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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2006

or

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

For the transition period from ___to ___.

Commission File Number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

(661) 775-5300
(Registrant's telephone number, including area code)

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

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

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

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

As of October 31, 2006, there were 49,959,888 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, 2006

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PART I: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
(In thousands except share data)

	September 30, 2006 (unaudited)	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 43,086	$ 56,037
Marketable securities	7,007	89,597
State research and development credit exchange receivable — current	918	1,194
Prepaid expenses and other current assets	11,702	3,044
Total current assets	62,713	149,872
Property and equipment — net	84,005	76,183
State research and development credit exchange receivable — net of current portion	2,625	2,031
Other assets	359	285
Total	$ 149,702	$ 228,371
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,673	$ 3,547
Note payable to principal stockholder	50,000	—
Accrued expenses and other current liabilities	31,034	17,818
Total current liabilities	87,707	21,365
Other liabilities	24	29
Total liabilities	87,731	21,394
Commitments and contingencies		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2006 and December 31, 2005	—	—
Common stock, $0.01 par value — 90,000,000 shares authorized; 49,895,691 and 50,314,108 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	499	503
Additional paid-in capital	778,053	763,775
Deficit accumulated during the development stage	(716,581)	(557,301)
Total stockholders' equity	61,971	206,977
Total	$ 149,702	$ 228,371

The accompanying notes are an integral part of these consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

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

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30,
	2006	2005	2006	2005	2006
Revenue	$ —	$ —	$ 100	$ —	$ 2,958
Operating expenses:					
Research and development	50,785	24,466	132,056	66,758	430,456
General and administrative	10,349	8,396	29,943	16,318	127,918
In-process research and development costs	—	—	—	—	19,726
Goodwill impairment	—	—	—	—	151,428
Total operating expenses	61,134	32,862	161,999	83,076	729,528
Loss from operations	(61,134)	(32,862)	(161,899)	(83,076)	(726,570)
Other income (expense)	51	(29)	160	(8)	(1,732)
Interest expense on note payable to principal stockholder	(689)	—	(689)	—	(689)
Interest income	802	1,161	3,153	2,038	12,431
Loss before provision for income taxes	(60,970)	(31,730)	(159,275)	(81,046)	(716,560)
Income taxes		—	(5)	(1)	(21)
Net loss	(60,970)	(31,730)	(159,280)	(81,047)	(716,581)
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	$(60,970)	$(31,730)	$(159,280)	$(81,047)	$ (739,793)
Net loss per share applicable to common stockholders — basic and diluted	$ (1.23)	$ (0.73)	$ (3.20)	$ (2.23)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	49,731	43,460	49,718	36,373	

The accompanying notes are an integral part of these consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30,
	2006	2005	2006
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(159,280)	$ (81,047)	$ (716,581)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,326	5,463	36,963
Stock-based compensation expense (benefit)	10,680	(587)	33,198
Accrued interest on investments, net of amortization of premiums	197	(107)	51
(Gain)/loss on sale and abandonment/disposal of property and equipment	51	(1)	3,418
In-process research and development	—	—	19,726
Discount on stockholder notes below market rate	—	—	241
Non-cash compensation expense of officer resulting from stockholder contribution	—	—	70
Accrued interest expense on notes payable to stockholders	—	—	1,538
Non-cash interest expense	—	—	3
Accrued interest on notes	—	—	(747)
Goodwill impairment	—	—	151,428
Loss on available-for-sale securities	—	—	229
Changes in assets and liabilities:			
State research and development credit exchange receivable	(318)	48	(3,543)
Prepaid expenses and other current assets	(8,658)	(186)	(11,702)
Other assets	(74)	(221)	(359)
Accounts payable	3,126	1,930	6,673
Accrued expenses and other current liabilities	13,216	5,359	31,034
Other liabilities	(5)	(40)	22
Payment of deferred compensation	—	(1,373)	—
Net cash used in operating activities	(134,739)	(70,762)	(448,338)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	(37,507)	(216,200)	(440,225)
Sales of marketable securities	119,900	114,695	432,940
Purchase of property and equipment	(14,231)	(10,428)	(124,600)
Proceeds from sale of property and equipment	32	90	214
Restricted cash	—	565	—
Net cash provided by (used in) investing activities	68,194	(111,278)	(131,671)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants for cash	3,594	172,291	496,845
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
Principal payments on notes payable	—	—	(1,667)
Borrowing on notes payable	—	—	3,460
Note payable to principal stockholder	50,000	—	50,000
Net cash provided by financing activities	53,594	172,291	623,095
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(12,951)	(9,749)	43,086
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	56,037	78,987	—
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 43,086	$ 69,238	$ 43,086

	Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30,
	2006	2005	2006
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$ 5	$ 1	$ 21
Interest paid in cash	—	—	80
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)

In connection with the Company's initial public offering, all shares of Series B and Series C convertible preferred stock, in the amount of $15,000,000 and $50,000,000, respectively, automatically converted into common stock in August 2004.

The accompanying notes are an integral part of these consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited consolidated financial statements of MannKind Corporation (the "Company"), have been prepared in accordance with generally accepted accounting principles in the United States of America 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 generally accepted accounting principles in the United States of America for complete financial statements. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's latest audited annual financial statements. The audited statements for the year ended December 31, 2005 are included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2005 filed with the SEC on March 16, 2006 (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, 2006 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 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 — MannKind Corporation is a biopharmaceutical company focused on the development and commercialization of therapeutic products for diseases such as diabetes and cancer. The Company's lead investigational product candidate, the Technosphere Insulin System, is currently in Phase 3 clinical trials in the U.S., Europe and Latin America to study its safety and efficacy in the treatment of diabetes. The Technosphere Insulin System consists of the Company's proprietary dry-powder Technosphere formulation of insulin that is inhaled deep into the lung using the Company's MedTone 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, 2006 the Company has reported accumulated net losses of $716.6 million, which include a goodwill impairment charge of $151.4 million, and negative cash flow from operations of $448.3 million. It is costly to develop therapeutic products and conduct clinical trials for these products. On August 2, 2006, the Company entered into a $150.0 million loan arrangement with its principal stockholder. Under this arrangement, the Company can borrow funds in one or more advances at any time through August 2, 2007 that the Company's cash balance falls below its projected cash requirements for the subsequent three months, provided that each advance be no less than $50.0 million. Principal repayment is due and payable one year from the date of each advance. The Company borrowed $50.0 million under the loan arrangement on August 2, 2006. On October 30, 2006, the loan arrangement was modified to provide that at no time shall the total principal amount borrowed exceed $150.0 million and that each advance be no less than $10.0 million. See Note 10 — Related-Party Loan Arrangement.

The Company believes that this loan arrangement with its principal stockholder will enable the Company to continue funding operations through the first quarter of 2007. Accordingly, the Company expects that it will need to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration with a pharmaceutical company or the establishment of other funding facilities, in order to continue the development and commercialization of its Technosphere Insulin System and other product candidates and to support its other ongoing activities. On November 2, 2006, the Company filed a shelf registration statement with the SEC providing for the issuance of up to $500 million of equity and debt securities from time to time in one or more transactions. However, the Company cannot provide assurances that it will raise capital on favorable terms or at all. If the Company fails to raise capital before the end of the first quarter of 2007 its business, financial condition and results of operations would be adversely effected and the Company would be forced to reduce or discontinue its operations. 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.

Segment Information — In accordance with Statement of Financial Accounting Standards ("SFAS") No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating entirely in the United States of America.

2. Investment in securities

The following is a summary of the available-for-sale securities classified as current assets:

	As of September 30, 2006		As of December 31, 2005	
(in thousands)	Cost basis	Fair value	Cost basis	Fair value
Auction rate municipal bonds	$ 7,007	$ 7,007	$ 89,597	$ 89,597

The Company's policy is to maintain a highly liquid short-term investment portfolio. The contractual maturities for auction rate municipal bonds at September 30, 2006 are between 22 and 40 years. Despite the long-term nature of their stated contractual maturities, the Company has the ability to quickly liquidate these securities. Proceeds from the sale and maturities of available-for-sale securities amounted to approximately $119.9 million and $114.7 million for the nine months ended September 30, 2006 and 2005, respectively, and $30.4 million and $56.5 million for the three months ended September 30, 2006 and 2005, respectively. Gross realized gains and losses for available-for-sale securities were insignificant for the three and nine months ended September 30, 2006 and 2005. Gross realized gains and losses for available-for-sale securities are recorded as other income (expense). The cost of securities sold is based on the specific identification method. Unrealized gains and losses for available-for-sale securities as of the periods presented in the table above were not material.

3. Accounting for stock-based compensation

On January 1, 2006, the Company adopted the provisions of SFAS No. 123R ("SFAS No. 123R"), *Share-based Payment: an Amendment of FASB Statements No. 123 and 95*, which is a revision of SFAS No. 123 ("SFAS No. 123"), *Accounting for Stock-Based Compensation*. Prior to January 1, 2006, the Company accounted for employee stock options and the employee stock purchase plan using the intrinsic value method in accordance with Accounting Principles Board ("APB") Opinion No. 25 ("APB No. 25"), *Accounting for Stock Issued to Employees*, and adopted the disclosure only alternative of SFAS No. 123. SFAS No. 123R eliminated the intrinsic value method of accounting for stock options which the Company followed until December 31, 2005. Further, SFAS No. 123R requires all share-based payments to employees, including grants of stock options and the compensatory elements of employee stock purchase plans, to be recognized in the income statement based upon the fair value of the awards at the grant date.

Upon adoption of SFAS No. 123R, the Company selected the modified prospective transition method whereby unvested awards at the date of adoption as well as awards that are granted, modified, or settled after the date of adoption will be measured and accounted for in accordance with SFAS No. 123R. Measurement and attribution of compensation cost for awards unvested as of January 1, 2006 is based on the same estimate of the grant-date or modification-date fair value and the same attribution method (straight-line) used previously under SFAS No. 123.

