MANNKIND CORP
Form 10-Q
October 29, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q

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

For the quarterly period ended September 30, 2010

Or

o **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 þ No o

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 o No o

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 o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of October 22, 2010, there were 124,769,494 shares of the registrant s common stock, $.01 par value per share, outstanding.

MANNKIND CORPORATION
Form 10-Q
For the Quarterly Period Ended September 30, 2010
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AFREZZA® and Technosphere® are our registered trademarks in the United States. We have also applied for and have registered company trademarks in other jurisdictions, including Europe and Japan.

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

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 97,928	$ 30,019
Marketable securities	117	2,475
State research and development credit exchange current	674	1,500
Prepaid expenses and other current assets	3,309	3,672
Total current assets	102,028	37,666
Property and equipment net	202,235	208,229
State research and development credit exchange receivable net of current portion	482	918
Other assets	404	584
Total	$ 305,149	$ 247,397
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 6,372	$ 6,519
Accrued expenses and other current liabilities	19,193	22,334
Total current liabilities	25,565	28,853
Senior convertible notes	209,023	112,765
Note payable to related party	252,000	165,000
Total liabilities	486,588	306,618
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, 2010 and December 31, 2009		
Common stock, $0.01 par value 200,000,000 and 150,000,000 shares authorized at September 30, 2010 and December 31, 2009, respectively; 123,363,865 and 113,025,291 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	1,234	1,130
Additional paid-in capital	1,553,763	1,544,112
Accumulated other comprehensive loss		(281)
Deficit accumulated during the development stage	(1,736,436)	(1,604,182)

Total stockholders deficit		(181,439)		(59,221)
Total	$	305,149	$	247,397

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three months ended September 30, 2010	Three months ended September 30, 2009	Nine months ended September 30, 2010	Nine months ended September 30, 2009	Cumulative period from February 14, 1991 (date of inception) to September 30, 2010
Revenue	$	$	$ 93	$	$ 3,081
Operating expenses:					
Research and development	31,411	30,494	88,062	113,232	1,241,875
General and administrative	11,129	12,273	32,436	40,727	331,725
In-process research and development costs					19,726
Goodwill impairment					151,428
Total operating expenses	42,540	42,767	120,498	153,959	1,744,754
Loss from operations	(42,540)	(42,767)	(120,405)	(153,959)	(1,741,673)
Other income (expense)	1,948	149	(98)	503	(1,990)
Interest expense on note payable to related party	(2,851)	(1,816)	(7,476)	(3,806)	(14,678)
Interest expense on senior convertible notes	(1,876)	(1,130)	(4,297)	(3,376)	(15,022)
Interest income	16	9	22	67	36,953
Loss before provision for income taxes	(45,303)	(45,555)	(132,254)	(160,571)	(1,736,410)
Income taxes					(26)
Net loss	(45,303)	(45,555)	(132,254)	(160,571)	(1,736,436)
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	$ (45,303)	$ (45,555)	$ (132,254)	$ (160,571)	$ (1,759,648)
	$ (0.40)	$ (0.42)	$ (1.17)	$ (1.54)	

Net loss per share applicable to common stockholders basic and diluted				
Shares used to compute basic and diluted net loss per share applicable to common stockholders	113,528	108,779	113,248	104,402

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, 2010	Nine months ended September 30, 2009	Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2010
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (132,254)	$ (160,571)	$ (1,736,436)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	12,916	14,020	92,055
Stock-based compensation expense	11,343	17,979	111,185
Stock expense for shares issued pursuant to research agreement			3,018
Loss on sale, abandonment/disposal or impairment of property and equipment		62	23,575
Accrued interest on investments, net of amortization of discounts		(12)	(191)
In-process research and development			19,726
Goodwill impairment			151,428
Loss on available-for-sale securities	644		873
Other, net	(5)	5	1,105
Changes in assets and liabilities:			
State research and development credit exchange receivable	1,262	800	(1,156)
Prepaid expenses and other current assets	363	736	(1,709)
Other assets	180	(36)	(404)
Accounts payable	(35)	(3,994)	5,954
Accrued expenses and other current liabilities	(4,096)	(15,695)	17,387
Other liabilities			(2)
Net cash used in operating activities	(109,682)	(146,706)	(1,313,592)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities		(2,000)	(792,601)
Sales/ maturities of marketable securities	2,000	17,800	792,565
Purchase of property and equipment	(5,607)	(16,679)	(316,316)
Proceeds from sale of property and equipment			284
Net cash used in investing activities	(3,607)	(879)	(316,068)
CASH FLOWS FROM FINANCING ACTIVITIES:			

Issuance of common stock and warrants, net	1,749	60,648	1,203,804
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	87,000	120,000	322,000
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		207,053
Payment of employment taxes related to vested restricted stock units	(3,337)	(6,793)	(11,519)
Net cash provided by financing activities	181,198	173,855	1,727,588
NET INCREASE IN CASH AND CASH EQUIVALENTS	$ 67,909	$ 26,270	$ 97,928
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	30,019	27,648	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 97,928	$ 53,918	$ 97,928
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 26
Interest paid in cash	8,654	4,159	27,141
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	1,463	1,239	1,463

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, 2009 are included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2009 filed with the SEC on March 16, 2010 (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, 2010 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 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, development and commercialization of therapeutic products for diseases such as diabetes and cancer. The Company s lead product candidate, AFREZZA, is an ultra rapid-acting insulin. In March 2009, the Company submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) requesting approval of AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, the Company received a Complete Response letter regarding this NDA from the FDA, requesting additional information. In July 2010, the FDA accepted the Company s reply to the Complete Response letter and set a target action date of December 29, 2010. 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, 2010, the Company has reported accumulated net losses of $1.7 billion and cumulative negative cash flow from operations of $1.3 billion. It is costly to develop therapeutic products and conduct clinical trials for these products. At September 30, 2010 the Company s capital resources consisted of cash, cash equivalents, and marketable securities of $98.0 million and $98.0 million of available borrowings under the loan agreement with The Mann Group LLC (The Mann Group), an entity controlled by the Company s principal stockholder (see Note 12 Related-party arrangements, of the Notes to the accompanying financial statements). On August 18, 2010, the Company completed a Rule 144A offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 resulting in net proceeds of approximately $95.8 million. Based upon the Company s current expectations, management believes the Company s existing capital resources, excluding any potential proceeds to the Company from its common stock purchase agreement with Seaside 88, LP (see Note 9 Common and preferred stock, of the Notes to the accompanying financial statements), will enable it to continue planned operations into the third quarter of 2011. 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 or entering a business collaboration, the Company may 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.

