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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2011

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 ☒ No ☐

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

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

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

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

As of October 21, 2011, there were 131,339,001 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 September 30, 2011

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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.

PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands except share data)

	September 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,786	$ 66,061
Marketable securities	513	4,370
State research and development credit exchange receivable — current	765	674
Prepaid expenses and other current assets	2,960	2,849
Total current assets	27,024	73,954
Property and equipment — net	196,374	202,356
State research and development credit exchange receivable — net of current portion	386	629
Other assets	230	317
Total	$ 224,014	$ 277,256
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,598	$ 3,294
Accrued expenses and other current liabilities	15,715	14,840
Total current liabilities	17,313	18,134
Senior convertible notes	210,308	209,335
Note payable to related party	277,203	235,319
Total liabilities	504,824	462,788
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2011 and December 31, 2010	—	—
Common stock, $0.01 par value — 250,000,000 and 200,000,000 shares authorized at September 30, 2011 and December 31, 2010, respectively; 131,337,279 and 127,793,178 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	1,313	1,278
Additional paid-in capital	1,616,981	1,587,858
Accumulated other comprehensive income	45	74
Deficit accumulated during the development stage	(1,899,149)	(1,774,742)
Total stockholders' deficit	(280,810)	(185,532)
Total	$ 224,014	$ 277,256

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30, 2011
	2011	2010	2011	2010	
Revenue	$ —	$ —	$ 50	$ 93	$ 3,131
Operating expenses:					
Research and development	23,132	31,411	79,717	88,062	1,345,809
General and administrative	9,641	11,129	30,293	32,436	369,894
In-process research and development costs	—	—	—	—	19,726
Goodwill impairment	—	—	—	—	151,428
Total operating expenses	32,773	42,540	110,010	120,498	1,886,857
Loss from operations	(32,773)	(42,540)	(109,960)	(120,405)	(1,883,726)
Other income (expense)	79	1,948	1,476	(98)	(1,141)
Interest expense on note payable to related party	(2,863)	(2,851)	(7,849)	(7,476)	(25,300)
Interest expense on senior convertible notes	(2,845)	(1,876)	(8,092)	(4,297)	(25,945)
Interest income	—	16	18	22	36,989
Loss before provision for income taxes	(38,402)	(45,303)	(124,407)	(132,254)	(1,899,123)
Income taxes	—	—	—	—	(26)
Net loss	(38,402)	(45,303)	(124,407)	(132,254)	(1,899,149)
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	$ (38,402)	$ (45,303)	$(124,407)	$(132,254)	$ (1,922,361)
Net loss per share applicable to common stockholders — basic and diluted	$ (0.31)	$ (0.40)	$ (1.02)	$ (1.17)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	122,130	113,528	121,636	113,248	

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine months ended September 30,		Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2011
	2011	2010	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(124,407)	$(132,254)	$(1,899,149)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	12,097	12,916	108,560
Stock-based compensation expense	8,023	11,343	121,445
Stock expense for shares issued pursuant to research agreement	—	—	3,018
(Gain) loss on sale, abandonment/disposal or impairment of property and equipment	(63)	—	23,512
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	—	644	873
Other, net	—	(5)	1,104
Changes in assets and liabilities:			
State research and development credit exchange receivable	152	1,262	(1,151)
Prepaid expenses and other current assets	(111)	363	(1,360)
Other assets	87	180	(230)
Accounts payable	(121)	(35)	1,581
Accrued expenses and other current liabilities	861	(4,096)	14,790
Other liabilities	—	—	(2)
Net cash used in operating activities	(103,482)	(109,682)	(1,456,046)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	—	—	(796,779)
Sales and maturities of marketable securities	3,828	2,000	796,393
Purchase of property and equipment	(6,703)	(5,607)	(326,954)
Proceeds from sale of property and equipment	63	—	347
Net cash used in investing activities	(2,812)	(3,607)	(326,993)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants	10,544	1,749	1,229,624
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	53,000	87,000	375,000
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	—	95,786	207,050
Payment of employment taxes related to vested restricted stock units	(525)	(3,337)	(12,099)
Net cash provided by financing activities	63,019	181,198	1,805,825
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (43,275)	$ 67,909	$ 22,786
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	66,061	30,019	—
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 22,786	$ 97,928	$ 22,786
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$ —	$ —	$ 26
Interest paid in cash, net of amounts capitalized	15,092	8,654	47,241
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	181	1,463	181
Cancellation of principal on note payable to related party	11,116	—	27,797

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.

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, 2010 are included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2010 filed with the SEC on March 16, 2011 (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 and nine months ended September 30, 2011 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, 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. Since its inception through September 30, 2011 the Company has reported accumulated net losses of $1.9 billion, which include a goodwill impairment charge of $151.4 million, and cumulative negative cash flow from operations of $1.5 billion. It is costly to develop therapeutic products and conduct clinical trials for these products. At September 30, 2011, the Company's capital resources consisted of cash, cash equivalents, and marketable securities of $23.3 million and $45.0 million of available borrowings under the loan agreement with an entity controlled by the Company's principal stockholder (see Note 12 — 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 first 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. If the Company is not successful in raising additional capital through equity or debt financing, entering a business collaboration, establishing other funding facilities, licensing arrangements, assets sales or other means, or increasing the borrowings available under the loan arrangement with its related party, the Company will be required to reduce expenses through the delay, reduction or curtailment of its projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will be substantial doubt about its ability to continue as a going concern.

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

Cash equivalents consist of highly liquid investments, with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of September 30, 2011 and December 31, 2010, the Company held $15.8 million and $52.8 million, respectively of cash equivalents, consisting of money market funds, U.S. Treasury notes and commercial paper. The $15.8 million of cash equivalents at September 30, 2011 consisted entirely of money market funds. 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).

The Company's marketable securities consist principally of a certificate of deposit with a maturity greater than 90 days, held as collateral for the Company's commercial credit card programs and a common stock investment that are classified as available-for-sale securities. The certificate of deposit is stated at 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 September 30, 2011 and December 31, 2010, there were marketable securities of $0.5 million and $4.4 million, 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).

	September 30, 2011		December 31, 2010	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
Notes due 2013	$ 113.7	$ 61.2	$ 113.3	$ 69.1
Notes due 2015	$ 96.6	$ 76.5	$ 96.0	$ 134.1

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, based on the market approach (Level 2 in the fair value hierarchy).

Derivative financial instruments are reported in "Other assets" or "Accrued expenses and other current liabilities" in the condensed consolidated balance sheets and measured at fair value. The fair value of foreign exchange hedging contracts equals the carrying value at each balance sheet date. The fair value of these contracts are determined using methodologies based on market observable inputs (Level 2 in the fair value hierarchy), including foreign currency spot rates. The Company has used derivative financial instruments to manage its exposure to foreign currency exchange risks related to quarterly purchases on insulin. The Company does not use derivative financial instruments for trading or speculative purposes, nor does it use leveraged financial instruments. Credit risk related to derivative financial instruments is considered minimal and is managed by requiring high credit standards for counterparties and through periodic settlements of positions.