In the three and nine months ended September 30, 2006, the Company recorded stock-based compensation expense of $3.2 million and $10.7 million, respectively, which caused loss before provision for income taxes to increase by $3.2 million and $10.7 million, respectively. The following table presents stock-based compensation expense included in operating expenses for the three and nine months ended September 30, 2006 and the pro forma stock-based compensation amounts that would have been included in the statements of operations for three and nine months ended September 30, 2005 had stock-based compensation expense been determined in accordance with the fair value method prescribed by SFAS No. 123:

(in thousands, except per share data)	Three months ended September 30, 2006	Three months ended September 30, 2005	Nine months ended September 30, 2006	Nine months ended September 30, 2005
Stock-based employee compensation expense determined under the fair value based method for all awards	$ 3,070	$ 3,481	$ 10,121	$ 10,345
Fair value of discount on employee stock purchase plan	113	67	325	243
Total stock-based employee compensation expense	$ 3,183	$ 3,548	$ 10,446	$ 10,588
Net loss — as reported		$ (31,730)		$(81,047)
Add: Stock-based employee compensation expense (benefit) included in reported net loss		2,296		(885)
Deduct: Stock-based compensation expense determined under fair value method		(3,548)		(10,588)
Net loss — pro forma		$ (32,982)		$(92,520)
Net loss per common share (basic and diluted):				
As reported		$ (0.73)		$ (2.23)
Pro forma		$ (0.76)		$ (2.54)

The fair value of each option is estimated on the grant date or modification date, if any, using the Black-Scholes option valuation model. The variables used by the Company for the three and nine months ended September 30, 2006 and 2005 are disclosed in the following table. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The stock price volatility used is based on the historical volatility of the stock of several of the Company's peers. The weighted average expected life is calculated using the "simplified" method, which is defined in Staff Accounting Bulletin No. 107, *Topic 14: Share-based Payment*, and is equal to one-half of the sum of the weighted average time to vest and the option's contractual term.

	Three months ended September 30, 2006	Three months ended September 30, 2005	Nine months ended September 30, 2006	Nine months ended September 30, 2005
Risk-free interest rate	4.70-4.86%	4.12%	4.59%-4.96%%	3.43%-4.12%
Dividend yield	0%	0%	0%	0%
Volatility factor	57%-58%	100%	57%-63%	100%
Weighted average expected life	6.08-6.60 years	4.00 years	6.08-6.60 years	4.00 years

Total stock-based compensation expense (benefit) recognized in the accompanying statements of operations is as follows (in thousands):

	Three months ended September 30, 2006	Three months ended September 30, 2005	Nine months ended September 30, 2006	Nine months ended September 30, 2005
Employee-related	$ 3,183	$ (2,296)	$ 10,446	$ (885)
Non-Employee-related	0	(107)	234	298
Total	$ 3,183	$ (2,403)	$ 10,680	$ (587)

Equity Incentive Plan

The Company's 2004 Equity Incentive Plan (the "Plan") provides for the granting of stock awards including stock options and restricted stock units, to employees, directors and consultants.

The Company's board of directors determines eligibility, vesting schedules and exercise prices for stock awards granted under the Plan. Options and other stock awards under the Plan expire not more than ten years from the date of the grant and are exercisable upon vesting. Stock options generally vest over four years and become exercisable at the rate of 25% after one year and ratably on a monthly basis over a period of 36 months thereafter. Restricted stock units generally vest over four years with consideration satisfied by service to the Company. Certain performance-based awards vest upon achieving three pre-determined performance milestones which are expected to occur over a period of 42 months. The Plan provides for full acceleration of vesting if an employee is terminated within thirteen months of a change in control, as defined.

In May 2006, the Company's stockholders approved an increase of 4.0 million shares in the number of shares reserved under the Plan for future issuance. As of September 30, 2006, 5,891,800 options and 823,102 restricted stock units were outstanding under the Plan and an additional 2,786,902 shares of common stock were available for issuance under the Plan.

On September 20, 2006, the Company's board of directors approved performance-based stock option grants under the Plan to purchase 400,000 shares of common stock at an exercise price of $19.08 per share and 98,000 performance-based restricted stock units. These performance-based awards become fully vested upon achieving three pre-determined performance milestones which are expected to occur over a period of 42 months. The options were valued at $11.57 per option share and restricted stock units were valued at $19.08 per share, which was the fair market value of the common stock on the grant date. The compensation cost of the awards of approximately $6.5 million is being expensed over the implicit service periods of the awards.

During 2004, the Company's board of directors and stockholders approved the 2004 Non-Employee Directors' Stock Option Plan. The plan provides for the automatic, non-discretionary grant of options to the Company's non-employee directors. As of September 30, 2006, 337,500 options were outstanding under the plan and an additional 462,500 shares of common stock were available for issuance under the plan.

The Company has two other stock award plans: the 1991 Stock Option Plan (the "1991 Plan") and the 1999 Stock Plan (the "1999 Plan"). Both of these plans provide for the granting of stock options to directors, employees and consultants. As of September 30, 2006, 73,084 options were outstanding under the 1991 Plan and 170,695 options were outstanding under the 1999 Plan. There were no additional shares available for issuance under the 1991 Plan or the 1999 Plan at September 30, 2006.

Also, as of September 30, 2006 there were an aggregate of 44,287 options outstanding under stock-based award plans that were assumed by the Company in connection with a merger between several entities in 2001.

During the year ended December 31, 2002, the Company's board of directors granted 240,972 options at an exercise price of $25.23 per share to an employee who is the principal stockholder. The options vest annually over four years. These options, which were not under any plan, were outstanding at September 30, 2006 and are included in the tables below.

A summary of option activity as of March 31, 2006, June 30, 2006 and September 30, 2006, and changes during each of those quarters, is presented below:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at December 31, 2005	4,985,831	$ 12.40		
Granted	153,480	16.13		
Exercised	(59,878)	9.41		
Forfeited	(93,120)	12.79		
Expired	(37,903)	19.97		
Outstanding at March 31, 2006	4,948,410	12.48	7.3	$ 39,389
Granted	291,330	17.00		
Exercised	(17,685)	10.74		
Forfeited	(53,412)	14.84		
Expired	(9,461)	11.09		
Outstanding at June 30, 2006	5,159,182	12.72	7.2	$ 44,321
Granted	832,975	17.87		
Exercised	(40,994)	10.27		
Forfeited	(56,237)	13.47		
Expired	(3,126)	13.32		
Outstanding at September 30, 2006	5,891,800	13.46	7.2	$ 32,659
Exercisable at December 31, 2005	1,937,918	11.55		
Exercisable at September 30, 2006	2,604,125	12.46	5.5	$ 17,025

A summary of restricted stock units activity as of March 31, 2006, June 30, 2006, and September 30, 2006, and changes during each of those quarters , is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2006	164,901	$ 11.00		
Granted	247,554	16.13		
Forfeited	(6,719)	11.41		
Outstanding at March 31, 2006	405,736	14.12	9.6	$ 8,293
Granted	177,703	17.00		
Forfeited	(4,990)	13.06		
Outstanding at June 30, 2006	578,449	15.02	9.5	$ 12,327
Granted	249,826	17.66		
Forfeited	(5,173)	12.60		
Outstanding at September 30, 2006	823,102	15.83	9.5	$ 15,639
Exercisable at September 30, 2006	—	—	—	—

The weighted-average grant-date fair value per share of options granted during the three months ended September 30, 2005 and 2006 was $8.17 and $10.70, respectively. The total intrinsic value of options exercised during the three months ended September 30, 2005 and 2006 was approximately $0.8 million and $0.3 million, respectively. The total fair value of options vested during the three months ended September 30, 2006 and 2005 was $4.4 million and $4.1 million, respectively. Cash received from the exercise of options during the three months ended September 30, 2006 and 2005 was approximately $0.4 million and $1.6 million, respectively. Cash received from the exercise of options during the nine months ended September 30, 2006 and 2005 was approximately $1.2 million and $1.8 million, respectively.

A summary of the status of the Company's nonvested shares, excluding restricted stock units, as of March 31, 2006, June 30, 2006, and September 30, 2006 and changes during each of the those quarters, is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested at January 1, 2006	3,048,631	$ 13.06
Granted	153,480	10.03
Vested	(151,504)	12.86
Forfeited	(93,120)	12.79
Nonvested at March 31, 2006	2,957,487	12.74
Granted	291,330	10.65
Vested	(217,194)	13.99
Forfeited	(53,413)	14.84
Nonvested at June 30, 2006	2,978,210	13.09
Granted	832,975	10.70
Vested	(467,273)	5.74
Forfeited	(56,237)	9.64
Nonvested at September 30, 2006	3,287,675	11.82

A summary of the status of the Company's restricted stock units, as of March 31, 2006, June 30, 2006, and September 30, 2006 and changes during each of those quarters, is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested at January 1, 2006	164,901	$ 11.00
Granted	247,554	16.13
Forfeited	(6,719)	11.41
Nonvested at March 31, 2006	405,736	14.12
Granted	177,703	17.00
Forfeited	(4,990)	13.06
Nonvested at June 30, 2006	578,449	15.02
Granted	249,826	17.66
Forfeited	(5,173)	12.60
Nonvested at September 30, 2006	823,102	15.83

As of September 30, 2006, there was $26.8 million and $10.3 million of unrecognized compensation cost related to options and restricted stock units, respectively, which is expected to be recognized over the remaining weighted average vesting period of 3.0 years.

In March 2004, the Company's board of directors approved the 2004 Employee Stock Purchase Plan. The aggregate number of shares that may be sold under the plan is 2,000,000 shares of common stock. On January 1 of each year, for a period of ten years beginning January 1, 2005, the share reserve automatically increases by the lesser of: 700,000 shares, 1% of the total number of shares of common stock outstanding on that date, or an amount as may be determined by the board of directors. However, under no event can the annual increase cause the total number of shares reserved under the purchase plan to exceed 10% of the total number of shares of capital stock outstanding on December 31 of the prior year. On January 1, 2005 and 2006, the purchase plan share reserve was increased by 327,562 and 503,141 shares, respectively. For the years ended December 31, 2004 and 2005, the Company sold 36,152 and 57,642 shares, respectively, of its common stock to employees participating in the plan. For the nine months ended September 30, 2006, the Company sold 50,894 shares to employees participating in the plan.

4. 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. 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 and warrants, that are not included in the diluted net loss per share calculation consisted of an aggregate of 9,741,538 shares and 7,916,772 shares as of September 30, 2006 and 2005, respectively.

5. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange eligible 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, 2006, the estimated amount receivable under the program was $3.5 million.

6. Property and equipment

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

	Estimated Useful Life (years)	September 30, 2006	December 31, 2005
Land	—	$ 5,273	$ 5,273
Buildings	39-40	9,566	9,566
Building improvements	5-40	43,626	39,543
Machinery and equipment	3-10	26,240	23,087
Furniture, fixtures and office equipment	5-10	2,930	2,573
Computer equipment and software	3	6,217	4,808
Leasehold improvements		36	5
Construction in progress		14,529	10,298
Deposits on equipment		6,788	6,411
		115,205	101,564
Less accumulated depreciation and amortization		(31,200)	(25,381)
Property and equipment — net		$ 84,005	$ 76,183

7. Common and preferred stock

The Company is authorized to issue 90,000,000 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, 2006 and December 31, 2005, 49,895,691 and 50,314,108 shares of common stock, respectively, were issued and outstanding. No shares of preferred stock were issued and outstanding at September 30, 2006 and December 31, 2005.