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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 The Mann Group cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment. The senior convertible notes due 2013 had a carrying value of $113.2 million and $112.8 million as of September 30, 2010 and December 31, 2009, respectively. The senior convertible notes due 2013 had an estimated fair value of $77.6 million as of September 30, 2010, calculated based on quoted prices in an inactive market and an estimated fair value of $80.3 million as of December 31, 2009, calculated based on quoted prices in an active market. The senior convertible notes due 2015 had a carrying value of $95.9 million as of September 30, 2010 The senior convertible notes due 2015 had an estimated fair value of $98.6 million as of September 30, 2010, calculated based on quoted prices in an inactive market. 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 recorded an unrealized loss on the foreign exchange hedging contracts of $0.3 million at September 30, 2010 and $0.3 million at December 31, 2009.

Recently Issued Accounting Standards On April 29, 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-17, *Milestone Method of Revenue Recognition,* which establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, which requires an entity to record the milestone payment in its entirety in the period received if the milestone meets all the necessary criteria to be considered substantive. The scope of the ASU is limited to research and development arrangements. The ASU is effective for fiscal years beginning on or after June 15, 2010, and interim periods within those years. Early application is permitted. Adoption of this guidance is expected to have a significant effect on the accounting for certain future revenue arrangements (principally research and development partnership arrangements) should the Company enter into such arrangements.

2. Investment in securities

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

	September 30, 2010			December 31, 2009		
	Cost Basis	Gross Unrealized Loss	Fair Value	Cost Basis	Gross Unrealized Loss	Fair Value
Available-for-sale securities	$ 117	$	$ 117	$ 2,761	$ (286)	$ 2,475

The Company s available-for-sale securities at September 30, 2010 consist of a common stock investment, which is stated at fair value based on quoted prices in an active market (Level 1 in the fair value hierarchy). The Company s available-for-sale securities at December 31, 2009 consist principally of US agency securities, which are stated at fair value based on quoted prices for similar securities in active markets (Level 2 in the fair value hierarchy). The common stock investment was considered to be other than temporarily impaired as of September 30, 2010. As a result, the Company recognized realized losses of $0.6 million and reduced the cost basis to $0.1 million for its available-for-sale securities. In September 2010, the $2.0 million certificate of deposit pledged as collateral for foreign exchange hedging instruments at December 31, 2009 matured. Gross unrealized gains and losses are included in other comprehensive income (loss).

3. Accrued expenses and other current liabilities

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

	September 30, 2010	December 31, 2009
Salary and related expenses	$ 9,872	$ 13,362

Research and clinical trial costs		511		3,169
Accrued interest		4,712		2,065
Construction in progress		1,045		203
Other		3,053		3,535
Accrued expenses and other current liabilities	$	19,193	$	22,334

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, 2010 and 2009 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2010	**2009**	**2010**	**2009**
Stock-based compensation	$ 3,338	$ 5,090	$ 11,343	$ 17,979

As of September 30, 2010, there were $15.6 million and $20.4 million of unrecognized compensation costs related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 2.8 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, 2010 and 2009, comprehensive loss consisted of (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2010	**2009**	**2010**	**2009**
Net loss	$ (45,303)	$ (45,555)	$ (132,254)	$ (160,571)
Other comprehensive loss:				
Unrealized gain (loss) on investments		10	286	(407)
Cumulative translation gain (loss)	1	2	(5)	5
Comprehensive loss	$ (45,302)	$ (45,543)	$ (131,973)	$ (160,973)

Included in the unrealized gain (loss) on investments for the three and nine months ended September 30, 2010 is a realized loss of $0.3 million and $0.6 million, respectively, due to the other than temporary impairment of marketable securities.

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 9 Common and preferred stock). As of September 30, 2010, 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 9, 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 31,034,946 shares and 18,123,648 shares as of September 30, 2010 and 2009, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement.

7. 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, 2010, the estimated amount receivable under the program was $1.2 million.

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8. Property and equipment net

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

	Estimated Useful Life (Years)	September 30, 2010	December 31, 2009
Land		$ 5,273	$ 5,273
Buildings	39-40	54,966	54,966
Building improvements	5-40	113,513	113,188
Machinery and equipment	3-15	74,130	72,958
Furniture, fixtures and office equipment	5-10	5,369	5,312
Computer equipment and software	3	16,117	15,840
Leasehold improvements		172	172
Construction in progress		10,798	6,261
		280,338	273,970
Less accumulated depreciation and amortization		(78,103)	(65,741)
Property and equipment net		$ 202,235	$ 208,229

Leasehold improvements are amortized over 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, 2010 and 2009 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Depreciation and amortization expense	$ 4,102	$ 4,658	$ 12,444	$ 13,638

9. Common and preferred stock

The Company is authorized to issue 200,000,000 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, 2010 and December 31, 2009, 123,363,865 and 113,025,291 shares of common stock, respectively, were issued and outstanding. Included in the common stock outstanding as of September 30, 2010 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 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. No shares of preferred stock were issued and outstanding at September 30, 2010 or December 31, 2009.

On August 10, 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 be at least $6.50 per share. If the ten-day volume weighted average trading price for a particular closing is below $6.50 per share, then that closing will not occur and the aggregate number of shares to be purchased will be reduced by 700,000 shares. The purchase price per share at each closing will be equal to 92% of that 10-day volume weighted average price. The agreement with Seaside will terminate on the day following the final closing under the agreement, or the Company may terminate the Seaside agreement at any time upon written notice. As of September 30, 2010, no shares of common stock had been sold to Seaside under the agreement.