The Company's derivative financial instruments are not designated as hedging instruments for accounting purposes, and gains or losses resulting from changes in the fair value are reported in "Other income (expense)", in the condensed consolidated statements of operations. The Company entered into foreign exchange hedging contracts with notional amounts totaling zero and $25.5 million at September 30, 2011 and December 31, 2010, respectively. The Company recorded an unrealized loss of $567,000 on the outstanding contracts at December 31, 2010. The Company recorded a realized gain of zero and $1.3 million for the three and nine months ended September 30, 2011, respectively and a realized loss of $961,000 and $1.3 million related to these foreign exchange hedging contracts for the three and nine months ended September 30, 2010, respectively. The Company terminated these contracts during the quarter ended March 31, 2011.

Recently Issued Accounting Standards — In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 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 adoption of this update will have an impact on the disclosure of comprehensive income on the Company's consolidated financial statements.

In May 2011, the FASB issued Accounting Standards Update No. 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 is currently evaluating the impact the adoption of this update will have on its consolidated financial statements.

2. Investment in securities

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

	September 30, 2011			December 31, 2010		
	Cost Basis	Gross Unrealized Gain	Fair Value	Cost Basis	Gross Unrealized Gain	Fair Value
Available-for-sale securities	$ 467	$ 46	$ 513	$4,295	$ 75	$4,370

The Company's available-for-sale securities at September 30, 2011 consist of a $0.4 million certificate of deposit with a maturity greater than 90 days, held as collateral for the Company's commercial credit card programs, and a common stock investment. The Company's available-for-sale securities at December 31, 2010 consist principally of $4.2 million of certificates of deposit with a maturity greater than 90 days, held as collateral primarily for foreign exchange hedging instruments, and a common stock investment.

Gross realized gains and losses for available-for-sale securities were insignificant and recorded as “Other income (expense)” in the condensed consolidated statements of operations. Gross unrealized gains and losses are included in “Other comprehensive gain (loss)” (see Note 5 — Comprehensive loss).

3. Accrued expenses and other current liabilities

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

	September 30, 2011	December 31, 2010
Salary and related expenses	$ 8,660	$ 5,624
Research and clinical trial costs	820	668
Accrued interest	4,868	4,993
Construction in progress	163	149
Other	1,204	3,406
Accrued expenses and other current liabilities	$ 15,715	$ 14,840

4. Accounting for stock-based compensation

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2011 and 2010 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Stock-based compensation	$3,321	$3,338	$8,023	$11,343

The Company issued stock awards to employees during the nine months ended September 30, 2011 primarily with a four-year vesting schedule. The grant date fair value of the 3,310,800 stock options and 2,462,590 restricted stock units issued during the nine months ended September 30, 2011 were $6.7 million and $7.7 million, respectively, with a grant date fair value per share of $2.03 and $3.12, respectively.

As of September 30, 2011, there was $14.2 million and $16.8 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 2.4 years.

5. Comprehensive loss

Accounting Standards Codification (“ASC”) 220-10-45 *Comprehensive Income Other Presentation* requires reporting and displaying comprehensive income (loss) and its components, which, for the Company, includes net loss and unrealized gains and losses on investments and cumulative translation gains and losses. In accordance with this guidance, the accumulated balance of other comprehensive income (loss) is disclosed as a separate component of stockholders’ equity. For the three and nine months ended September 30, 2011 and 2010, comprehensive loss consisted of (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Net loss	$(38,402)	$(45,303)	$(124,407)	$(132,254)
Other comprehensive loss:				
Unrealized gain (loss) on investments	15	—	(30)	286
Cumulative translation (loss) gain	(8)	1	1	(5)
Comprehensive loss	$(38,395)	$(45,302)	$(124,436)	$(131,973)

6. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing 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 10 — Common and preferred stock). As of September 30, 2011, 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 10, 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 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 33,895,480 shares and 31,034,946 shares as of September 30, 2011 and 2010, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement.

7. Restructuring charges

On February 10, 2011, the Company announced that following receipt of the Complete Response letter from the United States Food and Drug Administration ("FDA") regarding the new drug application ("NDA") for AFREZZA, it implemented a restructuring to streamline operations, reduce operating expenses, extend the cash runway and focus its resources on securing the FDA's approval of the NDA for AFREZZA. In connection with the restructuring, the Company reduced its total workforce by approximately 41% to 257 employees. The Company recorded charges of approximately $6.7 million for employee severance and other related termination benefits and recognized an initial liability of $6.7 million in February, which approximated fair value.

	Workforce Reduction
Restructuring Balance, February 11, 2011	$ 6,659
Cash payments	(6,032)
Adjustment	(222)
Restructuring Balance, September 30, 2011	$ 405

During the quarter ended September 30, 2011, the Company adjusted the restructuring balance based on the election of certain termination benefits by a portion of the terminated employees.

The remaining restructuring balance as of September 30, 2011 primarily consists of the remaining health benefits which are paid out over six months subsequent to termination.

The net $6.4 million of costs associated with the restructuring are included in "Research and development" and "General and administrative" operating expenses in the condensed consolidated statements of operations as $4.8 million and $1.6 million, respectively, for the nine months ended September 30, 2011.

8. 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 September 30, 2011 and December 31, 2010, the estimated amounts receivable under the program were $1.2 million and $1.3 million, respectively.

9. Property and equipment — net

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

	Estimated Useful Life (Years)	September 30, 2011	December 31, 2010
Land	—	$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	113,878	113,489
Machinery and equipment	3-15	83,819	73,812
Furniture, fixtures and office equipment	5-10	5,369	5,369
Computer equipment and software	3	16,332	16,306
Leasehold improvements		53	53
Construction in progress		8,946	14,496
		288,618	283,746
Less accumulated depreciation and amortization		(92,244)	(81,390)
Property and equipment — net		$ 196,374	$ 202,356

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

Depreciation and amortization expense related to property and equipment for the three and nine months ended September 30, 2011 and 2010 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Depreciation and amortization expense	$3,745	$4,102	$11,124	$12,444

10. Common and preferred stock

In June 2011, the Company's stockholders approved an increase in its authorized shares of common stock from 200,000,000 to 250,000,000. As such, the Company is authorized to issue 250,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company's board of directors. No other class of capital stock is authorized. As of September 30, 2011 and December 31, 2010, 131,337,279 and 127,793,178 shares of common stock, respectively, were issued and outstanding. Included in the common stock outstanding as of September 30, 2011 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 13 — 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 September 30, 2011 the Company had not issued any shares of undesignated preferred stock.