Registration rights — The holders of 17,132,000 shares of common stock together with warrants to purchase up to 3,426,000 shares of common stock, all of which were issued in the August 2005 private placement, have rights that require the Company to keep the registration of the shares of common stock purchased in the private placement or underlying warrants continuously effective until at least August 2007.

As of September 30, 2006 the holders of 916,715 shares of the Company's common stock and the holders of warrants to purchase 12,436 shares of the Company's common stock have rights, subject to some conditions, to require the Company to file registration statements covering their shares or to include their shares in registration statements that the Company may file for itself or other stockholders.

8. Warrants

During 1995 and 1996, the Company issued warrants to purchase shares of common stock. The warrants range in exercise price from $12.53 to $12.70 per share and expire at various dates through 2007. The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event the Company declares any stock dividends or effects any stock split, reclassification or consolidation of its common stock. The warrants also contain a provision that provides for an adjustment to the exercise price and the number of shares issuable in the event that the Company issues securities for a per share price less than a specified price. As of September 30, 2006, warrants to purchase 12,436 shares of common stock at a weighted average exercise price of $12.66 per share are outstanding and exercisable.

In connection with the sale of common stock in the private placement which closed on August 5, 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 on February 1, 2006 and expire in August 2010. In the nine months ended September 30, 2006, warrants for 157,612 shares were exercised for approximately $1.9 million and 98,441 shares were issued upon the cashless exercise of 254,528 warrant shares. As of September 30, 2006, 3,014,200 shares remain exercisable.

9. Commitments and contingencies

Guarantees and Indemnifications — In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. The Company has not recorded any liability for these indemnities in the accompanying 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. No such losses have been recorded to date.

Litigation — The Company is involved in various legal proceedings and other matters. In accordance with SFAS No. 5, *Accounting for Contingencies*, the Company would record a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

In May 2005, the Company's former Chief Medical Officer filed a complaint against the Company in the California Superior Court, County of Los Angeles, *Wayman Wendell Cheatham, M.D. v. MannKind Corporation*,

Case No. BC333845. The complaint alleges causes of action for wrongful termination in violation of public policy, breach of contract and retaliation, in connection with the Company's termination of Dr. Cheatham's employment. In the complaint, Dr. Cheatham seeks compensatory, punitive and exemplary damages in excess of $2.0 million as well as reimbursement of attorneys' fees. In June 2005, the Company answered the complaint, generally denying each of Dr. Cheatham's allegations and asserting various defenses. The Company believes the allegations in the complaint are without merit and is vigorously defending against them. The Company also filed a cross-complaint against Dr. Cheatham, alleging claims for libel per se, trade libel, breach of contract, breach of the implied covenant of good faith and fair dealing and breach of the duty of loyalty. The libel claims allege that Dr. Cheatham made certain false and malicious statements about the Company in a letter to the Food and Drug Administration ("FDA") with regard to a request by the Company to hold a meeting with the FDA. The remaining causes of action in the cross-complaint arise out of the Company's allegations that Dr. Cheatham had an undisclosed consulting relationship with a Company competitor during his employment with the Company, in violation of his agreement with the Company. In July 2005, Dr. Cheatham filed a demurrer, and a motion to strike the Company's cross-complaint under California's anti-SLAPP statute. In September 2005, the California Superior Court overruled Dr. Cheatham's demurrer and denied his motion to strike the Company's cross-complaint. In November 2005, Dr. Cheatham appealed the Court's ruling denying his motion to strike. Oral argument on the appeal is scheduled for November 21, 2006. In July 2006, the Company filed a motion for summary judgment, or in the alternative, for summary adjudication, requesting dismissal before trial of Dr. Cheatham's claims against the Company. In October 2006, the Superior Court denied the motion. Discovery as to Dr. Cheatham's claims against the Company is proceeding, and this case is currently scheduled for trial to commence in February 2007. The Company believes that the ultimate resolution of this matter will not have a material impact on the Company's financial position or results of operations.

10. Related-Party Loan Arrangement

On August 2, 2006 the Company entered into a $150.0 million loan arrangement with its principal stockholder. Under this arrangement, the Company can borrow in one or more advances at any time through August 2, 2007 that the Company's cash balance falls below its projected cash requirements for the subsequent three month period, provided that each advance be no less than $50.0 million. Principal repayment is due and payable one year from the date of each advance. The Company borrowed $50.0 million under the loan arrangement on August 2, 2006. Interest accrues on each outstanding advance at a fixed rate equal to the one year LIBOR rate in effect on the day of such advance plus 3% per annum and is payable quarterly in arrears. On September 29, 2006, the Company paid $0.7 million in accrued interest for the quarter ended September 30, 2006. The loan is unsecured and contains no financial covenants. There are no warrants associated with the loan nor is the loan convertible into the Company's stock. In the event of a default, all unpaid principal and interest becomes immediately due and payable and the interest rate increases to one year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. Upon the closing of certain financing events, including equity and debt financings or strategic transactions with third parties, in which the Company receives cash proceeds of at least $100.0 million, the Company is required to repay all or a portion of the principal and accrued and unpaid interest under the note equal to the difference between the Company's cash balance immediately following the financing event and its projected cash requirements for the six month period following the financing event.

On October 30, 2006, the loan arrangement was modified to provide that at no time shall the total principal amount borrowed exceed $150.0 million and that each advance be no less than $10.0 million. Any principal repaid can be re-borrowed by the Company subject to the limitations above.

11. Subsequent Event

On October 12, 2006, the Company entered into an agreement with The Technion Research and Development Foundation Ltd. ("TRDF"), an Israeli corporation affiliated with the Technion-Israel Institute of Technology (the "Technion") to license certain technology from TRDF and to collaborate with TRDF in the further research in and the development and commercialization of such technology. In exchange for the rights that the Company obtained under this agreement, the Company agreed to pay to TRDF aggregate license fees of $3 million and to issue to TRDF a total of 300,000 shares of the Company's common stock. The license fees will be paid and the shares issued in three equal installments, the first of which occurred on October 18, 2006 and the second and third installments to occur, subject to the accomplishment of certain milestones, on October 12, 2007 and October 12, 2008. The Company has also agreed to pay royalties to TRDF with respect to sales of certain products that contain or use the licensed technology or are covered by patents included in the licensed technology or are discovered through the use of the licensed technology. The Company agreed to pay up to $6 million of the royalties in advance upon the receipt of specified regulatory approvals. The Company agreed to pay to TRDF specified percentages of any lump-sum sub-license payments that the Company receives if it decides to sub-license the technology. The Company has also agreed to pay a total of $2 million to TRDF in three nearly equal installments to fund sponsored research to be conducted at TRDF by a team led by a faculty member at the Technion. The initial sponsored research

payment was made upon signing of the agreement, and the second and third sponsored research payments will occur, subject to the accomplishment of certain milestones, on October 12, 2007 and October 12, 2008. The Company also agreed to retain the services of the Technion faculty member as a consultant, for which the Company agrees to pay the consultant $60,000 per year and to grant the individual an option to purchase 60,000 shares of the Company's common stock.

Alfred E. Mann, our principal stockholder and chief executive officer, has established the Alfred Mann Institute for Biomedical Development at the Technion ("AMI-Technion") to expedite the translation of intellectual property and technology of the Technion into commercial medical products for the public benefit. Over a period of several years, Mr. Mann will establish a $100 million endowment for the AMI-Technion. Mr. Mann does not directly or indirectly have any interest in TRDF.

Under the terms of the agreement, the Company issued 100,000 shares of common stock to TRDF on October 12, 2006 and paid $1.6 million in license fees on October 18, 2006.

On November 2, 2006, the Company filed a registration statement with the SEC providing for the issuance of up to $500 million of equity and debt securities from time to time in one or more transactions.

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 (this "Quarterly Report"). The interim 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, 2005 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K for the fiscal year ended December 31, 2005 filed pursuant to Section 13 of the Securities Exchange Act of 1934. 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

MannKind Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead investigational product candidate, the Technosphere Insulin System, is currently in Phase 3 clinical trials in the United States, Europe and Latin America to study its safety and efficacy in the treatment of diabetes. This therapy consists of a proprietary dry powder formulation of insulin that is inhaled into the deep lung using our proprietary inhaler. We believe that the performance characteristics, unique kinetics, convenience and ease of use of the Technosphere Insulin System may have the potential to change the way diabetes is treated.

In particular, we have observed in our clinical trials to date that the Technosphere Insulin System produces a profile of insulin levels in the bloodstream that approximates the insulin profile normally seen in healthy individuals immediately following the beginning of a meal, but which is absent in patients with diabetes. Specifically, Technosphere Insulin is rapidly absorbed into the bloodstream following inhalation, reaching peak levels within 12 to 14 minutes. As a result of this rapid onset of action, most of the glucose-lowering activity of Technosphere Insulin occurs within the first three hours of administration — which is generally when glucose becomes available from a meal — instead of the much longer duration of action observed when insulin is injected subcutaneously. We believe that the relatively short duration of action of Technosphere Insulin reduces the need for patients to snack between meals in order to manage ongoing blood glucose excursions. Indeed, in our clinical trials, we have observed that patients using Technosphere Insulin have achieved significant reductions in post-meal glucose excursions and significant improvements in overall glucose control, as measured by decreases in HbA1c levels, without the weight gain typically associated with insulin therapy.

In our clinical trials to date, we have observed no difference in pulmonary function between patients treated with Technosphere Insulin and patients treated with standard diabetes care. However, the longest study that we have completed so far is a six-month trial. In September 2006, we completed patient enrollment in a pivotal, two-year, Phase 3, safety study of Technosphere Insulin that will compare the pulmonary function of diabetes patients randomized to either Technosphere Insulin or standard diabetes care. We are continuing to enroll patients in three other major Phase 3 clinical trials two of which are pivotal efficacy trials. Based on our discussions with the Food and Drug Administration (the "FDA"), we plan to accumulate two years of controlled safety data before we file a new drug application for the Technosphere Insulin System. We anticipate that our entire clinical trial program, including several special population studies, will involve more than 4,500 patients. Larger populations and longer durations of exposure may be necessary depending on the safety profile of our product.