In conjunction with the Seaside agreement, on August 10, 2010, the Company entered into a common stock purchase agreement with The Mann Group. Under this common stock purchase agreement, the Company is required to issue and sell, and The Mann Group is 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 purchases on each closing date under its agreement with the Company (see Note 12 Related-party arrangements, of the Notes to the accompanying financial statements).

10. Warrants

In connection with the sale of common stock in the private placement which closed in August 2005, the Company concurrently issued warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share. These warrants became exercisable in February 2006 and expired on August 5, 2010. During the nine months ended September 30, 2010, no warrants were exercised.

11. Commitments and contingencies

Supply Commitments As of September 30, 2010, the Company had a binding annual commitment for insulin purchases with N.V. Organon (now part of Merck & Co., Inc.) (Organon) aggregating approximately $83.0 million over the period from 2010 through 2012. If the Company terminates the supply agreement following failure to obtain or maintain regulatory approval of AFREZZA or either party terminates the agreement following the parties inability to agree to changes to product specifications mandated after regulatory approval, the Company will be required to pay Organon a specified termination fee if Organon is unable to sell certain quantities of insulin to other parties.

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 On September 16, 2010, John Arditi, the Company s former Senior Director GCP Regulatory Affairs, filed a lawsuit in the Law Division of the Superior Court of New Jersey (Bergen County), against the Company and its Chief Scientific Officer and its Vice President World Wide Regulatory Affairs. In the lawsuit, *Arditi v. MannKind Corporation*, Docket No. BER-L-8783-10, Mr. Arditi alleges 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 and intentional infliction of emotional distress. Mr. Arditi is seeking, among other relief, compensatory and punitive damages and counsel fees, costs and interest. The Company s deadline to respond to the complaint is December 3, 2010. Before Mr. Arditi filed his complaint, the Company had completed an internal investigation of his claims and retained an independent outside firm to conduct an independent investigation of his claims. Neither investigation found any basis for his claims. The Company believes that the allegations in the complaint are without merit and intends to defend against them vigorously.

From time to time, the Company becomes involved in various legal proceedings and other matters. In accordance with general accounting guidance for recording contingencies, the Company records a provision for a liability related to a legal proceeding when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company does not believe that any liability from any reasonably foreseeable disposition of such claims and litigation, individually or in the aggregate, would have a material adverse effect on its consolidated financial position or results of operations.

12. Related-party arrangements

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. On February 26, 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. On August 10, 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 $252.0 million and $165.0 million at September 30, 2010 and December 31, 2009, respectively. As of September 30, 2010, the Company had accrued interest of $2.9 million related to the amount outstanding and had $98.0 million of available borrowings under the loan arrangement.

On August 10, 2010, the Company entered into a common stock purchase agreement with The Mann Group. Under this common stock purchase agreement, the Company is required to issue and sell, and The Mann Group is obligated to purchase, the same number of shares of the Company s common stock that Seaside purchases on each closing date under its agreement with the Company. The price of the shares that the Company sells to The Mann Group under the agreement will be 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 issues and sells to The Mann Group will be paid by cancelling an equal amount of the outstanding principal under the $350.0 million loan arrangement provided by The Mann Group. To the extent that the outstanding principal amount owed under the loan arrangement is insufficient to pay the full purchase price for the shares of common stock to be acquired, The Mann Group will be obligated to pay cash for the balance of the shares of common stock it is obligated to purchase under the common stock purchase agreement. The common stock purchase agreement with The Mann Group will terminate on the day following the final closing under the Company s common stock purchase agreement with Seaside or upon termination of the Seaside agreement.

13. Senior convertible notes

	September 30, 2010	December 31, 2009
Notes due 2013		
Principal amount	$ 115,000	$ 115,000
Unamortized debt issuance expense	(1,835)	(2,235)
Net carrying amount	113,165	112,765
Notes due 2015		
Principal amount	$ 100,000	$
Unamortized debt issuance expense	(4,142)	
Net carrying amount	95,858	
Senior convertible notes	$ 209,023	$ 112,765

On August 18, 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 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, 2010, the Company had accrued interest of $0.4 million related to the Notes due 2015. The Notes due 2015 are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company s secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other liabilities of the Company s subsidiaries. The maturity date of the Notes due 2015 is August 15, 2015 and payment is due in full on that date for unconverted securities. Holders of the Notes due 2015 may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any 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

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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, 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 at a repurchase price of 100% of the principal amount of the Notes 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 2013 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. 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.

On December 12, 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 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, 2010 and December 31, 2009, the Company had accrued interest of $1.5 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. 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 Notes offerings during the three and nine months ended September 30, 2010 and 2009 was as follows (in thousands):

	Three months ended September 30,		**Nine months ended September 30,**	
	2010	**2009**	**2010**	**2009**
Amortization expense	$ 207	$ 129	$ 472	$ 382

14. Income taxes

As discussed in Note 14 to the financial statements in the Company s Annual Report, management of the Company has concluded, in accordance with applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, 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.

15. Subsequent events

On October 20, 2010, the Company issued and sold 700,000 shares of common stock to Seaside for net proceeds of $4.3 million in accordance with the Company s common stock purchase agreement with Seaside. Concurrently with the Seaside closing, the Company issued and sold 700,000 shares to The Mann Group for a total purchase price of $5.0 million, which was paid by the cancellation of outstanding principal under the Company s loan agreement with The Mann Group. As of October 20, 2010, the principal amount remaining under the loan agreement was $247.0 million, and the Company had $98.0 million of available borrowings under the loan arrangement.

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

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this quarterly report on Form 10-Q. These interim condensed consolidated financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes for the year ended December 31, 2009 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 has completed Phase 3 clinical trials that evaluated its safety and efficacy in the treatment of diabetes. In March 2009, we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, requesting approval of AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, we received a Complete Response letter regarding this NDA from the FDA, seeking additional information about AFREZZA. In July 2010, the FDA accepted our reply to the Complete Response letter and set a target action date of December 29, 2010. Our focus until then will be to work closely with the FDA as it evaluates our next-generation delivery system and the other information that we provided in our resubmission. We will also initiate the validation of equipment recently installed in our Danbury, Connecticut manufacturing facility for filling the cartridges used in our next-generation inhaler. We expect that these activities will continue into the third quarter of 2011.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2010, we have incurred a cumulative net loss of $1.7 billion and a stockholders deficit of $181.4 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity and convertible debt securities and borrowings under a related party loan. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding in the future, there would be substantial doubt about our ability to continue as a going concern.

