,213)
Interest income	1	2	2	17	36,990
Loss before provision for income taxes	(36,578)	(44,480)	(74,751)	(86,005)	(2,010,272)
Income taxes					(26)
Net loss	(36,578)	(44,480)	(74,751)	(86,005)	(2,010,298)
Deemed dividend related to beneficial conversion feature of convertible preferred stock					(22,260)
Accretion on redeemable preferred stock					(952)
Net loss applicable to common stockholders	$ (36,578)	$ (44,480)	$ (74,751)	$ (86,005)	$ (2,033,510)
Net loss per share applicable to common stockholders basic and diluted	$ (0.23)	$ (0.37)	$ (0.49)	$ (0.71)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	159,859	121,708	151,506	121,385	

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,		Cumulative period from February 14, 1991 (date of inception) to June 30,
	2012	2011	2012	2011	2012
Net Loss	$ (36,578)	$ (44,480)	$ (74,751)	$ (86,005)	$ (2,010,298)
Other comprehensive loss:					
Cumulative translation (loss) gain	6	4	5	9	1
Unrealized gain (loss) on investments:					
Unrealized holding gain (loss) during the period		(52)		(45)	(48)
Less: reclassification adjustment for gains (losses) included in net loss			48		48
Net unrealized (loss) gain on investments		(52)	48	(45)	
Comprehensive loss	$ (36,572)	$ (44,528)	$ (74,698)	$ (86,041)	$ (2,010,297)

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six months ended June 30, 2012	Six months ended June 30, 2011	Cumulative Period from February 14, 1991 (Date of Inception) to June 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (74,751)	$ (86,005)	$ (2,010,298)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,343	8,023	119,718
Stock-based compensation expense	5,951	4,701	130,577
Stock expense for shares issued pursuant to research agreement			3,018
(Gain) loss on sale, abandonment/disposal or impairment of property and equipment	(73)	(63)	23, 498
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
Fair value adjustment of warrant liability	(2,709)		(2,709)
Fair value of forward purchase contract	(12,011)		(12,011)
Other, net	(7)	9	1,095
Changes in assets and liabilities:			
State research and development credit exchange receivable	(185)	418	(658)
Prepaid expenses and other current assets	(15,731)	1,256	(16,756)
Other assets		87	(230)
Accounts payable	1,244	(447)	5,618
Accrued expenses and other current liabilities	33,308	4,574	53,282
Other liabilities			(2)
Net cash used in operating activities	(57,504)	(67,447)	(1,533,905)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities			(796,779)
Sales and maturities of marketable securities		3,828	796,393
Purchase of property and equipment	(448)	(6,109)	(327,557)
Proceeds from sale of property and equipment	73	63	450
Net cash used in investing activities	(375)	(2,218)	(327,493)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net of issuance costs	80, 992	10,424	1,311,013
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	18,000	381,250
Principal payments on notes payable to principal stockholder			(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	(405)	(50)	(12,526)
Net cash provided by financing activities	86, 837	28,374	1,893,037
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 28, 958	$ (41,291)	$ 31,639
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,681	66,061	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 31, 639	$ 24,770	$ 31,639
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 26
Interest paid in cash, net of amounts capitalized	4,751	10,136	54,148
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	2,343	1,039	2,343
Capitalization of interest on note payable to related party	11,876		11,876
Cancellation of principal on note payable to related party	77,187	11,116	104,984
Warrant liability	7,632		7,632
Forward purchase contract contribution to additional paid-in capital	1,080		1,080
Reclassification of forward purchase contract to additional paid-in capital	13,091		13,091

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

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (the Company), have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These statements should be read in conjunction with the financial statements and notes thereto included in the Company s latest audited annual financial statements. The audited statements for the year ended December 31, 2011 (which includes disclosures regarding the Company s ability to continue as a going concern) are included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2011 filed with the SEC on March 15, 2012 (the Annual Report).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the six months ended June 30, 2012 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 reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. 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 the valuation of warrant liabilities, the 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 and cancer. 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.