Our Technosphere Insulin System utilizes our proprietary Technosphere formulation technology, which is based on a class of organic molecules that are designed to self-assemble into small particles onto which drug molecules can be loaded. We are also developing additional Technosphere-based products for the delivery of other drugs. We plan to initiate Phase 1 clinical trials of a therapeutic cancer vaccine by the end of 2006.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2006, we have incurred a cumulative net loss of $716.6 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities.

We do not anticipate sales of any product prior to regulatory approval and commercialization of our Technosphere Insulin System. We currently do not have the required approvals to market any of our product candidates, and we may not receive any approvals. We may

not be profitable even if we succeed in commercializing any of our product candidates. We expect to make substantial and increasing expenditures and to incur additional operating losses for at least the next several years as we:

- continue the clinical development and commercialization of our Technosphere Insulin System for the treatment of diabetes;
- expand our manufacturing operations for our Technosphere Insulin System to meet our currently anticipated commercial production needs;
- expand our other research, discovery and development programs;
- expand our proprietary Technosphere platform technology and develop additional applications for the pulmonary delivery of other drugs; and
- enter into sales and marketing collaborations with other companies, if available on commercially reasonable terms, or develop these capabilities ourselves.

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, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

CLINICAL DEVELOPMENT ACTIVITIES

The Technosphere Insulin System

We are currently conducting a number of studies of the safety and efficacy of the Technosphere Insulin System, including the following trials that are currently underway or recently completed:

Study 010

This ongoing trial is a three-year evaluation of the safety and tolerability of Technosphere Insulin in patients with type 2 diabetes who have participated in study 008 or study 005. The primary objective is to evaluate pulmonary function with secondary objectives to examine changes in HbA1c levels, insulin antibodies, frequency of adverse events and quality of life.

Study 030

This is a two-year, prospective, multi-site study that incorporates two design strategies. The first component is a randomized, open-label trial comparing pulmonary function in two groups of patients with diabetes. One group of approximately 625 patients is being treated with Technosphere Insulin in combination with other antidiabetic therapy and the other group of approximately 625 patients is being treated with existing oral and/or injectable therapies. The second component is a comparison of pulmonary function in the patients with diabetes who are not treated with Technosphere Insulin to a group of 125 subjects without any abnormalities in glucose control. Enrollment for this study was completed in September 2006.

Study 014

This completed study compared the efficacy of mealtime use of Technosphere Insulin plus basal insulin to mealtime use of rapid-acting, subcutaneous insulin plus basal insulin in approximately 240 patients with type 2 diabetes who had a baseline HbA1c level greater than 7.0% and less than 11.5%. The primary efficacy endpoint for this study was mean change in HbA1c levels from baseline to treatment week 24. Enrollment was completed in July 2005 and the treatment period completed in February 2006. In this study, we observed that patients with type 2 diabetes using Technosphere Insulin achieved comparable improvements in glycemic control to patients treated with an injected rapid-acting insulin analog. In addition, we observed no adverse effect on pulmonary function in either treatment group. However, unlike the injected rapid-acting insulin analog group, patients using Technosphere Insulin lost weight during the treatment period.

Study 101

This trial compared mealtime use of Technosphere Insulin to mealtime use of rapid-acting, subcutaneous insulin in 110 patients with type 1 diabetes, who were evaluated over a 12-week period. The primary efficacy endpoint was the change in blood glucose levels following a standard meal. This study demonstrated that patients with type 1 diabetes using Technosphere Insulin can achieve comparable levels of control in HbA1c as patients treated with an injected rapid-acting insulin analog. In this study, the peak of the mean blood glucose values following a standardized meal test were lower for patients on Technosphere Insulin than those receiving injections of rapid-acting insulin analog. The study also showed that patients using Technosphere Insulin did not gain weight during the study in contrast to patients using the injected rapid-acting insulin analog. Furthermore, after twelve weeks of treatment, pulmonary function did not differ between the two patient groups.

Study 009

This study will evaluate Technosphere Insulin to prandial insulin analog both used in combination with basal insulin in approximately 500 patients with type 1 diabetes for a 12-month period. Efficacy will be evaluated on the basis of changes in HbA1c levels as well as changes in blood glucose levels after a standardized mixed meal. We began enrolling patients in this study in the first quarter of 2006.

Study 102

This study will compare the efficacy of mealtime use of Technosphere Insulin together with basal insulin to the twice-daily use of premixed insulin, a mixture of intermediate acting insulin and a rapid-acting insulin analog, in a population of approximately 500 patients with type 2 diabetes. Efficacy will be evaluated on the basis of changes in HbA1c levels as well as changes in blood glucose levels after a standardized mixed meal. We began enrolling patients in this study in the first quarter of 2006.

Study 103

This study will evaluate the efficacy of Technosphere Insulin alone and in combination with metformin, an oral medication, in approximately 500 patients with type 2 diabetes who are not achieving desired glucose control with a combination of metformin and sulphonylurea, another oral medication. Efficacy will be evaluated on the basis of changes in HbA1c levels after 26 weeks of treatment as well as changes in blood glucose levels after a standardized mixed meal. We began enrolling patients in this study in the second quarter of 2006.

Special population studies

We have two ongoing special population studies: one examining the impact of asthma and the other examining the impact of chronic smoking on the pharmacokinetics associated with Technosphere Insulin. We plan to use the results of these studies to conduct safety studies in patients with asthma and in chronic smokers that also have diabetes. We also plan to conduct a safety study in patients with both diabetes and chronic obstructive pulmonary disease. Other special population studies include a trial that will examine patients with kidney disease and a trial that will examine patients with liver disease.

Cancer immunotherapy program

We are also developing therapies for the treatment of solid tumor cancers. The lead product candidate in this program, MKC1106, is intended for the treatment of several solid-tumor cancers, including ovarian, colorectal, pancreatic, renal, breast and prostate carcinomas. We plan to commence clinical trials for MKC1106 late in the fourth quarter of 2006.

Our cancer therapy program utilizes the body's immune system to help eradicate tumor cells. The immune system is a network of cells and organs that defends the body against infection and abnormal cells, such as cancer. A key element of the immune system is its ability to distinguish between healthy cells and foreign or diseased cells that do not belong in the body. The immune system accomplishes this task by recognizing distinctive molecules called epitopes found on the surface of each cell as either normal or abnormal, and responding to them appropriately. Any substance capable of triggering an immune response is known as an antigen. An antigen can be all or part of a pathogenic organism or it can be a by-product of diseased cells. Certain specialized cells of the immune system sample antigens present in the body and present the epitopes associated with foreign antigens to other cells of the immune system whose function is to destroy any cell that expresses the same epitope; this is known as cell-mediated immunity. In this way, the immune system can launch a very specific response to infection or disease.

Our approach uses DNA- and peptide-based compounds that correspond to tumor-associated antigens that are expressed in a range of solid-tumor cancers. A patient is first "primed" by DNA-based compounds, or plasmids, that are injected directly into the patient's

lymph nodes. This is designed to sensitize the immune system to the tumor-associated antigens encoded by the plasmids. After a period of time, the patient's lymph nodes are then injected with synthetic peptides that are designed to "boost" or greatly amplify the immune response to the target antigens. This prime-boost regimen is designed to provoke a potent cell-mediated immune response that destroys cancer cells along with the underlying blood supply to a tumor.

We believe that our therapeutic approach addresses several deficiencies inherent in earlier approaches to cancer immunotherapy, including:

- *Specificity.* We target cancer epitopes to which the immune system has not developed a tolerance, instead of targeting the dominant epitopes expressed by cancerous cells, many of which are tolerated by the immune system. We have developed technology designed to identify the non-tolerated epitopes on the cancer cell surface, and we have developed a method of modifying these epitopes that is designed to activate an immune response. Through this process, we believe that the body's tolerance of the cancer cells can be broken, leading to the destruction of the cancer by the immune system.
- *Administration.* In contrast to the conventional subcutaneous or intramuscular route of administration, our compounds are delivered directly into the patient's lymph nodes, where studies have shown they will have the greatest impact. We believe that the direct delivery of our compounds will bring local high concentrations of the active components of our compounds into contact with high concentrations of the cells needed to generate a potent cell-mediated immune response.
- *Selectivity, potency and duration of response.* We deliver our therapeutic compounds in a manner that we believe primes the immune system to respond to cancer cells expressing specific epitopes, in much the same way that a chronic infection evokes a progressively increased immune response to invading bacteria. Our administrative regimen is designed to boost the immune response over the course of a treatment cycle so that it becomes increasingly potent and long acting.

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates which 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, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of laboratory equipment. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash.

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

Clinical development timelines, likelihood of success and total costs vary widely. We are focused primarily on advancing the Technosphere Insulin System through Phase 3 clinical trials and regulatory filings. We plan to commercialize our lead product as a treatment for diabetes. 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 the Technosphere Insulin System, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for commercialization. The costs required to complete the development of our Technosphere Insulin System will be largely dependent on the scope of our clinical trials, the cost and efficiency of our manufacturing process and discussions with the FDA on its requirements. We anticipate that our research and development expenses, particularly for the Technosphere Insulin System, will increase significantly with the continuation of existing clinical trials, the initiation of new trials, the resulting manufacturing costs associated with producing clinical trial materials, and the expansion, qualification and validation of our commercial manufacturing processes and facilities. Additionally, we expect non-cash stock-based compensation expense resulting from the adoption of SFAS No. 123R, *Share-based Payment: an Amendment of FASB Statement 123 and 95,* effective as of January 1, 2006, to be higher in future periods as compared to periods prior to January 1, 2006. See Critical Accounting Policies below and Note 3 — Accounting for Stock-Based Compensation in the notes to our financial statements.

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 business insurance and professional services costs.

We expect general and administrative expenses other than non-cash stock-based compensation expense to increase slightly in the future as a result of increased headcount, public company compliance and establishment of investor relations and marketing programs. We expect overall general and administrative expenses to be higher in future periods as compared to periods prior to the adoption of SFAS No. 123R. See Critical Accounting Policies below and Note 3 — Accounting for Stock-Based Compensation in the notes to our financial statements.

CRITICAL ACCOUNTING POLICIES

Other than the adoption of SFAS No. 123R, there have been no material changes to our critical accounting policies as described in Item 7 to our Annual Report.