We have held discussions with a number of pharmaceutical companies concerning potential strategic business collaborations for AFREZZA as well as our cancer immunotherapy and cancer drug programs. 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. There can be no assurance that we will obtain approval of AFREZZA by the FDA s target date or that we will complete the installation and validation of equipment in our manufacturing facility on our anticipated timeline. 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 delivery systems for the treatment of diabetes;
- seek regulatory approval to sell AFREZZA in the United States and other markets;
- seek sales and marketing collaborations for AFREZZA;
- seek development collaborations for our cancer immunotherapy and cancer drug programs; and

develop additional applications of our proprietary Technosphere platform technology for the pulmonary delivery of other drugs.

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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, 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.

Recent Developments

On August 10, 2010, we entered into an agreement with Seaside 88, LP, or Seaside, for the sale of up to 18,200,000 shares of our common stock in increments of 700,000 on a bi-weekly basis with the first closing date scheduled for September 22, 2010 provided that certain conditions are met, including that the volume weighted average price of the common stock for the ten days immediately prior to the closing date be equal to or greater than $6.50. The purchase price per share at each closing will be equal to 92% of that 10-day volume weighted average price. The agreement with Seaside will terminate on the day following the final closing under the agreement, or we may terminate the Seaside agreement at any time upon written notice. On August 10, 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, if any, invested by Seaside under its agreement with us. On October 20, 2010, we issued and sold the first tranche of 700,000 shares of common stock to Seaside for net proceeds of $4.3 million under the agreement.

On August 10, 2010, we also entered into a common stock purchase agreement with The Mann Group LLC, or The Mann Group, an entity controlled by our chief executive officer and principal stockholder. Under this common stock purchase agreement, we are required to issue and sell, and The Mann Group is obligated to purchase, the same number of shares of our common stock that Seaside purchases on each closing date under its agreement with us. The price of the shares that we sell to The Mann Group under the agreement will be 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 issue and sell to The Mann Group will be paid by cancelling an equal amount of the outstanding principal under a $350.0 million revolving loan arrangement provided by The Mann Group. At September 30, 2010, the principal amount outstanding under the loan arrangement was $252.0 million, and we had $98.0 million of available borrowings under the arrangement. To the extent that the outstanding principal amount owed under the loan arrangement is insufficient to pay the full purchase price for the shares of common stock to be acquired, The Mann Group will be obligated to pay cash for the balance of the shares of common stock it is obligated to purchase under the common stock purchase agreement. The common stock purchase agreement with The Mann Group will terminate on the day following the final closing under our agreement with Seaside or upon termination of the Seaside agreement. Concurrently with the sale of shares to Seaside on October 20, 2010, we issued and sold the first tranche of 700,000 shares to The Mann Group under the agreement for a total purchase price of $5.0 million, which was paid by the cancellation of outstanding principal under the loan arrangement.

On August 10, 2010, we also 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, to provide for the cancellation of indebtedness under the note as described above, to provide that The Mann Group may require us to prepay the note in an amount not to exceed $200 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 our 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.

On August 18, 2010, we entered into a purchase agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated, or Merrill Lynch, acting as representative of the several initial purchasers named in the agreement, and completed a Rule 144A offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015. The net proceeds to us from the sale of the notes were approximately $95.8 million, after deducting the discount to the initial purchasers of $3.3 million and the offering expenses paid by us. We intend to use the net proceeds from the sale of the notes to fund the costs of our clinical trials programs and other research and development activities, to expand our manufacturing operations, both on-going and planned, and for general corporate purposes, including working capital.

In connection with the offering of the notes, on August 18, 2010, we entered into a share lending agreement with Bank of America, N.A., an affiliate of Merrill Lynch, pursuant to which we lent 9,000,000 shares of our common stock to Bank of America, which is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to us 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.

Also on August 18, 2010, we entered into an underwriting agreement with Merrill Lynch and Bank of America, pursuant to which the borrowed shares were offered and sold to the public at a fixed price of $5.55 per share. We did not receive any proceeds from the sale of the borrowed shares to the public, but received a lending fee of $90,000 pursuant to the share lending agreement for the use by

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Bank of America of the borrowed shares. Bank of America received all of the net proceeds from the sale of the borrowed shares to the public.

On October 19, 2010, we announced the initiation of a Phase 2 clinical study of one of our investigational cancer therapy product candidates, MKC1106-MT, in patients with advanced melanoma.

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 quarter ended September 30, 2010 were purchases of insulin totaling $7.9 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 the majority of 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 manufacturing process and discussions with the FDA regarding its requirements.

GENERAL AND ADMINISTRATIVE EXPENSES

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

CRITICAL ACCOUNTING POLICIES

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

RESULTS OF OPERATIONS

Three and nine months ended September 30, 2010 and 2009

Revenues

During the three months ended September 30, 2010 we did not recognize any revenue, and during the nine months ended September 30, 2010 we recognized revenue of $93,000 under a license agreement. We did not recognize any revenue during the same periods in 2009. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFREZZA.