In August 2010, the Company entered into an agreement with Seaside 88, LP ("Seaside") for the sale of up to 18,200,000 shares of common stock in increments of 700,000 shares on a bi-weekly basis with the first closing date scheduled for September 22, 2010 provided that certain conditions are met, including for a particular closing to take place, the ten-day volume weighted average trading price for the Company's common stock immediately prior to such closing must meet or exceed a minimum priced set by the Company at $6.50 per share. If the ten-day volume weighted average trading price for a particular closing was below $6.50 per share, then that closing would not occur and the aggregate number of shares to be purchased would be reduced by 700,000 shares. The purchase price per share at each closing was equal to 92% of that 10-day volume weighted average price. During the quarter ended March 31, 2011, the Company issued and sold a total of 1.4 million shares of common stock to Seaside for net proceeds of $9.7 million. No additional shares of common stock were sold to Seaside under this agreement subsequent to the quarter ended March 31, 2011. As of September 30, 2011, the Company had issued and sold a total of 3,500,000 shares of common stock to Seaside for net proceeds of $23.8 million in accordance with the agreement. The agreement with Seaside terminated during the quarter ended September 30, 2011.

In conjunction with the Seaside agreement, in August 2010, the Company entered into a common stock purchase agreement with The Mann Group LLC ("The Mann Group"), an entity controlled by the Company's principal stockholder. Under this common stock purchase agreement, the Company was required to issue and sell, and The Mann Group was obligated to purchase at a price equal to the greater of $7.15 per share (the closing bid price of the Company's common stock on August 10, 2010) and the closing bid price of common stock on the trading day immediately preceding the applicable closing date, the same number of shares of the Company's common stock that Seaside purchased on each closing date under its agreement with the Company (see Note 12 — Related-party arrangements). During the quarter ended March 31, 2011, the Company issued and sold a total of 1.4 million shares of common stock to The Mann Group that resulted in reduction in the note payable to related party of $11.1 million. No additional shares were sold to The Mann Group under this agreement subsequent to the quarter ended March 31, 2011. As of September 30, 2011, the Company had issued and sold a total of 3,500,000 shares of common stock to The Mann Group that had resulted in total reduction in the note payable to related party of $27.8 million. The agreement with The Mann Group terminated during the quarter ended September 30, 2011.

11. Commitments and contingencies

***Supply Commitments* —** In November 2007, the Company entered into a long-term supply agreement (the "Supply Agreement") with N.V. Organon ("Organon"), now a subsidiary of Merck & Co., Inc., pursuant to which Organon manufactured and supplied specified quantities of recombinant human insulin to the Company. In June 2011, the Company entered into a letter agreement (the "Letter Agreement") with Organon to settle a dispute that arose between the Company and Organon in connection with the termination by the Company of the Supply Agreement. Under the terms of the Letter Agreement, the Company paid Organon an aggregate of $16.0 million in two installments, each of which was paid after the Company received certain quantities of recombinant human insulin manufactured and supplied by Organon. The Letter Agreement is in full and final settlement of, and the Company and Organon agreed to release each other from, any and all actions and claims that the Company and Organon had or may have against each other in connection with the dispute regarding the Supply Agreement and related maters. The Company has concluded that the Letter Agreement represents a multiple element arrangement consisting of two elements representing the purchase of insulin and a contract cancellation fee. The Company has allocated the $16.0 million settlement first to the fair value of the insulin with the residual being allocated to the contract cancellation fee. During the three months ended June 30, 2011, the Company received the first of two shipments of recombinant human insulin and paid the first installment of $8.0 million. The Company expensed $4.3 million for insulin received and recorded $3.7 million for a contract cancellation fee. As of June 30, 2011, the Company recorded a loss contingency of $3.9 million in connection with the Letter Agreement representing the portion of the second $8.0 million payment related to the contract cancellation fee. During the three months ended September 30, 2011, the Company received the second shipment of insulin, paid the second installment of $8.0 million and recorded expense of $4.1 million for the insulin received.

***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*, previously the Financial Accounting Standards Board ("FASB") Statement No. 5, *Accounting for 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.

On November 23, 2010, John Arditi, former Senior Director — GCP — Regulatory Affairs of the Company, filed a Demand for Arbitration against the Company and three of its employees — the Chief Scientific Officer, the Vice President — World Wide Regulatory Affairs, and the Chief Financial Officer — claiming that the Company terminated his employment in retaliation for his purported reporting of alleged unlawful practices in connection with the Company's clinical trials. Mr. Arditi has asserted claims for violation of the New Jersey Conscientious Employee Protection Act, wrongful discharge, breach of contract, breach of the implied covenant of good faith and fair dealing, defamation and intentional infliction of emotional distress. Mr. Arditi is seeking, among other relief, compensatory and punitive damages and counsel fees, costs and interest. Before Mr. Arditi filed his arbitration demand, the Company completed an internal investigation and retained an independent outside firm to conduct an independent investigation of Mr. Arditi's claims. Neither investigation found any basis for his claims. The Company believes the allegations made by Mr. Arditi are without merit and intends to defend against them vigorously. The Company has not accrued any liability in this matter, as the Company does not believe it is probable that a loss has been incurred as of September 30, 2011. In addition, the Company believes that any reasonably possible losses which may be incurred would not be material to the financial statements as a whole.

Following the receipt of the Complete Response letter from the FDA regarding the NDA for AFREZZA in January 2011 and the subsequent decline of the price of the Company's common stock, several complaints were filed in the U.S. District Court for the Central District of California against the Company and certain of its officers and directors on behalf of certain purchasers of the Company's common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Securities Exchange Act

1934, as amended, and have been brought as purported shareholder class actions. In general, the complaints allege that the Company and certain of its officers and directors violated federal securities laws by making materially false and misleading statements regarding the Company's business and prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking unspecified monetary damages and other relief. The complaints have been transferred to a single court and consolidated for all purposes. The court has appointed a lead plaintiff and lead counsel and a consolidated complaint was filed on June 27, 2011. On August 12, 2011, we filed a motion to dismiss the consolidated complaint. The hearing on this motion is set for November 14, 2011. The Company plans to continue vigorously defending against the claims advanced. Based on the early stage of the claim and evaluation of the facts available at this time, the amount or range of reasonably possible losses to which the Company is exposed cannot be estimated and the ultimate resolution of this matter and the associated financial impact to the Company, if any, remains uncertain at this time.