AFREZZA consists of the Company s proprietary Technosphere particles onto which insulin molecules are loaded. These loaded particles are then aerosolized and inhaled deep into the lung using the Company s AFREZZA inhaler.

Basis of Presentation The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. It is costly to develop therapeutic products and conduct clinical trials for these products. Since its inception through June 30, 2012 the Company has reported accumulated net losses of $2.0 billion, which include a goodwill impairment charge of $151.4 million, and cumulative negative cash flow from operations of $1.5 billion. At June 30, 2012, the Company s capital resources consisted of cash, cash equivalents, and a certificate of deposit of $32.0 million and $26.9 million of available borrowings under the loan agreement with an entity controlled by the Company s principal stockholder (see Note 11 Related-party arrangements). Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations into the fourth quarter of 2012. 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, whether 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, or an increase in the borrowings available under the loan arrangement with its related party, in order to continue the development and commercialization of AFREZZA and other product candidates and to support its other ongoing activities. This raises 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, available for sale securities, a certificate of deposit, and accounts payable, approximate their fair values due to their relatively short maturities. The fair value of the note payable to related party cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment.

Cash equivalents consist of highly liquid investments, with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of June 30, 2012 and December 31, 2011, the Company held $31.6 million and $2.7 million, respectively of cash and cash equivalents, consisting primarily of money market funds and the remaining funds in non-interest bearing checking accounts. The fair value of these investments was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

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The Company s available for sale securities consisted a common stock investment which the Company had determined to be other than temporarily impaired and had recorded a $117,000 realized loss in the quarter ended March 31, 2012. The certificate of deposit, having a maturity greater than 90 days, is held as collateral for the Company s commercial credit card programs. The carrying value of the certificate of deposit approximates fair value based on quoted prices for similar instruments in an active market (Level 2 in the fair value hierarchy) and the common stock investment is stated at fair value based on quoted prices in an active market (Level 1 in the fair value hierarchy). As of June 30, 2012 and December 31, 2011, there were available for sale securities and a certificate of deposit of $350,000 and $515,000, respectively.

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

	June 30, 2012		December 31, 2011	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
Notes due 2013	$ 114.1	$ 60.4	$ 113.9	$ 61.0
Notes due 2015	$ 97.1	$ 56.8	$ 96.8	$ 60.8

The estimated fair value of the senior convertible notes due 2013 was calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy). The estimated fair value of the senior convertible notes due 2015 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 long-term historical volatility (Level 3 in the fair value hierarchy). As there is no current observable market for the senior convertible notes due 2015, 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 warrant liability was calculated based on the Black-Scholes option pricing model (Level 3 in the fair value hierarchy). See Note 9 Warrant Liability for further discussion.

The estimated fair value of Mann Purchase Agreement was based on a forward purchase contract valuation (Level 3 in the fair value hierarchy). See Note 8- Common and Preferred Stock for further discussion.

The following roll-forward provides a summary of changes in fair value of the Company s Level 3 financial assets and liabilities (in thousands):

	Three months ended June 30, 2012		Six months ended June 30, 2012	
	Forward Purchase Contract	Warrant Liability	Forward Purchase Contract	Warrant Liability
Beginning Balance	$ 744	$ (7,915)	$	$
Issuance			1,080	(7,631)
Adjustments to fair value included in other income	12,347	2,993	12,011	2,709
Transfers to additional paid-in-capital	(13,091)		(13,091)	
Ending Balance	$	$ (4,922)	$	$ (4,922)

Recently Issued Accounting Standards 0 In June 2011, the FASB issued Accounting Standards Update No. 2011-05 (ASU 2011-05) for Comprehensive Income (Topic 220): Presentation of Comprehensive Income . This update improves the comparability, consistency and transparency of financial reporting and increases the prominence of items reported in other comprehensive income. This update is effective for interim and annual periods beginning after December 15, 2011. The Company has adopted all current required provisions of ASU 2011-05 on a retrospective basis.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04 (ASU 2011-04) for Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs . This update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this update are effective for interim and annual periods beginning after December 15, 2011. The Company has adopted all current required provisions of ASU 2011-04.