Research and Development Expenses

The following tables provide a comparison of the research and development expense categories for the three and nine months ended September 30, 2010 and 2009 (dollars in thousands):

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	Three months ended September 30,			
	2010	2009	$ Change	% Change
Clinical	$ 5,150	$ 8,467	$ (3,317)	(39%)
Manufacturing	20,723	15,907	4,816	30%
Research	3,384	3,791	(407)	(11%)
Research and development tax credit	196	(754)	950	(126%)
Stock-based compensation expense	1,958	3,083	(1,125)	(36%)
Research and development expenses	$ 31,411	$ 30,494	$ 917	3%

	Nine months ended September 30,			
	2010	2009	$ Change	% Change
Clinical	$ 18,976	$ 35,843	$ (16,867)	(47%)
Manufacturing	51,558	53,262	(1,704)	(3%)
Research	11,019	14,073	(3,054)	(22%)
Research and development tax credit	(238)	(1,104)	866	(78%)
Stock-based compensation expense	6,747	11,158	(4,411)	(40%)
Research and development expenses	$ 88,062	$ 113,232	$ (25,170)	(22%)

The increase in research and development expenses for the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, was primarily due to increased raw material purchases in the third quarter of 2010 offset by decreased costs associated with the clinical development of AFREZZA. The decrease in research and development expenses for the nine months ended September 30, 2010 compared to the same period in 2009 was primarily due to decreased costs associated with the clinical development of AFREZZA, reduced salary-related and other research costs as a result of a reduction in force that we implemented in April 2009 and decreased stock-based compensation expense as certain restricted stock units vested in the second quarter of 2009, which did not recur in 2010. We anticipate that our research and development expenses will decrease slightly in 2010 compared to the prior year as reduced product development costs will be mostly offset by increased raw material purchases as we prepare for commercialization of AFREZZA.

General and Administrative Expenses

The following tables provide a comparison of the general and administrative expense categories for the three and nine months ended September 30, 2010 and 2009 (dollars in thousands):

	Three months ended September 30,			
	2010	2009	$ Change	% Change
Salaries, employee related and other general expenses	$ 9,750	$ 10,266	$ (516)	(5%)
Stock-based compensation expense	1,379	2,007	(628)	(31%)
General and administrative expenses	$ 11,129	$ 12,273	$ (1,144)	(9%)

	Nine months ended September 30,			
	2010	2009	$ Change	% Change
Salaries, employee related and other general expenses	$ 27,841	$ 33,906	$ (6,065)	(18%)
Stock-based compensation expense	4,595	6,821	(2,226)	(33%)
General and administrative expenses	$ 32,436	$ 40,727	$ (8,291)	(20%)

General and administrative expenses for the three and nine months ended September 30, 2010 decreased as compared to the same periods in the prior year primarily due to decreased salary related costs resulting from the April 2009 reduction in force as well as the non-recurrence of costs related to the Pfizer transaction during the first half of 2009 and decreased professional fees related to market studies conducted in 2009. Additionally, stock-based compensation expense decreased as certain restricted stock units vested in the second quarter of 2009 and did not recur in 2010. Overall, we expect general and administrative expenses to decrease in 2010 as a result of the April 2009 reduction in force and decreased professional fees.

Interest Income and Expense

Interest income for the three months ended September 30, 2010 increased by $7,000 as compared to the same period in the prior year, while interest income for the nine months ended September 30, 2010 decreased by $45,000 as compared to the same period in the prior year.

Interest expense for the three and nine months ended September 30, 2010 increased by $1.8 million and $4.6 million, respectively, as compared to the same period in the prior year primarily due to increased interest expense related to the greater amounts outstanding under the borrowing arrangement with The Mann Group and the issuance of the senior convertible notes outstanding due 2015 in August 2010.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity and convertible debt securities and borrowings under a 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. 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. On August 10, 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 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. There are no warrants associated with the loan arrangement. As of September 30, 2010, the amount borrowed and outstanding under the arrangement was $252.0 million.

On August 10, 2010, Seaside and we entered into a common stock purchase agreement, or the Seaside purchase agreement. The Seaside purchase agreement requires us to issue and sell, and Seaside to buy, up to 700,000 shares of our common stock 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 sell to Seaside will be 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 be at least $6.50 per share. If the ten-day volume weighted average trading price for a particular closing is below $6.50 per share, then that closing will not occur and the aggregate number of shares to be purchased will be reduced by 700,000 shares. Seaside also has 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 has agreed not to engage in short sales of our common stock during the term of the Seaside purchase agreement and agreed that it will not sell more than 10% of the total number of shares of common stock traded on any trading day. On August 10, 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, if any, invested by Seaside under the Seaside purchase agreement. As of September 30, 2010, no shares had been sold to Seaside under the Seaside purchase agreement. On October 20, 2010, we issued and sold 700,000 shares of common stock to Seaside for net proceeds of $4.3 million under the agreement.

In conjunction with the Seaside agreement, on August 10, 2010, The Mann Group and we entered into a common stock purchase agreement, or the Mann purchase agreement. Under the Mann purchase agreement, we are required to issue and sell, and The Mann Group is obligated to purchase, the same number of shares of our common stock that Seaside purchases on each closing date under the Seaside purchase agreement. The price of the shares that we issue and sell to The Mann Group will be 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 issue and sell to The Mann Group will be paid by cancelling an equal amount of the outstanding principal under the $350.0 million revolving loan arrangement provided by The Mann Group. At September 30, 2010, the principal amount outstanding under the loan arrangement was $252.0 million, and we had $98.0 million of available borrowings under the arrangement. To the extent that the outstanding principal amount owed under the loan arrangement is insufficient to pay the full purchase price for the shares of common stock to be acquired, The Mann Group will be obligated to pay cash for the balance of the shares of common stock it is obligated to purchase under the Mann purchase agreement. The Mann purchase agreement will terminate on the day following the final closing under the Seaside purchase agreement or upon termination of the Seaside purchase agreement. As of September 30, 2010, no shares had been issued to

The Mann Group under the Mann purchase agreement. Concurrently with the sale of shares to Seaside on October 20, 2010, we issued and sold 700,000 shares to The Mann Group for a total purchase price of $5.0 million, which was paid by the cancellation of outstanding principal under the loan arrangement.

On August 18, 2010, we completed a Rule 144A offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015. The net proceeds to us from the sale of the notes were approximately $95.8 million, after deducting the discount to the initial purchasers of $3.3 million and the offering expenses paid by us. We intend to use the net proceeds from the sale of the notes to fund the costs of our clinical trials programs and other research and development activities, to expand our manufacturing operations, both on-going and planned, and for general corporate purposes, including working capital.

In connection with the offering of the notes, on August 18, 2010, we entered into a share lending agreement with Bank of America, pursuant to which we lent 9,000,000 shares of our common stock to Bank of America, which is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to us 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.