Starting 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 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 Company's directors and certain of its officers caused or allowed for the dissemination of materially false and misleading statements regarding the Company's business and prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking unspecified monetary damages and other relief, including reforms to the Company's corporate governance and internal procedures. The Superior Court of California for the County of Los Angeles has consolidated the actions pending before it. Likewise, the U.S. District Court for the Central District of California has consolidated the actions pending before it. The U.S. District Court for the Central District of California has also appointed lead plaintiffs and lead counsel. On August 12, 2011, the federal lead plaintiffs filed a consolidated complaint. On September 26, 2011, the Company and the individual defendants filed a motion to dismiss the consolidated complaint. The hearing on this motion is set for January 30, 2012. The Company plans to continue vigorously defending against the claims advanced. Based on the early stage of the claim and evaluation of the facts available at this time, the amount or range of reasonably possible losses to which the Company is exposed cannot be estimated and the ultimate resolution of this matter and the associated financial impact to the Company, if any, remains uncertain at this time.

12. 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 4.6% at September 30, 2011 and 4.7% at December 31, 2010. In August 2010, the Company amended and restated the promissory note to extend the maturity date from December 31, 2011 to December 31, 2012, to provide for the cancellation of indebtedness under the note as described below, to provide that The Mann Group may require the Company to prepay the note in an amount not to exceed $200.0 million (less the amount of cancelled indebtedness) upon 90 days' prior written notice or on December 31, 2012, whichever is earlier, and to limit the Company's ability to borrow and reborrow under the note through December 31, 2011 to an amount equal to $350.0 million less the amount of cancelled indebtedness. The Mann Group has agreed not to exercise its prepayment right if such prepayment would require the use of working capital resources to repay the loan. 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 was $277.2 million and $235.3 million at September 30, 2011 and December 31, 2010, respectively. As of September 30, 2011, the Company had accrued interest of $2.9 million related to the amount outstanding, had cancelled a total of $27.8 million indebtedness and had $45.0 million of available borrowings under the loan arrangement.

In August 2010, the Company entered into a common stock purchase agreement with The Mann Group. Under this common stock purchase agreement, the Company was required to issue and sell, and The Mann Group was obligated to purchase, the same number of shares of the Company's common stock that Seaside purchased on each closing date under its agreement with the Company. The price of the shares that the Company sold to The Mann Group under the agreement was equal to the greater of $7.15 per share (the closing bid price of the Company's common stock on August 10, 2010) and the closing bid price of the Company's common stock on the trading day immediately preceding the applicable closing date. The aggregate purchase price for the shares of common stock the Company issued and sold to The Mann Group was paid by cancelling an equal amount of the outstanding principal under the $350.0 million loan arrangement provided by The Mann Group. The common stock purchase agreement with The Mann Group terminated during the quarter ended September 30, 2011.

13. Senior convertible notes

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

	September 30 2011	December 31 2010
Notes due 2013		
Principal amount	$ 115,000	$ 115,000
Unamortized debt issuance expense	(1,282)	(1,699)
Net carrying amount	113,718	113,301
Notes due 2015		
Principal amount	$ 100,000	$ 100,000
Unamortized debt issuance expense	(3,410)	(3,966)
Net carrying amount	96,590	96,034
Senior convertible notes	$ 210,308	$ 209,335

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 September 30, 2011 and December 31, 2010, the Company had accrued interest of $0.7 million and $2.0 million, respectively, 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 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 September 30, 2011 and December 31, 2010, the Company had accrued interest of $1.3 million and $0.2 million, respectively, 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 nine months ended September 30, 2011 and 2010 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Amortization expense	$329	$207	$973	$472

14. Income taxes

As required by ASC 740 *Income Taxes* ("ASC 740"), formerly FASB Statement No. 109 *Accounting for Income Taxes*, 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.

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, 2010 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.

On January 18, 2011 we received a second Complete Response letter from the U.S. Food and Drug Administration, or FDA, regarding our new drug application, or NDA, for AFREZZA in which the principal issue was the usage of *in vitro* performance data and bioequivalence data to bridge our next-generation inhaler to the Phase 3 trials conducted using our MedTone (model C) inhaler. The FDA requested that we conduct two clinical studies with the next-generation 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 (model C) inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices. In the January 2011 Complete Response letter, the FDA also stated that after an adequate titration of study medication there should be at least 12 weeks of relatively stable insulin dosing during the treatment period. In addition to this request, the FDA requested additional information concerning the performance characteristics, usage, handling, shipment and storage of the next-generation inhaler, an update of safety information related to AFREZZA as well as information on proposed user training and changes to the proposed labeling of the device, blister pack, foil wrap and cartons.

On May 4, 2011, we held an End-of-Review meeting with the FDA to discuss the design of the requested Phase 3 clinical trials. In this meeting, we were able to clarify many details about the FDA's requirements for approval of AFREZZA, and we received further guidance on the design of the studies on May 27, 2011, when we received the agency's minutes of the End-of-Review meeting. Subsequently, we submitted the proposed protocols and requested a meeting with the FDA to reach agreement on the final protocol designs. The proposed study in patients with type 1 diabetes, known as study 171, is an open-label, forced-titration design that will evaluate the efficacy and safety of AFREZZA in combination with a basal insulin versus insulin aspart, or Novolog, in combination with a basal insulin over a 24-week treatment period. This study will also include a treatment group using the MedTone (model C) inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices. The design of the study in patients with type 2 diabetes, known as study 174, is subject to further discussion with the FDA, but in general terms we have proposed to evaluate the efficacy and safety of meal-time AFREZZA in insulin naïve patients that are inadequately controlled on metformin or metformin plus another oral antidiabetic drug. Following a meeting with the FDA on August 10, 2011, we have confirmed the design of two clinical studies that will evaluate the efficacy and safety of AFREZZA administered using our next-generation inhaler. There can be no assurance that we will be able to satisfy all of the FDA's requirements with these two studies or that the FDA will 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 the NDA.

One of these studies is an open-label study in patients with type 1 diabetes. After a run-in period, during which all patients will be optimized on their basal insulin regimen, subjects will be randomized to one of three arms: a control arm, in which patients utilize an injected insulin analog at mealtimes, or one of two AFREZZA arms, one each for our first-generation MedTone device and our next-generation Dreamboat device. After the mealtime insulin is titrated, there will be a 12-week observation period on relatively stable doses of the mealtime insulin to assess A1c levels, which is the primary outcome parameter. The inclusion of two AFREZZA arms will permit us to perform a head-to-head comparison of the pulmonary safety data for the two devices, which will, in turn, provide a bridge to the extensive safety data that we collected in our earlier clinical studies of the first-generation MedTone device. The basic design of this study (comparing different mealtime insulins in combination with a basal insulin regimen) is similar in design to a previous Phase 3 study that we conducted in patients with type 1 diabetes using our first-generation MedTone inhaler.

The other study will assess AFREZZA using the next-generation Dreamboat inhaler in patients with type 2 diabetes who are inadequately controlled on metformin with or without a second or third oral medication. Patients will be randomized to treatment with AFREZZA or placebo in a randomized fashion. The study will have a titration period, followed by a 12-week observation period to assess A1c levels. The goal of this study is to evaluate the efficacy of AFREZZA compared to placebo powder. We have previously compared AFREZZA to placebo powder in successful Phase 2 studies involving patients with type 2 diabetes.