Stock-based Compensation

Prior to January 1, 2006, we accounted for employee stock options and the employee stock purchase plan using the intrinsic value method in accordance with APB No. 25 and adopted the disclosure only alternative of SFAS No. 123. Upon adoption of SFAS No. 123R, we selected the modified prospective transition method whereby we recognized share-based employee costs from the beginning of 2006 as if the fair value accounting method had been used to account for all employee awards granted, modified, or settled after January 1, 2006 and to any awards that were not fully vested as of January 1, 2006. The measurement and attribution of compensation cost for awards that are unvested as of January 1, 2006 are based on the same estimate of the grant-date and the same attribution method used previously under SFAS No. 123. Including the effects of adoption of SFAS No. 123R, we recognized stock-based compensation expense of $10.7 million for the nine months ended September 30, 2006. We expect expensing of stock-based compensation will continue to have an impact on our statement of operations. As of September 30, 2006, there was $26.8 million and $10.3 million of unrecognized compensation cost related to options and restricted stock units, respectively, granted by the Company which is expected to be recognized over the remaining weighted average vesting period of 3.0 years.

RESULTS OF OPERATIONS

The discussion and analysis of our financial condition and results of operations for the three and nine months ended September 30, 2006 and 2005 are based upon our consolidated interim financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and as a result, actual condition or results may differ from our estimates under different assumptions or conditions.

Revenues

During the nine months ended September 30, 2006, we recognized $0.1 million in revenue under a license agreement. There were no revenues recorded for the three months ended September 30, 2006 or the three or nine months ended September 30, 2005. We do not anticipate sales of any product prior to regulatory approval and commercialization of our Technosphere Insulin System.

Research and Development Expense

The following table provides a comparison of the research and development expense categories for the three and nine months ended September 30, 2006 and 2005 (dollars in thousands):

	Three months ended September 30,			
	2006	2005	$ Change	% Change
Clinical	$ 30,067	$ 12,973	$ 17,094	132%
Manufacturing	11,012	5,609	5,403	96%
Research	8,005	5,394	2,611	48%
Stock-based compensation expense	1,701	490	1,211	247%
Research and development expense	$ 50,785	$ 24,466	$ 26,319	108%

	Nine months ended September 30,			
	2006	2005	$ Change	% Change
Clinical	$ 76,828	$ 34,568	$ 42,260	122%
Manufacturing	29,141	16,878	12,263	73%
Research	21,133	15,332	5,801	38%
Stock-based compensation expense (benefit)	4,954	(20)	4,974	(24,870)%
Research and development expense	$132,056	$ 66,758	$ 65,298	98%

The increase in research and development expenses for the three and nine months ended September 30, 2006, as compared to the same periods in the prior year was primarily due to ongoing expenses related to the clinical development of our Technosphere Insulin System. The expansion of our Phase 3 clinical trial program for our Technosphere Insulin System and the continuation of other preclinical studies increased our clinical research expenditures in 2006 as compared to the same period in 2005. This also resulted in increased Technosphere Insulin manufacturing costs to supply clinical trial materials. We also continue to expand our qualification and validation of our manufacturing system. Additionally, research activities related to toxicology studies for our Technosphere Insulin System, expanding our proprietary Technosphere platform technology, developing additional applications for the pulmonary delivery of other drugs and the discovery and development of programs primarily focused on cancer therapies resulted in increased research expenditures. We anticipate that our research and development expenses associated with our Technosphere Insulin System, expanding our Technosphere platform technology and the pursuit of cancer therapies will continue to increase in 2006. Specifically, we anticipate increased expenses related to the continuation of existing and initiation of new clinical trials, and the resulting manufacturing costs associated with producing clinical trial materials.

The increase in stock-based compensation expense for the three and nine months ended September 30, 2006 compared to the same periods in the prior year primarily resulted from the adoption of SFAS No. 123R which requires all share-based payments to employees, including grants of stock options and the compensatory elements of employee stock purchase plans, to be recognized in the income statement based upon the fair value of the awards at the grant date. As described in the Critical Accounting Policies above, we have adopted SFAS No. 123R as of the effective date of January 1, 2006. As a result of our adoption of SFAS No. 123R, we expect non-cash stock-based compensation expense to be higher in future periods as compared to periods prior to January 1, 2006. See Note 3 — Accounting for Stock-Based Compensation in the footnotes to our financial statements.

General and Administrative Expense

The following table provides a comparison of the general and administrative expense categories for the three and nine months ended September 30, 2006 and 2005 (dollars in thousands):

	Three months ended September 30,			
	2006	2005	$ Change	% Change
Salaries, employee related and other general expenses	$ 8,867	$ 6,571	$ 2,296	35%
Stock-based compensation expense	1,482	1,825	(343)	(19)%
General and administrative expenses	$ 10,349	$ 8,396	$ 1,953	23%

	Nine months ended September 30,			
	2006	2005	$ Change	% Change
Salaries, employee related and other general expenses	$ 24,217	$ 16,884	$ 7,333	43%
Stock-based compensation expense (benefit)	5,726	(566)	6,292	(1112)%
General and administrative expenses	$ 29,943	$ 16,318	$ 13,625	83%

General and administrative expenses for the three and nine months ended September 30, 2006 increased as compared to the same period in the prior year. Increased administrative services resulted in increased headcount, compensation adjustments and other employee related expenses. Additionally, litigation, public company compliance (including the Sarbanes-Oxley Act) and our establishment of a marketing function in late 2005 increased both professional fees and consulting expenses. Stock-based compensation expense decreased for the three months ended September 30, 2006 and increased for the nine months ended September 30, 2006 compared to the three and nine months ended September 30, 2005 due to the adoption of SFAS No. 123R. We expect general and administrative expenses other than non-cash stock-based compensation expense to increase slightly in the future as a result of increased headcount, public company compliance and establishment of investor relations and marketing programs. We expect non-cash stock-based compensation expense to be higher in future periods as compared to periods prior to January 1, 2006 as a result of the adoption of SFAS No. 123R. See Critical Accounting Policies above and Note 3 — Accounting for Stock-Based Compensation in the footnotes to our financial statements.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception in 1991 through September 30, 2006, we have reported accumulated net losses of $716.6 million, which include a goodwill impairment charge of $151.4 million, and negative cash flow from operations of $448.3 million and we anticipate that we will continue to generate significant losses from operations for the foreseeable future. It is costly to develop therapeutic products and conduct clinical trials for our products. In August 2006, we entered into a $150.0 million loan arrangement with our principal stockholder, which was amended on October 30, 2006. Under this arrangement, we can borrow funds in one or more advances at any time through August 2, 2007 that our cash balance falls below its projected cash requirements for the subsequent three months, provided that each advance be no less than $10.0 million and provided that at no time shall the total principal amount borrowed exceed $150.0 million. Principal repayment is due and payable one year from the date of each advance. We borrowed $50.0 million under the loan arrangement in August 2006.

We believe that this loan arrangement with our principal stockholder will enable us to continue funding operations through the first quarter of 2007. Accordingly, we expect that we will need to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration with a pharmaceutical company or the establishment of other funding facilities, in order to continue the development and commercialization of our Technosphere Insulin System and other product candidates and to support our other ongoing activities. On November 2, 2006, we filed a shelf registration statement with the SEC providing for the issuance of up to $500 million of equity and debt securities from time to time in one or more transactions. However, we cannot provide assurances that we will be able to raise capital on favorable terms or at all. If we fail to raise capital before the end of the first quarter of 2007, our business, financial condition and results of operations would be adversely effected and we would be forced to reduce or eliminate expenditures for certain of our programs, including our Technosphere Insulin System development activities. 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.

During the nine months ended September 30, 2006, we used $134.7 million of cash for our operations. We had a net loss of $159.3 million for the nine months ended September 30, 2006, of which $17.0 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 our Technosphere Insulin System.

Investing activities provided $68.2 million of cash during the nine months ended September 30, 2006. Cash provided by investing activities was from net sales of marketable securities of $82.4 million offset by $14.2 million used to purchase machinery and equipment to expand our manufacturing operations and quality systems in support of our expansion of clinical trials for Technosphere Insulin System. We expect to make significant purchases of equipment in the foreseeable future.

Our financing activities provided cash of $53.6 million for the nine months ended September 30, 2006. Cash from financing activities was primarily from the loan arrangement with Mr. Mann.

We intend to use our capital resources to continue the development of our Technosphere Insulin System 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 solid-tumor cancers. We anticipate that we will expend 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 our Technosphere Insulin System, but are not disclosing the number of potential partners or their identities. To date, we have not reached agreement with any of these companies on a collaboration. While we are continuing to engage in such discussions, we believe that we will have to expend significant additional time and effort before we could reach agreement and we cannot predict when, if ever, we could conclude such an agreement with a partner. There can be no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms, if at all.

If we enter into a strategic business collaboration with a pharmaceutical company, we would expect, as part of the transaction, to receive reimbursements for a portion of the future costs associated with the development, manufacture and commercialization of our Technosphere Insulin System and to sell equity and/or debt securities to such partner. We also expect to pursue the sale of equity and/or debt securities to other parties, or the establishment of other funding facilities. On November 2, 2006, we filed a shelf registration statement with the SEC providing for the issuance by us of up to $500 million of our equity and debt securities from time to time in one or more transactions. The shelf registration is intended to provide us with the flexibility to take advantage of financing opportunities when and if deemed appropriate by our management. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in raising additional equity financing or entering a business collaboration, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including our Technosphere Insulin System development activities, or further reduction of costs for facilities and administration.

Off-Balance Sheet Arrangements

As of September 30, 2006, we did not have any off-balance sheet arrangements.