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2. Available for sale securities and certificate of deposit

The following is a summary of the available-for-sale securities classified as current assets (in thousands).

	June 30, 2012			December 31, 2011		
	Cost Basis	Gross Unrealized Gain	Fair Value	Cost Basis	Gross Unrealized Gain	Fair Value
Common stock investment	$	$	$	$ 117	$ 48	$ 165

During the three months ended March 31, 2012, the Company determined its common stock investment to be other than temporarily impaired and recorded the $117,000 realized loss for available-for-sale securities as Other income (expense) in the condensed consolidated statements of operations. Gross unrealized gains and losses are included in Other comprehensive gain (loss).

The Company s $350,000 certificate of deposit, having a maturity greater than 90 days, is held as collateral for the Company s commercial credit card programs.

3. Accrued expenses and other current liabilities

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

	June 30, 2012	December 31, 2011
Salary and related expenses	$ 6,791	$ 8,997
Research and clinical trial costs	7,087	2,383
Accrued interest	2,461	8,262
Construction in progress	2,100	
Warrant liability	4,922	
Accrued litigation settlement liability	24,547	
Other	1,716	1,094
Accrued expenses and other current liabilities	$ 49,624	$ 20,736

4. Accounting for stock-based compensation

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2012 and 2011 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Stock-based compensation	$ 3,072	$ 1,993	$ 5,951	$ 4,701

On May 17, 2012, the Compensation Committee approved a management proposal designed to encourage employee retention. The proposal involved the grant of stock options and restricted stock units to employees, including executive officers of the Company. 3,942,500 options were granted with vesting terms subject to the achievement of certain performance milestones. 3,942,500 options were granted with time-based vesting terms of 25% every 6 months beginning November 1, 2012, to be fully vested on May 1, 2014. 62,700 options were granted with time-based vesting terms of 25% after one year and ratably on a monthly basis over a period of 36 months thereafter. 50,600 restricted stock units were granted with time-based vesting terms of 25% per year commencing on the first anniversary. The performance-based options, time-based stock options, and restricted stock units had a grant date per share fair value of $0.60, $1.12 and $1.69, respectively.

The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options. Restricted stock units are valued based on the market price on the grant date. The Company calculated the fair value of employee stock options for the three months ended June 30, 2012 using the following assumptions:

	Performance-based	Time-based
Risk-free interest rate	0.20% 0.32%	0.74% 1.16%
Expected lives	1.2 2.1 years	5.6 6.1 years
Volatility	35% 70%	81% 83%
Dividends		

As of June 30, 2012, there was $14.0 million and $11.5 million of unrecognized compensation cost related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 1.9 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period. As of June 30, 2012, there was $128,000 and $3.7 million of unrecognized expenses related to performance options and restricted stock units, respectively, for milestones not considered probable of achievement.

5. 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 under the share lending arrangement (see Note 8   Common and preferred stock). As of June 30, 2012, 9,000,000 shares of the Company   s common stock, which were loaned to a share borrower pursuant to the terms of a share lending agreement as described in Note 12,

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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 61,741,900 shares and 32,048,936 shares as of June 30, 2012 and 2011, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement.

6. 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. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. At June 30, 2012 and December 31, 2011, the estimated amounts receivable under the program were $658,000 and $473,000, respectively.

7. Property and equipment net

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

	Estimated Useful Life (Years)	June 30, 2012	December 31, 2011
Land		$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	114,225	114,247
Machinery and equipment	3-15	82,402	83,476
Furniture, fixtures and office equipment	5-10	5,135	5,249
Computer equipment and software	3	12,177	13,049
Leasehold improvements		48	53
Construction in progress		11,187	8,498
		285,395	284,793
Less accumulated depreciation and amortization		(96,236)	(91,764)
Property and equipment net		$ 189,159	$ 193,029

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

Depreciation and amortization expense related to property and equipment for the three and six months ended June 30, 2012 and 2011 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Depreciation and amortization expense	$ 3,304	$ 3,580	$ 6,661	$ 7,379