Also on August 18, 2010, we entered into an underwriting agreement with Merrill Lynch and Bank of America, pursuant to which the borrowed shares were offered and sold to the public at a fixed price of $5.55 per share. We did not receive any proceeds from the sale of the borrowed shares to the public, but received a lending fee of $90,000 pursuant to the share lending agreement for the use by Bank of America of the borrowed shares. Bank of America received all of the net proceeds from the sale of the borrowed shares to the public.

During the nine months ended September 30, 2010, we used $109.7 million of cash for our operations compared to using $146.7 million for our operations in the nine months ended September 30, 2009. We had a net loss of $132.3 million for the nine months ended September 30, 2010, of which $24.3 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

We used $3.6 million of cash for investing activities during the nine months ended September 30, 2010, compared to using $0.9 million of cash for investing activities for the nine months ended September 30, 2009. For the nine months ended September 30, 2010 and 2009, $5.6 million and $16.7 million, respectively, were used to purchase machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFREZZA.

Our financing activities generated $181.2 million of cash for the nine months ended September 30, 2010, compared to $173.9 million for the same period in 2009. For the nine months ended September 30, 2010, cash from financing activities was primarily from the offering of 5.75% Senior Convertible Notes due 2015 and related party borrowings, as well as the exercise of stock options.

As of September 30, 2010, we had $98.0 million in cash, cash equivalents, and marketable securities. Although we believe our existing cash resources, including the $98.0 million remaining available under our loan arrangement with The Mann Group but excluding any proceeds to us from the Seaside purchase agreement, will be sufficient to fund our anticipated cash requirements into the third quarter of 2011, we will require significant additional financing in the future to fund our operations and if we are unable to do so, there would be substantial doubt about our ability to continue as a going concern. Accordingly, we expect that we will need to raise additional funds, either through the sale of equity and/or debt securities, the entry into a strategic business collaboration with a pharmaceutical or biotechnology company or the establishment of other funding facilities, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. However, we cannot provide assurances that we will be able to continue to raise funds on favorable terms, if at all. As of September 30, 2010, we had a stockholders deficit of $181.4 million which may raise concerns about our solvency and affect our ability to raise additional funds. Also, we have reserved substantially all of our authorized but unissued shares of common stock for future issuance pursuant to outstanding equity awards, our equity plans, our convertible notes, the Seaside purchase agreement and the Mann purchase agreement. As a result, our ability to issue shares of common stock, or debt securities convertible into shares of common stock, other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

We intend to use our capital resources to continue the development and commercialization of AFREZZA, if approved, and to develop additional applications for our proprietary Technosphere platform technology. In addition, portions of our capital resources will be devoted to expanding our other product development programs for the treatment of different types of cancers. We are expending a portion of our capital to scale up our manufacturing capabilities in our Danbury facilities. We also intend to use our capital resources for general corporate purposes, which may include in-licensing or acquiring additional technologies.

We have 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.

We also may seek to raise additional funds by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets. 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 funds, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

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 we are not successful in raising additional funds, 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, 2010 we did not have any off-balance sheet arrangements.

Contractual Obligations

The only material change to our contractual obligations disclosed in Item 7 of our Annual Report was the additional borrowing of $87.0 million from The Mann Group during the nine months ended September 30, 2010. (See Note 12 Related-party arrangements of the Notes to the accompanying financial statements.)

On August 18, 2010, we sold $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 in a Rule 144A offering. Interest is payable in cash semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2011. The maturity date of these notes is August 15, 2015 and payment is due in full on that date for unconverted securities.

Recent Accounting Pronouncements

On April 29, 2010, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, No. 2010-17, *Milestone Method of Revenue Recognition,* which establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, which requires an entity to record the milestone payment in its entirety in the period received if the milestone meets all the necessary criteria to be considered substantive. The scope of the ASU is limited to research and development arrangements. The ASU is effective for fiscal years beginning on or after June 15, 2010, and interim periods within those years. Early application is permitted. Adoption of this guidance is expected to have a significant effect on how certain future revenue arrangements are reflected in the 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 investment at September 30, 2010 is a common stock investment. We have entered into a foreign exchange hedging transaction as part of our risk management program. We continue to utilize our $350.0 million credit facility to fund operations. As of September 30, 2010, the amount borrowed and outstanding under the credit facility was $252.0 million. The interest rate is fixed at the time of the draw. If interest rates were to increase from levels at September 30, 2010 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, 2010. 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, 2010 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 September 16, 2010, John Arditi, our former Senior Director GCP Regulatory Affairs, filed a lawsuit in the Law Division of the Superior Court of New Jersey (Bergen County), against us and our Chief Scientific Officer and our Vice President World Wide Regulatory Affairs. In the lawsuit, *Arditi v. MannKind Corporation*, Docket No. BER-L-8783-10, Mr. Arditi alleges 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 and intentional infliction of emotional distress. Mr. Arditi is seeking, among other relief, compensatory and punitive damages and counsel fees, costs and interest. Our deadline to respond to the complaint is December 3, 2010. Before Mr. Arditi filed his complaint, we had completed an internal investigation and retained an independent outside firm to conduct an extensive external investigation of Mr. Arditi s claims. Neither investigation found any basis for his claims. We believe the allegations in the complaint are without merit and we intend to defend against them vigorously.

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, and our other product candidates, which are in early clinical or preclinical development.*

To date, we have not commercialized any product candidates. In March 2009, we submitted an NDA to the FDA requesting approval of AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, we received a Complete Response letter regarding this NDA from the FDA. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form. In July 2010, the FDA accepted our reply to the Complete Response letter and set a target action date of December 29, 2010. There can be no assurance that the FDA will find our proposed approach for addressing its questions acceptable. The FDA could also 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.

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.

We have expended significant time, money and effort in the development of AFREZZA, which has not yet received regulatory approval and which may not be approved by the FDA 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 are seeking to develop and expand our portfolio of product candidates through our internal research programs and through licensing or otherwise acquiring the rights to therapeutics in the areas of cancer and other indications. All of these product candidates will require additional research and development and 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 are conducting involves new and unproven compounds and technologies, including AFREZZA, Technosphere platform technology and immunotherapy product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. 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 become profitable.*

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 and, as of September 30, 2010, we had incurred a cumulative net loss of $1.7 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, 2010, we had a stockholders deficit of $181.4 million. Our ability to achieve and sustain 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 be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will become profitable, if at all.