Contractual Obligations

There have been no material changes to our contractual obligations disclosed in Item 7 to our Annual Report other than those in the ordinary course of our business, such as contracts related to the continuation of existing clinical trials, the initiation of new trials and the expansion, qualification and validation of our commercial manufacturing processes and facilities. Additionally, in August 2006, we entered into a $150.0 million loan arrangement with our principal stockholder, which was amended on October 30, 2006. Under this arrangement, we can borrow funds in one or more advances at any time through August 2, 2007 that our cash balance falls below its projected cash requirements for the subsequent three months, provided that each advance be no less than $10.0 million and provided that at no time shall the total principal amount borrowed exceed $150.0 million. Principal repayment is due and payable one year from the date of each advance.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have not used derivative financial instruments. However, we are exposed to market risk related to changes in interest rates. Our current policy is 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. Our cash is deposited in and invested through highly rated financial institutions in North America. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by ten percent from levels at September 30, 2006, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We currently borrow on a short-term basis, with the rate established at the time of each advance. As of September 30, 2006, the rate on the our first advance was established and fixed over a 12-month period. Future borrowings under this loan arrangement are subject to market risk if there were an adverse change in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or Securities Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission'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 Rule 13a-15(b) of the Securities Exchange Act) as of September 30, 2006. 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, 2006 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

As previously disclosed in our Annual Report, in May 2005, our former Chief Medical Officer, Wayman Wendell Cheatham, M.D., filed a complaint against us in the California Superior Court, County of Los Angeles in the case styled, *Wayman Wendell Cheatham, M.D. v. MannKind Corporation*, Case No. BC333845. The complaint alleges causes of action for wrongful termination in violation of public policy, breach of contract and retaliation, in connection with our termination of Dr. Cheatham's employment. In the complaint, Dr. Cheatham seeks compensatory, punitive and exemplary damages in excess of $2.0 million, as well as reimbursement of attorneys' fees. In June 2005, we answered the complaint, generally denying each of Dr. Cheatham's allegations and asserting various defenses. We believe the allegations in the complaint are without merit and we are vigorously defending against them. We also filed a cross-complaint against Dr. Cheatham, alleging claims for libel per se, trade libel, breach of contract, breach of the implied covenant of good faith and fair dealing and breach of the duty of loyalty. The libel claims allege that Dr. Cheatham made certain false and malicious statements about us in a letter to the FDA with regard to a request by us to hold a meeting with the FDA. The remaining causes of action in the cross-complaint arise out of our allegations that Dr. Cheatham had an undisclosed consulting relationship with a competitor during his employment with us, in violation of our agreement. In July 2005, Dr. Cheatham filed a demurrer and motion to strike our cross-complaint under California's anti-SLAPP statute. On September 28, 2005, the California Superior Court overruled Dr. Cheatham's demurrer and denied his motion to strike our cross-complaint. Dr. Cheatham has appealed the Court's ruling denying his motion to strike. On November 4, 2005, Dr. Cheatham filed a notice of appeal of the Court's ruling denying his motion to strike. Oral argument on the appeal is scheduled for November 21, 2006. In July 2006, the Company filed a motion for summary judgment, or in the alternative, for summary adjudication, requesting dismissal before trial of Dr. Cheatham's claims against the Company. In October 2006, the Superior Court denied the motion. Discovery as to Dr. Cheatham's claims against us is proceeding, and this case is currently scheduled for trial to commence in February 2007. We believe that the ultimate resolution of this matter will not have a material impact on our financial position or results of operations.

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 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 associated with our business as previously disclosed in Item 1A to our annual report on Form 10-K for the fiscal year ended December 31, 2005. 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 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 our Technosphere Insulin System are still in 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 anticipate that our Technosphere Insulin System will not be commercially available for several years, if at all.

We have never been profitable, and, as of September 30, 2006, we had an accumulated deficit of $716.6 million. The accumulated deficit 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. This accumulated deficit may increase significantly as we expand 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. Our ability to achieve and sustain profitability depends upon obtaining regulatory approvals for and successfully commercializing our Technosphere Insulin System, 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 products and conduct clinical trials for these products. Although we currently are focusing on our Technosphere Insulin System as our lead product candidate, we may in the future conduct clinical trials for a number of additional product candidates. Our future revenues may not be sufficient to support the expense of these activities.

In August 2006, we entered into a $150.0 million loan arrangement with our principal stockholder, which was amended on October 30, 2006. Under this arrangement, we can borrow funds in one or more advances at any time through August 2, 2007 should our cash balance fall below its projected cash requirements for the subsequent three months, provided that each advance be no less than $10.0 million and provided that at no time shall the total principal amount borrowed exceed $150.0 million. Principal repayment is due and payable one year from the date of each advance. We borrowed $50.0 million under the loan arrangement in August 2006. We believe that this loan arrangement with our principal stockholder will enable us to continue funding operations through the first quarter of 2007.

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 plan to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration or the establishment of other funding facilities, in order to continue the development and commercialization of our Technosphere Insulin System and other product candidates and to support our other ongoing activities. On November 2, 2006, we filed a shelf registration statement with the SEC providing for the issuance by us of up to $500 million of our equity and debt securities from time to time in one or more transactions. The shelf registration is intended to provide us with the flexibility to take advantage of financing opportunities when and if deemed appropriate by our management. 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 our Technosphere Insulin System or our other product candidates;
- 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; and
- the costs of discontinuing projects and technologies or decommissioning existing facilities, if we undertake those activities.

We have raised capital in the past primarily through the sale of equity securities. We may in the future pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact your rights as a holder of our common stock, may dilute your ownership percentage and 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, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sale or license 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, licensing arrangements, sales of securities 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 our Technosphere Insulin System development activities, or further reduction of costs for facilities and administration.

We depend heavily on the successful development and commercialization of our lead product candidate, the Technosphere Insulin System, which is still under development, and our other product candidates, which are in preclinical development.*

To date, we have not completed the development of any products through to commercialization. Only our Technosphere Insulin System is currently undergoing clinical trials, while our other product candidates are in research 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 our Technosphere Insulin System.

We have expended significant time, money and effort in the development of our lead product candidate, the Technosphere Insulin System, which has not yet received regulatory approval and which may never be commercialized. Before we can market and sell our Technosphere Insulin System, we will need to advance our Technosphere Insulin System through Phase 3 clinical trials and demonstrate in these trials that our Technosphere Insulin System is safe and effective. We have initiated all of our pivotal Phase 3 clinical trials as well as several special population studies, all of which will require additional time and substantial expenditure of resources. We must also receive the necessary approvals from the FDA and similar foreign regulatory agencies before this product can be marketed in the United States or elsewhere. Even if we were to receive regulatory approval, we ultimately may be unable to gain market acceptance of our Technosphere Insulin System 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 our Technosphere Insulin System, 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 areas. 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 our Technosphere Insulin System, 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 our Technosphere Insulin System 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.

If we do not achieve our projected development 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 compared to our estimates — in many cases for reasons beyond our control — depending on numerous factors, including:

- the rate of progress, costs and results of our clinical trial and research and development activities, which will be impacted by the level of proficiency and experience of our clinical staff;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including insulin and other materials for our Technosphere Insulin System;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent of scheduling conflicts with participating clinicians and clinical institutions;
- the receipt of approvals by our competitors and by us from the FDA and other regulatory agencies; and
- other actions by regulators.

In addition, if we do not obtain sufficient additional funds through sales of securities, strategic collaborations or the sale or license of our assets on a timely basis, we may be required to reduce expenses by delaying, reducing or curtailing our Technosphere Insulin System 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, 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.*

We initially are focusing on the development of the Technosphere Insulin System for the treatment of diabetes, and we face intense competition in this area. In January 2006, the FDA and the European Commission approved Exubera, developed by Pfizer, Inc. in collaboration with Nektar Therapeutics, for the treatment of adults with type 1 and type 2 diabetes. Exubera has been launched in Germany, Ireland, the United Kingdom and, to a limited extent, the United States. Pfizer has announced that it will begin an expanded roll-out of Exubera to primary-care physicians in January 2007. In July 2005, Eli Lilly and Company, in collaboration with Alkermes, Inc., initiated a pivotal Phase 3 safety trial of their AIR inhaled insulin system, which completed patient enrollment in June 2006. We believe Lilly plans to submit a New Drug Application or NDA for the AIR inhaled insulin system in 2009. In September 2006, Novo Nordisk A.S. began recruiting patients for a two-year Phase 3 safety trial of their AERx inhaled insulin system, after previously suspending clinical trials of the AERx product. In addition, 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.

The rapid rate of scientific discoveries and technological changes could result in one or more of our products becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology and our Technosphere Insulin System less competitive, uneconomical or obsolete. Pfizer, the first to commercialize an inhaled insulin system, will have an advantage in being able to gain reputation and market share as well as set parameters for the inhaled insulin market, such as pricing and reimbursement strategies. Our future success will depend not only on our ability to develop our products but to improve them and to 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 our Technosphere Insulin System, we may not be able to execute on our business model.*

We are currently evaluating potential collaborations with respect to our Technosphere Insulin System. If we are not able to enter into a collaboration on terms that are favorable to us, we could be required to undertake and fund product development, clinical trials, manufacturing and marketing activities solely at our own expense. We currently estimate that the cost to continue the development of the Technosphere Insulin System over the next 12 months would be up to $250 million. However, this estimate may change based on how the program proceeds. Failure to enter into a collaboration with respect to our Technosphere Insulin System could substantially increase our requirements for capital, which might not be available on favorable terms, if at all. Alternatively, we would have to substantially reduce our development efforts, which would delay or otherwise impede the commercialization of our Technosphere Insulin System.

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 and if our third-party collaborators do not perform satisfactorily or if our collaborations fail, development or commercialization of our Technosphere Insulin System may be delayed and our business could be harmed.

We currently rely on clinical research organizations and hospitals to conduct, supervise or monitor some or all aspects of clinical trials involving our Technosphere Insulin System. Further, we may also enter into license agreements, partnerships or other collaborative arrangements to support financing, development and marketing of our Technosphere Insulin System. 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 our Technosphere Insulin System 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.

Testing of our Technosphere Insulin System or another product candidate may not yield successful results, and even if it does, we may still be unable to commercialize that product candidate.

Our research and development programs are designed to test the safety and efficacy of our Technosphere Insulin System and our other product candidates through extensive preclinical 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 our Technosphere Insulin System or any of our other product candidates, including the following:

- safety and efficacy results obtained in our preclinical 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.

We have initiated a pivotal Phase 3 safety study of our Technosphere Insulin System to evaluate pulmonary function over a period of two years. Our Technosphere Insulin System is intended for multiple uses per day. Due to the size and timeframe over which existing and planned clinical trials are conducted, the results of clinical trials, including our existing Phase 3 trials, may not be indicative of the effects of the use of our Technosphere Insulin System over longer terms. If long-term use of our Technosphere Insulin System results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell our Technosphere Insulin System, 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, the FDA, other regulatory authorities, any collaborator or we may suspend or terminate clinical trials or marketing of our Technosphere Insulin System 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 we are unable to transition successfully from an early-stage development company to a company that commercializes therapeutics, our operations would suffer.*

We are at a critical juncture in our development, having transitioned from an early-stage development company to one with multiple Phase 3 clinical trials. Phase 3 development of the Technosphere Insulin System is far more complex than the earlier phases. Overall, we plan to support a significant number of studies in the near term. We have not previously implemented the range of studies contemplated for our Phase 3 clinical program. Moreover, as a company, we have no previous experience in the Phase 3-through-new drug application, or NDA, stage of product development.