8. Common and preferred stock

On February 8, 2012, the Company sold 35,937,500 units in an underwritten public offering, including 4,687,500 units, sold pursuant to 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. All of the securities were offered by the Company at a combined price to the public of $2.40 per unit and the underwriters purchased the units at a price of $2.256 per unit. Net proceeds from this offering were approximately $80.6 million, excluding any warrant exercises. The 21,562,500 warrants are exercisable at $2.40 per share and expire four years from the date of the issuance (See Note 9 Warrant liability). The shares of common stock and warrants are immediately separable and were issued separately. Concurrent with the underwritten public offering, The Mann Group LLC (The Mann Group) agreed to purchase $77.2 million worth of restricted shares of common stock which will be paid, at the discretion of the Company, by cash or by cancellation of principal indebtedness under the amended loan arrangement, subject to stockholder approval to increase the number of our authorized shares (see Note 11 Related-party arrangements).

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The Company concluded that the Mann Group common stock purchase agreement represented a contingent forward purchase contract that met the definition of a derivative instrument in accordance with ASC 815 *Derivatives and Hedging.* Of the 31,250,000 shares pursuant to the 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 16.7 million shares (Non-Equity Portion) required classification outside of equity as the Company did not have sufficient available shares at the time of issuance and at March 31, 2012. The Company revalues the Non-Equity Portion of the forward purchase contract at each reporting date and records a fair value adjustment within Other income . At the time of issuance, the fair value of the forward purchase contract was $2.0 million. The Equity Portion of $0.9 million was classified as equity, and the Non-Equity Portion of $1.1 million was initially recorded to Prepaid expenses and other current assets.

On May 17, 2012, the Company s stockholders approved an increase in its authorized shares of common stock from 250,000,000 to 350,000,000. Accordingly, the shares of common stock needed to consummate the Mann Group common stock purchase agreement became available. As of May 17, 2012, the fair value of the Non-Equity Portion was $13.1 million. As of result of receiving stockholder approval of the increase in authorized shares, the Non-Equity Portion met the criteria for equity classification. Consequently, the Company reclassified the $13.1 million from Prepaid expenses and other current assets to Additional paid-in capital.

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. As of and for the six months ended June 30, 2012, the Company recognized the change in fair value of $12.0 million in Other income. The Company revalued the Non-Equity Portion using a forward contract valuation formula, in which the forward contract is estimated to be equal to the valuation date stock price of $2.40 at issuance and $1.69 at May 17, 2012 minus the strike price discounted to the valuation date using a risk-free rate of 0.08% at issuance and 0.18% at May 17, 2012. As the shares which would be received upon settlement are currently unregistered, the Company applied a discount for lack of marketability of 10.27% at issuance and 1.67% at May 17, 2012 based on quantitative put models, adjusted to take into account qualitative factors, including the fact that the Company s stock is publicly traded and the fact that there is no contractual restriction on the unregistered shares being registered.

The Company is authorized to issue 350,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company s board of directors. No other class of capital stock is authorized. As of June 30, 2012 and December 31, 2011, 199,300,833 and 131,522,945 shares of common stock, respectively, were issued and outstanding. Included in the common stock outstanding as of June 30, 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 12 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. As of June 30, 2012 the Company had not issued any shares of undesignated preferred stock.

9. Warrant liability

In connection with the sale of units in February 2012, the Company issued separable warrants representing 21,562,500 shares of common stock which are exercisable at $2.40 per share and are exercisable any time prior to February 8, 2016. Warrants representing 60 shares of common stock have been exercised as of June 30, 2012.

Of the 21,562,500 shares represented by warrants, 16,145,833 shares were recorded as equity as they met the criteria for equity classification under ASC 815-40 *Derivatives and Hedging, Contracts in an Entity s Own Stock*. The remaining warrants representing 5,416,667 shares require liability classification in accordance with ASC 480, *Distinguishing Liabilities from Equity,* as the Company did not have sufficient registered shares available at the time of issuance. The fair value of these shares was recorded in accrued expenses and other current liabilities in the condensed consolidated balance sheet. The warrants will be reported as a liability until they are exercised, or at the time that the Company has sufficient registered shares available, at which time the warrants will be adjusted to fair value and reclassified from liabilities to stockholders equity.