If we fail to raise additional capital our financial condition and business would suffer.*

It is costly to develop therapeutic product candidates and conduct clinical trials for these product candidates. Although we are currently focusing on AFREZZA as our lead product candidate, we have begun to conduct clinical trials for additional product candidates. Our existing capital resources will not be sufficient to support the expense of fully commercializing AFREZZA or completely developing any of our product candidates.

Based upon our current expectations, we believe that our existing capital resources, including the loan arrangement with The Mann Group but excluding any proceeds to us from the Seaside purchase agreement, will enable us to continue planned operations into the third quarter of 2011. 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. Accordingly, we may raise additional funds through the sale of equity or debt securities, the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements and/or asset sales, 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 the sale of equity or debt securities. As of September 30, 2010, we had a stockholders deficit of $181.4 million which may raise concerns about our solvency and affect our ability to raise additional funds. Also, we have reserved substantially all of our authorized but unissued shares of common stock for future issuance pursuant to outstanding equity awards, our equity plans, our convertible notes, the Seaside purchase agreement and the Mann purchase agreement. As a result, our ability to issue shares of common stock, or debt securities convertible into shares of common stock, other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

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 expanding our own 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 costs of discontinuing projects and technologies or decommissioning existing facilities, if we undertake those activities; and

the costs of performing additional clinical trials to demonstrate safety and efficacy if our current trials do not deliver results sufficient for FDA approval and commercialization.

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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. For example, on August 10, 2010, we entered into the Seaside purchase agreement and the Mann purchase agreement for the sale and issuance by us of up to 36,400,000 shares of our common stock over a period of approximately 50 weeks. 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 strategic collaboration opportunities, sales of securities, credit facilities, licensing arrangements and/or asset sales on a timely basis, we may 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 would 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.

Deteriorating global economic conditions may have an adverse impact on the loan facility with The Mann Group, which we currently cannot predict.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing 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 the loan facility with The Mann Group. If we are unable to draw on this financial resource, our business and financial condition will 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 materials and 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;

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- 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 may be required to reduce expenses by delaying, reducing or curtailing our development of AFREZZA or other product development activities, which would impact our ability to meet milestones. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development goals in the timeframes we announce and expect (or within the timeframes expected by analysts or investors), our business and results of operations will be harmed and the market price of our common stock may decline.

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

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

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

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

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

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

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. To date we have not reached an agreement with any of these companies on a collaboration. 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 obtained in our nonclinical and initial clinical testing may be inconclusive or may not be predictive of results obtained in later-stage clinical trials or following long-term use, and we may as a result be forced to stop developing product candidates that we currently believe are important to our future;

- the data collected from clinical trials of our product candidates may not 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 have a long-term agreement with N.V. Organon for the supply of insulin. In June 2009, we purchased from Pfizer, a portion of its inventory of bulk insulin and acquired an option to purchase the remainder of Pfizer s insulin inventory, in whole or in part, at a specified price to the extent that Pfizer has not otherwise disposed of or used the retained insulin.

We obtain FDKP, the precursor raw material for AFREZZA, from a major multinational chemical manufacturer. We have completed a successful validation campaign of FDKP at commercial scale. We can also utilize our in-house chemical manufacturing plant for supplemental capacity. We believe our contract manufacturer has the capacity to supply our current and future commercial requirements. We obtain our intended commercial AFREZZA inhaler and cartridges from a plastic molding company located in the United States.

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 facility to formulate AFREZZA, fill plastic cartridges with AFREZZA, blister package the cartridges, place the blister packs into foil bags and package three bags plus two inhalers and the package insert as units in 90-unit boxes (and single bag packs for trials). There can be no assurance that the equipment in this facility will be qualified by the FDA or that the equipment will not need modification in order to be validated and/or approved by the FDA. The facility was designed for a different cartridge that had undergone inspection and been fully qualified by the FDA. A new fill/finish system for the new commercial AFREZZA cartridge has been installed and is undergoing qualification. 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.

Additionally, when we manufacture commercial material on a significantly larger production scale than the production scale for clinical trial materials, we are required by the FDA to establish that the results obtained from the clinical trials may reasonably be extrapolated to such commercial material. We have submitted documentation to the FDA to show correlation to the clinical-scale production materials but can provide no assurance that approval will be obtained. 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.

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, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. Even though we believe we carry commercially reasonable liability insurance and stage-appropriate business interruption insurance, and our contractors may carry liability insurance that protect us in certain events, 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.*

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Our research and development work involves the controlled storage and use of hazardous materials, including chemical, radioactive and biological materials. In addition, our manufacturing operations involve the use of a chemical that is stable and non-hazardous under normal storage conditions, but 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 governing how we use, manufacture, store, handle and dispose of these materials. 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 million per occurrence and $2 million in the aggregate and is supplemented by an umbrella policy that provides a further $4 million of coverage; however, our insurance policy excludes pollution 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.

When we purchased the facilities located in Danbury, Connecticut in 2001, there was a soil cleanup plan in process. As part of the purchase, we obtained an indemnification from the seller related to the remediation of the soil 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. 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 are limited to the purchase price that we paid for the Danbury facilities.

During the construction of our expanded manufacturing facility, we completed the final stages of the soil cleanup plan in the third quarter of 2008, at a cost of approximately $2.25 million. We have reached an agreement with the party responsible for their contribution to past clean-up costs and were reimbursed $1.625 million in July 2010. The responsible party has agreed to pay for or indemnify us for any future costs and expenses 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, we plan 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 competitor s 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;

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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 potential for profitability 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 million. We believe these limits are reasonable to cover us from potential damages arising from current and previous clinical trials of AFREZZA. 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.

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

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

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

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

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

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

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and 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.

In March 2009, we submitted an NDA for AFREZZA. The FDA has advised us that it will regulate 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 AFREZZA inhaler used to administer the insulin). The FDA s 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.

In March 2010, we received a Complete Response letter regarding this NDA from the FDA. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form. In July 2010, the FDA accepted our reply to the Complete Response letter and set a target action date of December 29, 2010. There can be no assurance that the FDA will find our proposed approach for addressing its questions acceptable. The FDA could also 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.