Subject to the timely enrollment of patients in these studies, we currently expect to complete both of these studies during 2012 and to submit the results as an amendment to our new drug application to the FDA by the first half of 2013.

There can be no assurance that we will be able to 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 September 30, 2011, we have incurred a cumulative net loss of $1.9 billion and an accumulated stockholders' deficit of $280.8 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," 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 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 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. Included in research and development expenses for the nine months ended September 30, 2011 were insulin purchases totaling $8.4 million.

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.

During the first quarter of 2011, we implemented a restructuring to streamline operations, reduce operating expenses, extend our cash runway and focus our resources on securing FDA approval of the NDA for AFREZZA. In connection with the restructuring, we recorded charges to research and development expenses of approximately $4.8 million for employee severance and other related termination benefits. The remaining liability of approximately $0.3 million is expected to be paid out in the fourth quarter of 2011. The restructuring is anticipated to result in research and development operating cost savings of approximately $9.9 million in 2011. These savings will be partially offset by increased costs associated with the additional trials required by the FDA.

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.

In connection with the restructuring, we recorded charges to general and administrative expenses of approximately $1.6 million for employee severance and other related termination benefits. The remaining liability of approximately $0.1 million is expected to be-paid out in the fourth quarter of 2011. The restructuring is anticipated to result in general and administrative operating cost savings of approximately $2.9 million in 2011. These savings may be offset by increased professional fees.

CRITICAL ACCOUNTING POLICIES

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

RESULTS OF OPERATIONS

Three and nine months ended September 30, 2011 and 2010

Revenues

We did not recognize any revenue for the three months ended September 30, 2011 and 2010, respectively. We recognized revenue of $50,000 and $93,000 under a license agreement for the nine months ended September 30, 2011 and 2010, respectively. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFREZZA.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the three and nine months ended September 30, 2011 and 2010 (dollars in thousands):

	Three months ended September 30,			
	2011	2010	$ Change	% Change
Clinical	$ 5,245	$ 5,150	$ 95	2%
Manufacturing	13,917	20,723	(6,806)	(33%)
Research	2,528	3,384	(856)	(25%)
Research and development tax credit	(265)	196	(461)	(235%)
Stock-based compensation expense	1,707	1,958	(251)	(13%)
Research and development expenses	$23,132	$31,411	$(8,279)	(26%)

	Nine months ended September 30,			
	2011	2010	$ Change	% Change
Clinical	$17,870	$18,976	$(1,106)	(6%)
Manufacturing	49,377	51,558	(2,181)	(4%)
Research	9,266	11,019	(1,753)	(16%)
Research and development tax credit	(522)	(238)	(284)	119%
Stock-based compensation expense	3,726	6,747	(3,021)	(45%)
Research and development expenses	$79,717	$88,062	$(8,345)	(9%)

The decrease in research and development expenses for the three months ended September 30, 2011, as compared to the three months ended September 30, 2010, was primarily due to a $4.1 million decrease in raw material purchases. Additionally, salary related costs decreased $3.3 million and stock based compensation expense decreased $0.3 million as a result of the February 2011 reduction in force as well as the positive impact of our cost cutting measures on operating expenses. Clinical expenses increased slightly over the prior year quarter as AFREZZA study 171 was initiated in the current quarter.

Research and development expenses for the nine months ended September 30, 2011 decreased as compared to the nine months ended September 30, 2010, primarily due to decreases of $3.4 million in salary related costs and $3.0 million in stock based compensation expense due to the February 2011 restructuring as well as the positive effect of our cost cutting measures. In June 2011, we entered into a letter agreement with N.V. Organon, or Organon, now a subsidiary of Merck, to settle a dispute that arose between us and Organon in connection with the termination by us of the Supply Agreement. In connection with the letter agreement, we received two shipments of recombinant human insulin from Organon in exchange for payments totaling $16.0 million. During the nine months ended September 30, 2011, we expensed $8.4 million for insulin received and recorded $7.6 million for a contract cancellation fee. This transaction resulted in an increase of $3.2 million in raw material purchases compared to the same period in the prior year.

We anticipate that our research and development expenses for 2011 will be slightly lower than the prior year due to lower purchases of raw materials and a smaller workforce going forward, partially offset by increased costs associated with the additional trials required by the FDA.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the three and nine months ended September 30, 2011 and 2010 (dollars in thousands):

	Three months ended September 30,			
	2011	2010	$ Change	% Change
Salaries, employee related and other general expenses	$8,027	$ 9,750	$(1,723)	(18%)
Stock-based compensation expense	1,614	1,379	235	17%
General and administrative expenses	$9,641	$11,129	$(1,488)	(13%)

	Nine months ended September 30,			
	2011	2010	$ Change	% Change
Salaries, employee related and other general expenses	$25,996	$27,841	$(1,845)	(7%)
Stock-based compensation expense	4,297	4,595	(298)	(6%)
General and administrative expenses	$30,293	$32,436	$(2,143)	(7%)

General and administrative expenses for the three months ended September 30, 2011 decreased as compared to the same period in the prior year primarily due to decreased salary related costs of $1.0 million as a result of the February 2011 reduction in force as well as the positive impact of our cost cutting measures on other general operating expenses.

General and administrative expenses for the nine months ended September 30, 2011 decreased as compared to the same period in the prior year primarily due to decreased salary related costs of $0.7 million and stock based compensation of $0.3 million as a result of the February 2011 reduction in force as well as the positive impact of our cost cutting measures on other general operating expenses.

Overall, we expect general and administrative expenses for 2011 to be consistent with the prior year as we may incur increased professional fees, offset by reduced expenses as a result of our cost cutting measures.

Other Income and Expense

Other income for the three months ended September 30, 2011 was $79,000 compared to $1.9 million in the same period in the prior year. In the prior year quarter we received a reimbursement of $1.6 million in connection with a soil cleanup plan, recorded a net gain of $0.6 million related to our foreign exchange hedging contracts and recognized a $0.3 million other than temporary impairment on marketable securities.

Other income for the nine months ended September 30, 2011 was $1.5 million compared to other expense of $98,000 in the same period in the prior year. We recorded a realized gain of $1.3 million on foreign exchange hedging contracts for the nine months ended September 30, 2011. The foreign exchange hedging contracts were terminated during the quarter ended March 31, 2011. During the nine months ended September 30, 2010, we received a reimbursement of $1.6 million in connection with a soil cleanup plan, recorded a $1.2 million loss on foreign exchange hedging contracts and recognized a $0.6 million other than temporary impairment on marketable securities.