The warrants requiring liability classification were recorded at fair value at issuance and will be adjusted to fair value at each reporting period until exercised or expiration. The fair value of the warrant liability at the date of issuance was $7.6 million and was estimated using the Black-Scholes option pricing model, based on the following assumptions: expected dividend yield of 0%; expected volatility of 93%; risk free interest rate of 0.59%; and contractual term of 4.0 years.

As of March 31, 2012, the fair value of the warrant liability was $7.9 million and was estimated using the Black-Scholes option pricing model based on the following assumptions: expected dividend yield of 0%; expected volatility of 93%; risk-free interest rate of 0.59%; and contractual term of 4 years. Any change in fair value between reporting periods is recorded as other income (expense) in the condensed consolidated statements of operations. During the quarter ended March 31, 2012, a loss of $284,000 was recognized from the fair value adjustment of the warrant liability.

As of June 30, 2012, the fair value of the warrant liability was $4.9 million and was estimated using the Black-Scholes option pricing model based on the following assumptions: expected dividend yield of 0%; expected volatility of 75.7%; risk-free interest rate of 0.41%; and contractual term of 3.6 years. Any change in fair value between reporting periods is recorded as other income (expense) in the condensed consolidated statements of operations. During the quarter ended June 30, 2012, a gain of $3.0 million was recognized from the fair value adjustment of the warrant liability. The fair value of the warrant liability is highly sensitive to the volatility rate used in the option pricing model and an increase in the volatility rate would cause an increase in the warrant liability. The volatility assumption is calculated based on historical activity.

10. 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. No such losses have been recorded to date.

Litigation The Company is involved in various legal proceedings and other matters. In accordance with ASC 450 *Contingencies*, the Company records 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.

The Securities Action. Beginning January 31, 2011, several complaints were filed in the U.S. District Court for the Central District of California against us and four of our officers Alfred E. Mann, Hakan S. Edstrom, Dr. Peter C. Richardson and Matthew J. Pfeffer on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been brought as purported shareholder class actions. In general, the complaints allege that the defendants violated federal securities laws by making materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of the Company s common stock. The U.S. District Court for the Central District of California has consolidated the pending actions for all purposes and appointed lead counsel.

On July 23, 2012, the Company, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Securities Action, and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Securities Action. Subject to preliminary and final approval of the settlement by the U.S. District Court and notice to potential class members, and in exchange for a release of all claims by the class members, among others, and a dismissal of the consolidated lawsuits, the Company has agreed (i) to cause the Company s insurers to pay class members and their attorneys a total of $16 million; and (ii) to issue class members and their attorneys 2,777,778 shares of the Company s common stock. The Company has also agreed that if the consolidated closing bid price for the Company s common stock is below $1.00 per share on the date the U.S. District Court enters an order of final judgment, then the Company will issue class members and their attorneys an additional one million shares of its common stock. Following final approval of the settlement by the U.S. District Court, the shares will be issued pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act of 1933, as amended.

The Derivative Action. In February 2011, shareholder derivative complaints were filed in the Superior Court of California for the County of Los Angeles and in the U.S. District Court for the Central District of California against all of the Company s directors and certain of its officers. The complaints in the shareholder derivative actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that the defendants caused or allowed for the dissemination of materially false and misleading statements regarding its business and prospects for AFREZZA, thereby artificially inflating the price of its common stock. The Superior Court of California for the County of Los Angeles has consolidated the actions pending before it and appointed lead counsel. The U.S. District Court for the Central District of California has also consolidated the derivative actions pending before it.