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.

We are developing AFREZZA as a new treatment for diabetes utilizing unique, proprietary components. As a combination product, any changes to either the AFREZZA inhaler, or AFREZZA, including new suppliers, could possibly result in FDA requirements to repeat certain studies. For example, we plan to launch AFREZZA with our next-generation inhaler rather than the device that was used in pivotal clinical studies, and in our July 2010 reply to the FDA s Complete Response letter, we submitted information on the comparability of our next-generation inhaler to the device that was used in pivotal clinical studies. As a result of our change to our next-generation inhaler, the FDA could yet require us to undertake additional clinical trials and other studies, which could significantly delay the development and commercialization of AFREZZA. Our product candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.

We also must obtain final approval from the FDA for the trade name of our product. In September 2009, we proposed AFREZZA as a trade name, which the FDA found conditionally acceptable in December 2009.

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 until 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. Based on currently available clinical studies, we believe that AFREZZA may have certain advantages over currently approved insulin products including its approximation of the natural early insulin secretion normally seen in healthy individuals following the beginning of a meal. Nonetheless, there are no assurances that these or any other 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.

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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 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 insulin supplier does not yet supply human recombinant insulin for an FDA-approved product.*

Our insulin supplier for purposes of the AFREZZA NDA sells its product outside of the United States. The FDA has inspected this supplier and found it to be acceptable. If we were required to find a new or additional supplier of insulin, we would be required to evaluate the new supplier s ability to provide insulin that meets 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 device 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 or difficulties in obtaining approval of AFREZZA. 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.

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 U.S. Patent and Trademark Office 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.

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

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 an 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 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. Although we intend to defend any opposition to our trademark registrations, 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;
- the issuance and sale of our common stock pursuant to the Seaside purchase agreement and the Mann purchase agreement over the terms of these agreements;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- 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 recently-completed 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, statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym may be difficult to verify 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, 2010, Mr. Mann beneficially owned approximately 38.9% 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 and lockup restrictions in connection with the recently-completed sale of our 5.75% convertible notes due 2015, 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, 2010, we had 123,363,865 shares of common stock outstanding including the 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement. 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.

On August 10, 2010, we entered into the Seaside purchase agreement and the Mann purchase agreement, which together provide for the sale and issuance by us of up to 36,400,000 shares of our common stock over a period of approximately 50 weeks; as of

September 30, 2010, we had not sold any shares to Seaside or The Mann Group pursuant to these agreements. However, on October 20, 2010, we issued and sold a total of 1,400,000 shares under these agreements. The future issuance of shares of our common stock pursuant to these two agreements, or the expectation that these issuances will occur, may further depress the price of 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.

We have reserved for future issuance substantially all of our authorized but unissued shares of common stock, which may impair our ability to conduct future financing and other transactions.*

Our certificate of incorporation currently authorizes us to issue up to 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2010, we had a total of 76,636,135 shares of common stock that were authorized but unissued. We have reserved substantially all of our authorized but unissued shares for future issuance pursuant to outstanding equity awards, our equity plans, our 3.75% senior convertible notes due 2013, our 5.75% senior convertible notes due 2015 and the Seaside purchase agreement and Mann purchase agreement. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

If we are unable to enter into new arrangements to issue shares of our common stock or securities convertible or exercisable into shares of our common stock, our ability to complete equity-based financings or other transactions that involve the potential issuance of our common stock or securities convertible or exercisable into our common stock, will be limited. In lieu of issuing common stock or securities convertible into our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which may require us to grant security interests in our assets and property and/or impose covenants upon us that restrict our business. If we are unable to issue additional shares of common stock or securities convertible or exercisable into our common stock, our ability to enter into strategic transactions such as acquisitions of companies or technologies, may also be limited. If we propose to amend our certificate of incorporation to increase our authorized shares of common stock, such a proposal would require the approval by the holders of a majority of our outstanding shares of common stock, and we cannot assure you that such a proposal would be adopted. If we are unable to complete financing, strategic or other transactions due to our inability to issue additional shares of common stock or securities convertible or exercisable into our common stock, our financial condition and business prospects may be materially harmed.

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

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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

There were no sales of equity securities by us that were not registered under the Securities Act of 1933, as amended, during the third quarter of 2010.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. (REMOVED AND RESERVED)

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	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)	Amended and Restated Bylaws.
4.1(5)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated November 1, 2006.
4.2(6)	First Supplemental Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated December 12, 2006.
4.3(6)	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(7)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010.
4.7(7)	Form of 5.75% Senior Convertible Note due 2015.
10.1(7)	Purchase Agreement, by and between MannKind and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representative for the initial purchasers named therein, dated August 18, 2010.
10.2(7)	Share Lending Agreement, by and between MannKind and Bank of America, N.A., dated August 18, 2010.
10.3(7)	Letter Agreement, dated August 18, 2010, related to Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated August 10, 2010.
10.4(8)	Common Stock Purchase Agreement, by and between MannKind and Seaside 88, LP, dated August 10, 2010.
10.5(8)	Letter Agreement, by and between MannKind and Omni Capital Corporation, dated August 10, 2010.
10.6(8)	Common Stock Purchase Agreement by and between MannKind and The Mann Group LLC, dated August 10, 2010.
10.7(8)	Amended and Restated Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 10, 2010.
31.1	

	Certification of the Chief Executive Officer Pursuant to Rules 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 Rules 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 Rules 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).

(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.

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(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 current report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007.

(5) Incorporated by reference to MannKind s registration statement on Form S-3 (File No. 333-138373), filed with the SEC on November 2, 2006.

(6) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on December 12, 2006.

(7) Incorporated by reference to MannKind s

current report on Form 8-K (File No. 000-50865), filed with the SEC on August 24, 2010.

(8) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on August 11, 2010.

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SIGNATURE

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

Dated: October 29, 2010	MANNKIND CORPORATION
	By: /s/ Matthew J. Pfeffer
	Matthew J. Pfeffer
	Corporate Vice President and Chief Financial Officer
	(Principal Financial and Accounting Officer)

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