We require a well-structured plan to make this transition. In the past year, we have added a significant number of new executive personnel, particularly in clinical development, regulatory and manufacturing production, including personnel with significant Phase 3-to-commercialization experience. We have aligned our management structure to accommodate the increasing complexity of our operations, and we are implementing the following measures, among others, to accommodate our transition, complete development of our Technosphere Insulin System and successfully implement our commercialization strategy for our Technosphere Insulin System:

- expand our manufacturing capabilities;
- develop comprehensive and detailed commercialization, clinical development and regulatory plans; and
- implement standard operating procedures, including those for protocol development.

If we are unable to accomplish these measures in a timely manner, we would be at considerable risk of failing to:

- complete our Phase 3 clinical trial program in a deliberate fashion, on time and within budget; and
- develop through our Phase 3 trials the key clinical data needed to obtain regulatory approval and compete successfully in the marketplace.

If our suppliers fail to deliver materials and services needed for the production of our Technosphere Insulin System 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 our Technosphere Insulin System to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our MedTone inhaler, the related cartridges and other materials. We currently have a long-term supply agreement with Diosynth B.V., an independent supplier of insulin and a subsidiary of Akzo Nobel, which is currently our sole supplier for insulin. We are aware of at least five other suppliers of bulk insulin but to date we have not entered into a commercial relationship with any of the five. Currently we obtain our Technosphere precursor raw material from Degussa AG, a major chemical manufacturer with facilities in Europe and North America. We utilize our in-house chemical manufacturing plant as a back up facility. Degussa AG has the capacity to supply our current clinical and future commercial requirements. We entered into a long-term supply agreement with Vaupell, Inc., the supplier of our MedTone inhaler and cartridges. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with current drug Good Manufacturing Practices, or cGMP, and the production of MedTone inhaler and related cartridges in accordance with device Quality System Regulations, or QSR. The supply of all of these materials may be limited or the manufacturer may not meet relevant regulatory requirements, and if we are unable to obtain 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 our Technosphere Insulin System may be delayed. Any such events would delay the submission of our Technosphere Insulin System for regulatory approval or market introduction and subsequent sales 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 our Technosphere Insulin System or any other product candidate 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 currently obtain our Technosphere precursor raw material primarily from Degussa AG. We use our Danbury, Connecticut facility to formulate Technosphere Insulin, fill plastic cartridges with Technosphere Insulin and blister package the cartridges for our clinical trials. We presently intend to increase our formulation, fill and finishing capabilities at Danbury in order to accommodate our activities through initial commercialization. This expansion will involve a number of third-party suppliers of equipment and materials as well as engineering and construction services. Our suppliers may not deliver all of the required equipment, materials and services in a timely manner or at reasonable prices. If we encounter difficulties in our relationships with these suppliers, or if a supplier becomes unable to provide us with goods or services at the agreed-upon price, our facilities expansion could be delayed or its costs increased.

We have never manufactured our Technosphere Insulin System or any other product candidate in commercial quantities. As our product candidates move through the regulatory process, we will need to either develop the capability of manufacturing on a commercial scale or engage third-party manufacturers with this capability, and we cannot offer assurances that we will be able to do either successfully. 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. In addition, before we would be able to produce commercial quantities of Technosphere Insulin at our Danbury facility, it would have to undergo a pre-approval inspection by the FDA. The expansion process and preparation for the FDA's pre-approval inspection for commercial production at the Danbury facility could take an additional six months or longer. If we use a third-party supplier to formulate Technosphere Insulin or produce raw material, the transition could also require significant start-up time to qualify and implement the manufacturing process. If we engage a third-party manufacturer, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs and 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 we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for such products and we would lose potential revenues.

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

Our research and development work involves the controlled storage and use of hazardous materials, including chemical, radioactive and biological materials. In addition, our manufacturing operations involve the use of CBZ-lysine, which 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 is, in turn, indemnified for these known environmental conditions by the previous owner. We initiated the final stages of the soil cleanup plan which we estimate will cost $1.5 to $2.0 million to complete by the end of 2007. 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. In the event that any cleanup costs are imposed on us and we are unable to collect the full amount of these costs and expenses from the seller or the party responsible for the contamination, we may be required to pay these costs and 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.*

A broad base of physicians, including primary care physicians, internists and endocrinologists, treat patients with diabetes. A large sales force will be required in order to educate and support these physicians. Therefore, we may enter into collaborations with one or more pharmaceutical companies to market, distribute and sell our Technosphere Insulin System, 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 we estimate that establishing a specialty sales force would cost more than $35 million. Because of our size, we would be at a disadvantage to our potential competitors, all of which either are or have collaborated with large pharmaceutical companies that have substantially more resources than we do. As a result, we would not initially be able to field a sales force as large as our competitors or provide the same degree of market research or marketing support. In addition, our competitors would have a greater ability to devote research resources toward expansion of the indications for their products. 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 payors and the healthcare community, we may be unable to generate significant revenue, if any.

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

The degree of market acceptance of our Technosphere Insulin System and our other product candidates will depend on many factors, including:

- the claims for which FDA approval can be obtained, including superiority claims;
- the perceived advantages and disadvantages of competitive products;
- the willingness and ability of patients and the healthcare community to adopt new technologies;
- the ability to manufacture the product in sufficient quantities with acceptable quality and at an acceptable cost;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of the product compared to those of competing products or therapies;

- the convenience and ease of administration of the product relative to existing treatment methods;
- the pricing and reimbursement of the product relative to existing treatment therapeutics and methods; and
- marketing and distribution support for the product.

Physicians will not recommend a product until clinical data or other factors demonstrate the safety and efficacy of the product. Even if the clinical safety and efficacy of our product candidates is established, physicians may elect not to recommend these product candidates for a variety of factors, including the reimbursement policies of government and third-party payors and the effectiveness of our competitors in marketing their therapies. Because of these and other factors, any product that we may develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. In addition, because each third-party payor 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 payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be considered cost-effective or that 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 our Technosphere Insulin System 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 our Technosphere Insulin System. In addition, we carry local policies per trial in each country in which we conduct clinical trials that requires us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales in the future if our Technosphere Insulin System 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, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and, if so, our business and results of operations would be harmed and the market price of our common stock may decline.

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

In order to commercialize our product candidates successfully, we will be required to expand our work force, particularly in the areas of manufacturing, 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 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 also serving as the Chairman and Co-Chief Executive Officer of Advanced Bionics Corporation, a wholly owned subsidiary of Boston Scientific Corporation. Mr. Mann 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.

We have been sued by our former Chief Medical Officer. As a result of this litigation, we may incur material costs and suffer other consequences, which may adversely affect us.*

In May 2005, Dr. Cheatham filed a complaint against us in the California Superior Court. The complaint alleges causes of action for wrongful termination in violation of public policy, breach of contract and retaliation in connection with the termination of Dr. Cheatham's employment. In the complaint, Dr. Cheatham seeks compensatory, punitive and exemplary damages in excess of $2.0 million as well as reimbursement of attorneys' fees. In June 2005, we answered the complaint and also filed a cross-complaint against Dr. Cheatham, alleging claims for libel per se, trade libel, breach of contract, breach of the implied covenant of good faith and fair dealing and breach of the duty of loyalty. In July 2005, Dr. Cheatham filed a demurrer, and a motion to strike our cross-complaint under California's anti-SLAPP statute. In September 2005, the California Superior Court overruled Dr. Cheatham's demurrer and denied his motion to strike the Company's cross-complaint. In November 2005, Dr. Cheatham appealed the Court's ruling denying his motion to strike. Oral argument on the appeal is scheduled for November 21, 2006. In July 2006, the Company filed a motion for summary judgment, or in the alternative, for summary adjudication, requesting dismissal before trial of Dr. Cheatham's claims against the Company. In October 2006, the Superior Court denied the motion. Discovery as to Dr. Cheatham's claims against us is proceeding, and this case is scheduled for trial to commence in February 2007.

The litigation will result in costs and divert management's attention and resources, any of which could adversely affect our business, results of operations or financial position. We are also concerned that, despite the findings by an independent counsel following an investigation and despite the endorsement of the independent counsel's report by our board of directors, investors could give undue weight to Dr. Cheatham's allegations, resulting in damage to our reputation, or the FDA could begin an investigation, either of which could adversely affect the trading price of our common stock. To date, we have not been notified of any investigation by the FDA. If we are not successful in this litigation, we could be forced to make a significant settlement or judgment payment to Dr. Cheatham, which could adversely affect our business, results of operations or financial position.

Our facilities that are located in Southern California may be affected by natural disasters.

Our headquarters and some of our research and development activities are located in Southern California, where they are subject to an enhanced risk of natural and other disasters such as power and telecommunications failures, mudslides, fires and earthquakes. A fire, earthquake or other catastrophic loss that causes significant damage to our facilities or interruption of our business could harm our business. We do not carry insurance to cover losses caused by earthquakes, and the insurance coverage that we carry for fire damage and for business interruption may be insufficient to compensate us for any losses that we may incur.

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, management's assessment of 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 error 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 ineffective 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 preclinical 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 our Technosphere Insulin System, 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 regulation 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 expect, based on our discussions with the FDA and on our understanding of the interactions between the FDA and other pharmaceutical companies developing inhaled insulin delivery systems, that we will need safety data covering at least two years from patients treated with our Technosphere Insulin System and that we must complete a two-year carcinogenicity study and an additional six-month carcinogenicity study of Technosphere Insulin in rodents to obtain approval, among other requirements. We cannot be certain when or under what conditions we will undertake further clinical trials. 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 our Technosphere Insulin System. 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 our Technosphere Insulin System, 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 all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products for government reimbursement. 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. On January 26, 2006, the FDA approved the first inhaled insulin product, Exubera. This may impact the development and registration of our Technosphere Insulin System in many ways, including: the approval of Exubera may increase the difficulty of enrolling patients in our clinical trials; Exubera may be viewed as standard of care by the FDA and used as a reference for the safety/efficacy evaluations of our Technosphere Insulin System; and the approval standards set for Exubera may be applied to other products that follow including our Technosphere Insulin System. The FDA has advised us that it will regulate our Technosphere Insulin System as a "combination product" because of the complex nature of the system that includes the combination of a new drug (Technosphere Insulin) and a new medical device (the MedTone inhaler used to administer the insulin). The FDA indicated that the review of a future drug marketing application for our Technosphere Insulin System will involve three separate review groups of the FDA: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health within the FDA that reviews medical devices. We currently understand that the Metabolic and Endocrine Drug Products Division will be the lead group and will obtain consulting reviews from the other two FDA groups. The FDA has not made an official final decision in this regard, however, and we can make no assurances at this time about what impact FDA review by multiple groups will have on the review and approval of our product or whether we are correct in our understanding of how the Technosphere Insulin System will be reviewed and approved.