On August 3, 2012, the Company, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Derivative Actions and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Derivative Action. Subject to preliminary and final approval of the settlement by the U.S. District Court and notice to shareholders, and in an exchange for a release of all claims by the plaintiffs, among others, and a dismissal of the Derivative Actions, the Company has agreed (i) to adopt certain corporate governance measures, (ii) to cause the Company s insurers to pay the plaintiffs attorneys a total of $800,000, and (iii) to issue plaintiffs attorneys 225,000 shares of the Company s common stock. Following final approval of the settlement by the U.S. District Court, the shares will be issued pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act of 1933, as amended.

As a result of settlement discussions with the plaintiffs taking place in the latter part of the quarter ended June 30, 2012 and entering into the stipulation of settlement for the Securities Action on July 23, 2012 and for the Derivative Action on August 3, 2012, the Company determined that the liabilities pertaining to both the securities and derivative lawsuits were probable as of June 30, 2012. The Company s financial statements as of and for the three months ended June 30, 2012 reflect the following accruals:

(i) *Cash consideration*. The Company recorded a current liability of $16.8 million under Accrued expense and other current liabilities and a corresponding current asset under Prepaid expenses and other current asset to reflect a receivable from the Company s insurers. The Company has determined that the collectability of the receivable from the insurers is probable. The cash obligation resulted in no charge to the Company s Condensed Consolidated Statements of Operations for the period.

(ii) *Stock consideration*. The Company recorded a charge to General and administrative expenses and an estimated current liability under Accrued expense and other current liabilities of $7.7 million representing the estimated fair value of the 3,002,778 common shares to be issued in the aggregate subject to court approval.

(iii) *Additional stock consideration*. The Company concluded that the contingent obligation to issue an additional one million shares of its common stock, as defined in the stipulation of settlement agreement, met the definition of a derivative instrument in accordance with ASC 815 *Derivatives and Hedging*. The Company estimated the fair value of the derivative instrument using the Monte Carlo simulation model to forecast the contingent obligation applying probabilities that the stock price will be lower than $1.00 based on the following assumptions: expected volatility of 60%, risk free interest rate of 0.16% and final judgment dates ranging from four to six months. As a result, the Company estimated the fair value of this contingent obligation to be immaterial.

11. 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 principal stockholder being licensed as a finance lender under the California Finance Lenders Law. Accordingly, the lender was revised to The Mann Group. Interest accrues on each outstanding advance at a fixed rate equal to the one-year LIBOR rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum and is payable quarterly in arrears. The borrowing rate was 4.5% at both June 30, 2012 and December 31, 2011, respectively. In August 2010, the Company amended and restated the promissory note to extend the maturity date from December 31, 2011 to December 31, 2012. In January 2012, the Company amended the note with The Mann Group to extend the maturity date from December 31, 2012 to March 31, 2013 and to extend the date through which the Company can continue to borrow under the amended terms of the note until June 30, 2012. In addition, interest is payable on the first day of the calendar quarter following the calendar quarter in which an advance is made, or such other time as the Company and The Mann Group mutually agree. On May 9, 2012, the Company amended the note with The Mann Group to extend the maturity date of the $350.0 million loan arrangement from March 31, 2013 to July 1, 2013. Under the amended and restated promissory note The Mann Group may 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. On June 27, 2012, the Company amended the note with the Mann Group to allow accrued and unpaid interest that becomes due and payable under the note to be paid-in-kind and capitalized into new principal

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indebtedness upon agreement of the parties. In addition, the Company and The Mann Group agreed that the cancelled principal amount related to the common stock purchase agreement (see Note 6 Common and preferred stock) would be permanently retired and not available for re-borrowing under the note. The amendment also extends the date through which the Company can borrow under the note to December 31, 2012.

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 rate 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.

The principal amount outstanding under the loan arrangement as of June 30, 2012, subsequent to the completion of the common stock purchase agreement was as follows (in thousands):

Principal amount outstanding at December 31, 2011	$ 277,216
Borrowings	6,250
Capitalization of accrued and unpaid interest due and payable as of June 27, 2012	11,876
Cancellation of principal indebtedness related to the common stock purchase agreement completed on June 27, 2012	(77,200)
Principal amount outstanding at June 30, 2012	$ 218,142

As of June 30, 2012, the Company had accrued interest of $97,500 related to the remaining principal outstanding and $26.9 million of available borrowings remained under the loan arrangement.