Interest Expense

Interest expense for the three and nine months ended September 30, 2011 increased by $1.0 million and $4.2 million, respectively, as compared to the same periods in the prior year primarily due to the additional interest expense associated with our issuance of 5.75% Senior Convertible Notes in August 2010 (See Note 13 — Senior convertible notes, of the Notes to the accompanying financial statements) as well as additional drawdowns on our note payable to our principal stockholder.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity securities, convertible debt securities and borrowings under our related party note.

In October 2007, we entered into a loan arrangement with our principal stockholder allowing us to borrow up to a total of $350.0 million. In February 2009, as a result of our principal stockholder being licensed as a finance lender 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. 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.

In August 2010, we amended and restated the existing promissory note evidencing the loan arrangement with The Mann Group to extend the maturity date from December 31, 2011 to December 31, 2012. Under the amended and restated promissory note, 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. 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 our working capital resources, including the proceeds from the sale of our 5.75% Senior Convertible Notes due 2015. In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at the lender'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. As of September 30, 2011, the amount borrowed and outstanding under the arrangement was $277.2 million and we had $45.0 million of available borrowings under the arrangement.

In August 2010, Seaside and we entered into a common stock purchase agreement, or the Seaside purchase agreement. The Seaside purchase agreement required us to issue and sell, and Seaside to buy, up to 18,200,000 shares of our common stock in installments of 700,000 shares once every 14 days, subject to the satisfaction of certain closing conditions at each closing, beginning on September 22, 2010 and ending approximately 50 weeks after the initial closing. The price of the shares that we sold to Seaside was at an 8% discount to the volume weighted average trading price for our common stock for the ten consecutive trading days immediately preceding each closing date. For a particular closing to take place, the ten-day volume weighted average trading price for our common stock immediately prior to such closing must have met or exceeded a minimum price set by us at $6.50 per share. If the ten-day volume weighted average trading price for a particular closing was below $6.50 per share, then that closing would not occur and the aggregate number of shares to be purchased would be reduced by 700,000 shares. Seaside also had the right not to complete a purchase of shares at a closing if it would cause Seaside's beneficial ownership of our common stock, calculated in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, to exceed 10% of our outstanding common stock immediately after such subsequent closing. Seaside had agreed not to engage in short sales of our common stock during the term of the Seaside purchase agreement and had agreed that it would not sell more than 10% of the total number of shares of common stock traded on any trading day. In August 2010, we entered into an agreement with Omni Capital Corporation to pay that firm a finder's fee in an amount equal to 1% of the aggregate value of all cash invested by Seaside under the Seaside purchase agreement. As of September 30, 2011, a total of 3,500,000 shares had been sold to Seaside under the Seaside purchase agreement for net proceeds of $23.8 million. The Seaside purchase agreement terminated during the quarter ended September 30, 2011.

In conjunction with the Seaside agreement, in August 2010, The Mann Group and we entered into a common stock purchase agreement, or the Mann purchase agreement. Under the Mann purchase agreement, we were required to issue and sell, and The Mann Group was obligated to purchase, the same number of shares of our common stock that Seaside purchased on each closing date under the Seaside purchase agreement. The price of the shares that we issued and sold to The Mann Group was equal to the greater of $7.15 per share (the closing bid price of our common stock on August 10, 2010) and the closing bid price of our common stock on the trading day immediately preceding the applicable closing date. The aggregate purchase price for the shares of common stock we issued and sold to The Mann Group was paid by cancelling an equal amount of the outstanding principal under the $350.0 million revolving loan arrangement provided by The Mann Group. As of September 30, 2011, a total of 3,500,000 shares had been issued to The Mann Group under the Mann purchase agreement, which were paid for by the cancellation of $27.8 million of outstanding principal under the loan arrangement. The Mann purchase agreement terminated during the quarter ended September 30, 2011.

During the nine months ended September 30, 2011, we used $103.5 million of cash for our operations and had a net loss of $124.4 million for the nine months ended September 30, 2011, of which $20.1 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. By comparison, during the nine months ended September 30, 2010, we used $109.7 million of cash for our operations and had a net loss of $132.3 million, of which $24.3 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. Cash used for our operations for the nine months ended September 30, 2011 decreased by $6.2 million compared to cash used for our operations for the nine months ended September 30, 2010 due primarily to reduced salary-related costs and the positive impact of cost cutting measures on operating costs as a result of our February 2011 restructuring. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

We used $2.8 million of cash for investing activities during the nine months ended September 30, 2011, compared to $3.6 million of cash used for the nine months ended September 30, 2010. For the nine months ended September 30, 2011 and 2010, $6.7 million and $5.6 million, respectively, were used to purchase machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFREZZA. Cash used in investing activities for the nine months ended September 30, 2011

decreased $0.8 million compared to the same period in prior year due to an increase of $1.8 million in proceeds received from sales and maturities of marketable securities. We received cash of $3.8 million for the nine months ended September 30, 2011 related to the early termination of certificates of deposit that were previously held as collateral for foreign exchange hedging instruments compared to $2.0 million received in the same period in prior year as a certificate of deposit matured. Cash generated from marketable securities was offset by an increase of $1.1 million of cash used to purchase machinery and equipment compared to the same period in the prior year.

Our financing activities generated $63.0 million of cash for the nine months ended September 30, 2011, compared to $181.2 million for the same period in 2010. For the nine months ended September 30, 2011, cash from financing activities was primarily from $53.0 million of related party borrowings and $10.5 million related to the sale of common stock to Seaside during the first quarter of 2011 as well as the exercise of stock options. For the nine months ended September 30, 2010, cash from financing activities was primarily from the issuance of $95.8 million of 5.75% Senior Convertible Notes due 2015 in August 2010, $87.0 million of related party borrowings and $1.8 million related to the sale of common stock as well as the exercise of stock options. Cash from financing activities for the nine months ended September 30, 2011 decreased by $118.2 million compared to cash from financing for the same period in the prior year due to proceeds from the issuance of the 5.75% Senior Convertible Notes due 2015 in August 2010 as well as decreased related party borrowings, offset by increased sales of common stock primarily to Seaside.

As of September 30, 2011, we had $23.3 million in cash, cash equivalents and marketable securities. Although we believe our existing cash resources, including the $45.0 million remaining available under our loan arrangement with The Mann Group, will be sufficient to fund our anticipated cash requirements into the first quarter of 2012, we will require significant additional financing in the future to fund our operations and if we are unable to do so, there will be substantial doubt about our ability to continue as a going concern. Accordingly, we expect that 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, or an increase in the borrowings available under the loan arrangement with our related party, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities.

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 facility. We also intend to use our capital resources for general corporate purposes.