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 our Technosphere Insulin System as a combination product therapy may lengthen the product development and regulatory approval process, increase our development costs and delay or prevent the commercialization of our Technosphere Insulin System.

We are developing our Technosphere Insulin System as a new treatment for diabetes utilizing unique, proprietary components. As a combination product, any changes to either the MedTone inhaler, the Technosphere material or the insulin, including new suppliers, could possibly result in FDA requirements to repeat certain clinical studies. This means, for example, that switching to an alternate delivery system could require us to undertake additional clinical trials and other studies, which could significantly delay the development and commercialization of our Technosphere Insulin System. Our product candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.

We currently expect that our inhaler will be reviewed for approval as part of the NDA for our Technosphere Insulin System. No assurances exist that we will not be required to obtain separate device clearances or approval for use of our inhaler with our

Technosphere Insulin System. This may result in our being subject to medical device review user fees and to other device requirements to market our inhaler and may result in significant delays in commercialization. Even if the device component is approved as part of our NDA for the Technosphere Insulin System, numerous device regulatory requirements still apply to the device part of the drug-device combination.

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 our Technosphere Insulin System and other product candidates until we have obtained regulatory approval. We have 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. Regulatory authorities may limit the segments of the diabetes population to which we or others may market our Technosphere Insulin System or limit the target population for our other product candidates. Based on currently available clinical studies, we believe that our Technosphere Insulin System 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 and other advantages, if any, of the Technosphere Insulin System have clinical significance or can be confirmed in head-to-head clinical trials against appropriate approved comparator insulin drug products. Such comparative clinical trials are required to make these types of superiority claims in labeling or advertising. These aforementioned observations and others may therefore not be capable of substantiation in comparative clinical trials prior to our NDA submission, if at all, or otherwise may not be suitable for inclusion in product labeling or advertising and, as a result, our Technosphere Insulin System may not have competitive advantages when compared to other insulin products.

The manufacture, marketing and sale of these product candidates will be subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning safety or efficacy of the product occur following approval. In response to questions that have been raised about the safety of certain approved prescription products, including the lack of adequate warnings, the FDA and Congress are currently considering new regulatory and legislative approaches to advertising, monitoring and assessing the safety of marketed drugs, including legislation providing the FDA with authority to mandate labeling changes for approved pharmaceutical products, particularly those related to safety. We also cannot be sure that the current Congressional and FDA 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 and will likely be subject to an FDA preapproval inspection before the agency will approve a future marketing application for our Technosphere Insulin System.*

Our insulin supplier sells its product outside of the US, however, we can make no assurances that our insulin supplier will be acceptable to the FDA. 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 our Technosphere Insulin System. We also depend on suppliers for other materials that comprise our Technosphere Insulin System, including our MedTone inhaler and cartridges. All of our device suppliers must comply with relevant regulatory requirements including QSR. It also is likely that major suppliers will be subject to FDA preapproval inspections before the agency will approve a future marketing application for our Technosphere Insulin System. At the present time our insulin supplier is certified to the ISO9001:2000 Standard. There can be no assurance, however, that if the FDA were to conduct a preapproval inspection of our insulin supplier or other suppliers, that the agency would find that the supplier substantially comply 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.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the indicated uses for which the product candidate may be marketed or contain requirements for potentially costly post-marketing follow-up clinical trials.

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 our product 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 the pulmonary delivery of insulin, we could encounter delays in the timing of our clinical trials or difficulties in obtaining the approval of our Technosphere Insulin System. As well, the public perception of our products 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 product.

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, know-how 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 similar 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 US. 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 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 infringer 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 US Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

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

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

Over the past three decades the number of patents issued to biotechnology companies has expanded dramatically. As a result it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner's patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry. For example, in August 2006, Novo Nordisk filed a lawsuit against Pfizer claiming that Pfizer's product Exubera infringes certain patents owned by Novo Nordisk that cover inhaled insulin treatment for diabetes. In its lawsuit, Novo Nordisk is seeking compensatory damages and permanent injunctive relief and has filed a motion for a preliminary injunction, seeking a court order that, if granted could substantially impact Pfizer's ability to commercialize Exubera while the lawsuit is in progress.

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.

Although we own a number of domestic and foreign patents and patent applications relating to our Technosphere Insulin System and cancer vaccine products under development, we have identified certain third-party patents having claims relating to chemical compositions of matter and pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of our Technosphere Insulin System. We have also identified third-party patents disclosing methods of use and compositions of matter related to DNA-based vaccines that also may trigger an allegation of infringement upon the commercial manufacture and sale of our cancer therapy. 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 final trade names for some of our products and product candidates; therefore, we have not filed trademark registrations for our potential trade names for those products 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. 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;

- announcements by us or our competitors concerning their clinical trial results, acquisitions, strategic alliances, technological innovations and newly approved commercial products;
- the availability of critical materials used in developing and manufacturing our Technosphere Insulin System or other product candidates;
- developments concerning our patents, proprietary rights and potential infringement claims;
- developments in our litigation with our former Chief Medical Officer;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- changes in securities analysts' estimates of our financial and operating performance;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders; and
- discussion of our Technosphere Insulin System, 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.

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 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.*

Mr. Mann has been our primary source of financing to date. At September 30, 2006, Mr. Mann beneficially owned approximately 48.9% of our outstanding shares of capital stock. Members of Mr. Mann's family beneficially owned at least an additional 2.0% of our outstanding shares of common stock, although Mr. Mann does not have voting or investment power with respect to these shares. By virtue of his holdings, Mr. Mann can and will continue to be able 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 federal and state securities laws, Mr. Mann is free to sell the shares of our stock he holds at any time. Upon his death, we have been advised by Mr. Mann that his shares of our capital stock will be left to the Alfred E. Mann Medical Research Organization, or AEMMRO, and AEM Foundation for Biomedical Engineering, or AEMFBE, not-for-profit medical research foundations that serve as funding organizations for Mr. Mann's various charities, including the Alfred Mann Foundation, or AMF, and the Alfred Mann Institutes at the University of Southern California and at the Technion-Israel Institute of Technology, 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, four of his children and Dr. Joseph Schulman, the director of AMF. The AEMFBE is

a membership foundation consisting of five members, including Mr. Mann and the same four 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 could negatively affect our stock price.*

As of September 30, 2006, we had approximately 49.7 million shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registrations rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

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

Our amended and restated certificate of incorporation and bylaws include anti-takeover 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, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

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

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

On February 24, 2006, we issued 979 shares of our common stock to a holder of one of our outstanding warrants upon that holder's cash exercise of the warrant. The warrant had an exercise price of $12.228 per share, for an aggregate exercise price paid to us of $11,971. For this issuance, we relied on the exemption provided by Section 4(2) of the Securities Act.

On March 20, 2006, we issued 98,441 shares of our common stock to a holder of one of our outstanding warrants upon the net exercise of the warrants by the holder. For these issuances, we relied on the exemption provided by Section 4(2) of the Securities Act.

On September 22, 2006, we issued 156,633 shares of our common stock to a holder of one of our outstanding warrants upon that holder's cash exercise of the warrant. The warrant had an exercise price of $12.228 per share, for an aggregate exercise price paid to us of $1,915,308. For this issuance, we relied on the exemption provided by Section 4(2) of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

(a) On October 30, 2006, we entered into an Allonge #1 to the promissory note made by us in favor of Alfred E. Mann dated August 2, 2006. Pursuant to the Allonge, the minimum amount that we can borrow under the note was reduced from $50 million to $10 million, and we are now permitted to re-borrow any principal amount that we previously borrowed and repaid, subject to the limitations in the note.

(b) There were no material changes to the procedures by which security holders may recommend nominees to our board of directors.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(1)	Form of common stock certificate.
4.2(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.
10.1(2)	Promissory Note made by MannKind in favor of Alfred E. Mann dated August 2, 2006.
10.2	Allonge #1 dated October 30, 2006 to Promissory Note made by MannKind in favor of Alfred E. Mann.
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 filed with the SEC on August 3, 2006.

SIGNATURE

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

Dated: November 1, 2006

MannKind Corporation

By: /s/ Richard L. Anderson
Richard L. Anderson
Corporate Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 10.2

ALLONGE # 1

This Allonge # 1 is hereby attached to and made a part of the Promissory Note dated August 2, 2006 (the "Note") executed by **MannKind Corporation**, a Delaware corporation ("Borrower") in the original principal amount of $150,000,000 in favor of **Alfred E. Mann** ("Lender"). All capitalized terms not otherwise defined herein shall have the meanings ascribed to such terms in the Note.

1. Section 4.4 of the Note is hereby amended by deleting the last sentence thereof and substituting therefor: "Any amount prepaid pursuant to Section 4.2 or Section 4.3 hereof may be reborrowed in accordance with Section 5 hereof."

2. Section 5 of the Note is hereby amended by deleting "$50,000,000" in the 7th line thereof and substituting therefor "$10,000,000".

IN WITNESS WHEREOF, the parties hereto have caused this Allonge # 1 to be executed and delivered by their duly authorized officers on October 30, 2006.

MannKind Corporation

By: /s/ Dick Anderson
Name: Dick Anderson
Title: Chief Financial Officer

/s/ Alfred E. Mann
Alfred E. Mann

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

I, Alfred E. Mann, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the three months ended September 30, 2006 of MannKind Corporation;

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

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

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

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

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

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

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

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

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

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

Date: November 1, 2006

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

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

I, Richard L. Anderson, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the three months ended September 30, 2006 of MannKind Corporation;

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

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

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

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

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

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

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

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

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

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

Date: November 1, 2006

/s/ Richard L. Anderson
Richard L. Anderson
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
RULE 13a-14(b) OR 15d-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (18 U.S.C. § 1350)

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended September 30, 2006, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report") and pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Alfred E. Mann, Chief Executive Officer of MannKind Corporation (the "Company"), and Richard L. Anderson, Chief Financial Officer of the Company, each hereby certifies to the best of his knowledge that:

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

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

Date: November 1, 2006

/s/ Alfred E. Mann	/s/ Richard L. Anderson
Alfred E. Mann Chief Executive Officer	Richard L. Anderson Chief Financial Officer

These certifications are being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.