On February 8, 2012, the Company sold $86.3 million worth of units in an underwritten public offering, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock. Concurrent with this public offering, The Mann Group LLC purchased $77.2 million worth of restricted shares of common stock and on June 27, 2012, the Company completed the closing of the sale of 31,250,000 share of its common stock (see Note 8 Common and preferred stock and Note 11 Related-party arrangements).

12. Senior convertible notes

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

	June 30 2012	December 31 2011
Notes due 2013		
Principal amount	$ 115,000	$ 115,000
Unaccreted debt issuance expense	(852)	(1,140)
Net carrying amount	114,148	113,860
Notes due 2015		
Principal amount	$ 100,000	$ 100,000
Unaccreted debt issuance expense	(2,964)	(3,218)
Net carrying amount	97, 036	96,782
Senior convertible notes	$ 211,184	$ 210,642

In August 2010, the Company completed a Rule 144A offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015. The Notes due 2015 are governed by the terms of an indenture dated as of August 24, 2010 (the 2015 Note Indenture). The Notes due 2015 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. As of June 30, 2012 and December 31, 2011, the Company had accrued interest of $2.2 million related to the Notes due 2015. The Notes due 2015 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 Notes due 2015 is August 15, 2015 and payment is due in full on that date for unconverted securities. Holders of the Notes due 2015 may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any

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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 Notes due 2015 converted in connection with a fundamental change by increasing the conversion rate on such Notes due 2015, 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 Notes due 2015 will have the option to require the Company to repurchase all or any portion of such holder s Notes due 2015 at a repurchase price of 100% of the principal amount of the Notes due 2015 to be repurchased plus accrued and unpaid interest, if any. The Company may elect to redeem some or all of the Notes due 2015 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 Notes due 2015 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 Notes due 2015 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. The Company performed an analysis at the time of the offering of the Notes due 2015 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 in excess of the maximum number of shares that could be required to be delivered during the contract period under existing commitments, including the outstanding convertible notes, stock options, restricted stock units, warrants, and other potential common stock issuances. The Company incurred approximately $4.2 million in issuance costs which are recorded as an offset to the Notes due 2015 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 Notes due 2015.

In December 2006, the Company completed a registered offering of $115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013. The Notes due 2013 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 Notes due 2013 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. As of June 30, 2012 and December 31, 2011, the Company had accrued interest of $192,000 related to the Notes due 2013. The Notes due 2013 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 Notes due 2013 is December 15, 2013 and payment is due in full on that date for unconverted securities. Holders of the Notes due 2013 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 Notes due 2013 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 Notes due 2013 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. The Company performed an analysis at the time of the offering of the Notes due 2013 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 in excess of the maximum number of shares that could be required to be delivered during the contract period under existing commitments, including the outstanding convertible notes, stock options, restricted stock units, warrants, and other potential common stock issuances.

The Company incurred approximately $3.7 million in issuance costs which are recorded as an offset to the Notes due 2013 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 Notes due 2013.

Amortization of debt issuance expense in connection with the offerings of the Notes due 2015 and the Notes due 2013 during the three and six months ended June 30, 2012 and 2011 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Amortization expense	$ 343	$ 324	$ 682	$ 644

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13. 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.

14. Subsequent event

On July 23, 2012, the Company entered into a stipulation of settlement to resolve the consolidated class action securities lawsuits. The current and former officers and directors named as individual defendants in the consolidated lawsuits have also entered into the stipulation of settlement which remains subject to preliminary and final approval by the U.S. District Court.

Subject to preliminary and final approval of the settlement by the U.S. District Court, and in exchange for a release of all claims by the class members, among others, and a dismissal of the consolidated lawsuits, the Company has agreed (i) to cause its insurers to pay class members and their attorneys a total of $16 million; and (ii) to issue to class members and their attorneys 2,777,778 shares of the Company s common stock. The Company has also agreed that if the consolidated closing bid price for its common stock is below $1.00 per share on the date the U.S. District Court enters an order of final judgment, then the Company will issue class members and their attorneys an additional one million shares of its common stock.