On September 23, 2011, we announced that we proposed to offer, subject to market conditions, senior secured discount notes due 2017 expected to yield gross proceeds of approximately $370.0 million. There can be no assurances, however, that we will be able to raise additional capital through this offering on acceptable terms, or at all. If the offering is consummated, the net proceeds from the offering of the notes would be used for development and operating capital, including completion of the Phase 3 clinical trials of our lead product candidate, AFREZZA, preparing for commercialization of AFREZZA, continuing the build-out of our Danbury, Connecticut manufacturing facility, ongoing research and development efforts, and general corporate purposes.

We have also held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. We cannot predict when, if ever, we could 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 will 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 that are commercially favorable to us.

However, we cannot provide assurances 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. 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 be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of September 30, 2011 we did not have any off-balance sheet arrangements.

Contractual Obligations

In June 2011, we entered into a letter agreement, or the Letter Agreement, with Organon, to settle a dispute that arose between us and Organon in connection with the termination by us of the supply agreement between us and Organon dated November 16, 2007, or the Supply Agreement. Under the terms of the Letter Agreement, we will pay Organon an aggregate of $16.0 million in two installments, each of which will be paid after we receive certain quantities of recombinant human insulin manufactured and supplied by Organon. The Letter Agreement is in full and final settlement of, and we and Organon agreed to release each other from, any and all actions and claims that we and Organon had or may have against each other in connection with the dispute regarding the Supply Agreement and related matters. In the quarter ended June 30, 2011, we received the first of two shipments of recombinant human insulin and paid the first installment of $8.0 million. During the quarter ended September 30, 2011, we received the second shipment of insulin and paid the second installment of $8.0 million. (See Note 11 — Commitments and contingencies of the Notes to the accompanying financial statements.)

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 our credit facility with The Mann Group. The interest rate on our credit facility with The Mann Group is 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. 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. Our short-term investments at September 30, 2011 are comprised mainly of a certificate of deposit and a common stock investment. We continue to utilize our $350.0 million credit facility to fund operations. As of September 30, 2011, the amount borrowed and outstanding under the credit facility was $277.2 million, with $45.0 million of available borrowings. The interest rate is fixed at the time of the draw. If interest rates were to increase from levels at September 30, 2011 we could experience a higher level of interest expense than assumed in our current operating plan.

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 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.

Our chief executive officer and chief financial officer performed an evaluation under the supervision and with the participation of our management, of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of September 30, 2011. 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.

There has been no change in our internal control over financial reporting during the fiscal quarter ended September 30, 2011 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

On November 23, 2010, John Arditi, our former Senior Director — GCP — Regulatory Affairs, filed a Demand for Arbitration against us and three employees — our Chief Scientific Officer, our Vice President — World Wide Regulatory Affairs, and our Chief Financial Officer — claiming that we terminated his employment in retaliation for his purported reporting of alleged unlawful practices in connection with our clinical trials. Mr. Arditi has asserted claims for violation of the New Jersey Conscientious Employee Protection Act, wrongful discharge, breach of contract, breach of the implied covenant of good faith and fair dealing, defamation and intentional infliction of emotional distress. Mr. Arditi is seeking, among other relief, compensatory and punitive damages and counsel fees, costs and interest. Before Mr. Arditi filed his arbitration demand, we had completed an internal investigation and retained an independent outside firm to conduct an independent investigation of Mr. Arditi's claims. Neither investigation found any basis for his claims. We believe the allegations made by Mr. Arditi are without merit and we intend to defend against them vigorously.

Following the receipt by us of the Complete Response letter from the FDA regarding the NDA for AFREZZA in January 2011 and the subsequent decline of the price of our common stock, several complaints were filed in the U.S. District Court for the Central District of California against us and certain of our officers and directors 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 we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. The complaints have been transferred to a single court and consolidated for all purposes. The court has appointed a lead plaintiff and lead counsel and a consolidated complaint was filed on June 27, 2011. On August 12, 2011, we filed a motion to dismiss the consolidated complaint. The hearing on this motion is set for November 14, 2011. We will vigorously defend against the claims advanced.

Starting 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 our directors and certain of our 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 our directors and certain of our officers caused or allowed for the dissemination of materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief, including reforms to our corporate governance and internal procedures. The Superior Court of California for the County of Los Angeles has consolidated the actions pending before it. Likewise, the U.S. District Court for the Central District of California has consolidated the actions pending before it. The U.S. District Court for the Central District of California has also appointed lead plaintiffs and lead counsel and a consolidated complaint was filed on August 12, 2011. We moved to dismiss the complaint on September 26, 2011. The hearing on this motion is set for January 30, 2012. We will vigorously defend against the claims advanced.

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 solely on the successful development and commercialization of AFREZZA.

In January 2011, the FDA requested that we conduct additional clinical studies of AFREZZA using our next-generation inhaler. In early May 2011, we held an End-of-Review meeting with the agency to discuss the protocols for the additional studies. In August 2011, we confirmed with the FDA the design of two clinical studies that will evaluate the efficacy and safety of AFREZZA administered using our next-generation inhaler. We plan to continue working closely with the FDA in our effort to ensure that our clinical studies address the agency's requests for additional information about AFREZZA. There can be no assurance that we will be able to satisfy all of the FDA's requirements or that the FDA will find our proposed approach to these clinical studies acceptable. 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 and similar foreign regulatory agencies before AFREZZA can be marketed and sold in the United States or elsewhere. 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 cost effectiveness. 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, Technosphere platform technology and immunotherapy product candidates. Even if our research programs identify candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to successfully complete the development and commercialization of AFREZZA or develop or expand our other product candidates, or are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

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

We are a development stage company with no commercial products. All of our product candidates are still being developed, and all but AFREZZA are still in the early stages of development. Our product candidates will require significant additional development, clinical 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 September 30, 2011, we had incurred a cumulative net loss of $1.9 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 September 30, 2011, we had a stockholders' deficit of $280.8 million. Our ability to achieve and sustain positive cash flow from operations and profitability 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 doubt about our ability to make payment on the notes or even continue as a going concern.*

Based upon our current expectations, we believe that our existing capital resources, including the loan arrangement with The Mann Group, will enable us to continue planned operations into the first quarter of 2012. 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. In any event, we plan to raise additional funds, whether 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 our related party, 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 September 30, 2011, we had a stockholders' deficit of $280.8 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 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 and the timing and amount of any payments we might receive from any collaboration we are able to establish;
- actions taken by the FDA and other regulatory authorities affecting our products and competitive products;
- our degree of success in commercializing AFREZZA;
- the emergence of competing technologies and products and other adverse market developments;
- the timing and amount of payments we might receive from potential licensees;
- 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, including those expenses associated with the securities class actions and derivative lawsuits filed against us and certain of our executive officers and directors and any settlement or damages payments associated with litigation;
- the costs of discontinuing projects and technologies; and
- the costs of decommissioning existing facilities, if we undertake 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. On September 23, 2011, we announced that we proposed to offer, subject to market conditions, senior secured discount notes due 2017 expected to yield gross proceeds of approximately $370.0 million. There can be no assurances, however, that we will be able to raise additional capital through this 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 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 our proposed senior note offering, strategic collaboration opportunities, sales of securities, credit 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 commercialization, 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.

Because we will not be able to generate operating cash flow unless and until AFREZZA is commercialized, which we expect will require us to reach an agreement with a commercialization partner, we 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 substantial doubt about our ability to make payment on the notes or even continue as a going concern.

Deteriorating global economic conditions may have an adverse impact on our loan facility with The Mann Group or our ability to complete our proposed senior note offering.*

As widely reported, 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 these events on our loan facility with The Mann Group or our ability to complete our proposed senior note offering. If we are unable to draw on The Mann Group loan facility or complete the proposed offering, 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 would 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 will decline.

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

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

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

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

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

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

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. To date we have not reached an agreement on a collaboration with any of these companies. We cannot predict when, if ever, we could 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. 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 effort.

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;
- 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 QSR. 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 should 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, place the two blister packs into foil pouches and package three pouches plus two inhalers and the package insert as units in 90-unit boxes (and single blister pouch packs for trials). Although this 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 the next-generation Dreamboat inhaler before we can be approved to distribute the manufactured products 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.

We and certain of our executive officers and directors have been named as defendants in recently initiated securities class actions and derivative lawsuits that could result in substantial costs and divert management's attention.*

We are aware of lawsuits in which we, and certain of our executive officers, have been sued for alleged violations of federal securities laws related to alleged false and misleading statements regarding AFREZZA. We are also aware of state and federal derivative lawsuits that have been filed against certain of our directors and executive officers. We intend to engage in a vigorous defense of such litigation. If we are not successful in our defense of such litigation, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

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. 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, there was a soil and groundwater investigation and remediation being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection, or CT DEP, which is continuing. As part of the purchase, we obtained an indemnification from the seller for all known environmental conditions that existed at the time the seller acquired the property. The seller was, in turn, indemnified for these known environmental conditions by the previous owner and its operator (responsible party). We also received an

indemnification from the seller for environmental conditions created during its ownership of the property and for environmental problems unknown at the time that the seller acquired the property. These additional indemnities have since expired and were limited to the purchase price we paid for the Danbury facilities.

During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location in the third quarter of 2008, at a cost of approximately $2.25 million. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of $1.625 million in July 2010. The responsible party has further agreed to conduct at its expense all work and make all filings necessary to achieve closure for the environmental investigation and remediation being conducted at the site and agreed to pay for or indemnify us for any future costs and expenses we may incur that are directly related to the final closure of the environmental remediation. 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.

If we fail to enter into collaborations with third parties, we would be required to establish our own sales, marketing and distribution capabilities, which could impact the commercialization of our products and harm our business.

Our products 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 will be required in order to educate these physicians about the benefits and advantages of AFREZZA and to provide adequate support for them. Therefore, our primary strategy is to enter into collaborations with one or more pharmaceutical companies to market, distribute and sell AFREZZA, if it is 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, all 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.

If any product that we may develop does not become widely accepted by physicians, patients, third-party payers 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 payers 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;
- 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 payers, regarding the safety, efficacy and benefits compared to competing products or therapies;
- convenience and ease of administration relative to existing treatment methods;
- 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 payers do not reimburse consumers for our products, our products might not be used or purchased, which would adversely affect our revenues.*

Our future revenues and ability to generate cash flow from operation may be affected by the continuing efforts of governments and third-party payers 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 payers 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 payers, such as governmental and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. In addition, because each third-party payer individually approves reimbursement, obtaining these approvals 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 payer 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 reimbursement to the consumer would be available, in which case our business and results of operations would be harmed and the market price of our common stock could decline.

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.*

In order to commercialize our product candidates successfully, we will be required to expand our work force, particularly in the areas of manufacturing and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel. 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.

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. With the exception of our Chief Scientific Officer, Dr. Peter C. Richardson, 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 internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

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

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

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;
- 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. Our product candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.

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

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

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing 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. As well, the public perception of AFREZZA might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company's products or product candidates.

There are also a number of clinical 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 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 and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

Interference proceedings brought by the 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. Litigation 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 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.

Over the past three decades the number of patents issued to biotechnology companies has expanded dramatically. 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 and/or our cancer vaccines 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 and cancer vaccine products under development, 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, as well as third-party patents disclosing methods of use and compositions of matter related to cancer vaccines that also may trigger an allegation of infringement upon the commercial manufacture and sale of our cancer immunotherapy. If a court were to determine that our insulin products or cancer therapies were infringing any of these patent rights, we would have to establish with the court that these patents were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business would be harmed and our profitability could be materially adversely impacted.

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

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

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

We have not selected trade names for some of our product candidates; therefore, we have not filed trademark registrations for all of our potential trade names for our product candidates in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere or 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 litigation against us and certain of our executive officers and directors;
- the existence of, and the issuance of shares of our common stock pursuant to, the share lending agreement and the short sales of our common stock effected in connection with the sale of our 5.75% convertible notes due 2015; and
- discussion of AFREZZA, our other product candidates, competitors' products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.

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

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

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

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 September 30, 2011, Mr. Mann beneficially owned approximately 39.2% 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 or the conversion of our senior convertible notes into common stock could negatively affect our stock price.*

As of September 30, 2011, we had 131,337,279 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 could adversely affect the trading price of our common stock. In addition, the existence of these notes may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

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

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

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. (REMOVED AND RESERVED)

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(3)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.4(4)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.5(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(1)	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.
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.

(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.

SIGNATURE

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

Dated: November 4, 2011

MANNKIND CORPORATION

By: /s/ Matthew J. Pfeffer
Matthew J. Pfeffer
Corporate Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Alfred E. Mann, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2011 of MannKind Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2011

/s/ Alfred E. Mann

Alfred E. Mann
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Matthew J. Pfeffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2011 of MannKind Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2011

/s/ Matthew J. Pfeffer

Matthew J. Pfeffer
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATION OF
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)

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended September 30, 2011, as filed with the Securities and Exchange Commission on or about the date hereof to which this certification is attached as Exhibit 32 (the "Report") and pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Alfred E. Mann, Chief Executive Officer of the Company, and Matthew J. Pfeffer, Chief Financial Officer of the Company, each hereby certifies that to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2011

In witness whereof, the undersigned have set their hands hereto as of the 4th day of November, 2011.

/s/ Alfred E. Mann	/s/ Matthew J. Pfeffer
Alfred E. Mann	Matthew J. Pfeffer
Chief Executive Officer	Chief Financial Officer

This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not deemed filed for purposes of Section 18 of the Exchange Act or the Securities Act of 1933, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language contained in such filing.