On August 3, 2012, the Company, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Derivative Actions, and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Derivative Actions. Subject to preliminary and final approval of the settlement by the U.S. District Court and notice to shareholders, and in an exchange for a release of all claims by the plaintiffs, among others, and a dismissal of the Derivative Actions, the Company has agreed (i) to adopt certain corporate governance measures, (ii) to cause the Company s insurers to pay the plaintiffs attorneys a total of $800,000, and (iii) to issue plaintiffs attorneys 225,000 shares of the Company s common stock. Following final approval of the settlement by the U.S. District Court, the shares will be issued pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act of 1933, as amended.

As a result of settlement discussions with the plaintiff taking place in the latter part of the quarter ended June 30, 2012 and entering into the stipulation of settlement for Securities Action on July 23, 2012 and for the Derivative Action on August 3, 2012, the Company determined that the liabilities pertaining to both the securities and derivative lawsuits were probable as of June 30, 2012. Accordingly, the Company recorded a litigation settlement accrual in its financial statements as of and for the three months ended June 30, 2012 (see Note 10 Commitments and contingencies).

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, 2011 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 and cancer. Our lead product candidate, AFREZZA (insulin human [rDNA origin]) inhalation powder, is an ultra rapid-acting insulin that is in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

In January 2011, we received a second Complete Response letter in which the FDA requested that we conduct two clinical studies with the Dreamboat inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one trial including a treatment group using the MedTone inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices. By the fourth quarter of 2011, we were recruiting subjects into both studies. We expect to complete screening for these studies during the third quarter of 2012 and complete the treatment stage of the studies in the second quarter of 2013. We then would expect to submit the results to the FDA as an amendment to our NDA during in the third quarter of 2013. However, the data collected from these clinical trials may not reach statistical significance or 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 beyond the currently planned studies in order to provide sufficient data for approval of AFREZZA.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of June 30, 2012, we have incurred a cumulative net loss of $2.0 billion and an accumulated stockholders deficit of $244.4 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities, convertible debt securities and borrowings under our related party loan. As discussed below in Liquidity and Capital Resources, this raises substantial doubt about our ability to continue as a going concern.

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. 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 profitable 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 our lead product candidate 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.

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

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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. Based on the results of preclinical studies, we plan to develop additional applications of our Technosphere technology. Additionally, we anticipate that we will continue to determine which research and development projects to pursue, and how much funding to direct to each project, on an ongoing basis, in response to the scientific and clinical success of each product candidate. We cannot be certain when any revenues from the commercialization of our products will commence.

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, and litigation settlement charges.

CRITICAL ACCOUNTING POLICIES

There have been no material changes to our critical accounting policies as described in Item 7 of our Annual Report on Form 10-K.

RESULTS OF OPERATIONS

Three and six months ended June 30, 2012 and 2011

Revenues

We did not recognize any revenue for the three months ended June 30, 2012 and 2011 or for the six months ended June 30, 2012. We recognized revenue of $50,000 under a license agreement for the six months ended June 30, 2011. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFREZZA.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the three and six months ended June 30, 2012 and 2011 (dollars in thousands):

	Three months ended June 30,			
	2012	2011	$ Change	% Change
Clinical	$ 13,327	$ 6,175	$ 7,152	116%
Manufacturing	9,899	21,131	(11,232)	(53%)
Research	2,182	2,525	(343)	(14%)
Research and development tax credit	(93)	(157)	64	(41%)
Stock-based compensation expense	1,323	622	701	(113%)

Research and development expenses	$ 26,638	$ 30,296	$ (3,658)	(12)%

	Six months ended June 30,			
	2012	**2011**	**$ Change**	**% Change**
Clinical	$ 24,206	$ 12,624	$ 11,582	92%
Manufacturing	19,992	35,460	(15,468)	(44%)
Research	4,122	6,737	(2,616)	(39%)
Research and development tax credit	(185)			