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, 2005

or

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

For the transition period from _____ to _____.

Commission File Number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☑

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

As of November 8, 2005, there were 50,234,454 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, 2005

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ITEM 1. FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
(In thousands except share data)

	September 30, 2005 (unaudited)	December 31, 2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 69,238	$ 78,987
Marketable securities	113,166	11,546
Restricted cash	18	583
State research and development credit exchange receivable	1,233	1,500
Prepaid expenses and other current assets	3,451	3,265
Total current assets	187,106	95,881
PROPERTY, PLANT AND EQUIPMENT – net	71,387	66,511
STATE RESEARCH AND DEVELOPMENT CREDIT EXCHANGE RECEIVABLE – net of current portion	1,249	1,030
OTHER ASSETS	282	61
TOTAL	$ 260,024	$ 163,483
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,407	$ 3,477
Accrued expenses and other current liabilities	13,553	8,194
Deferred compensation	—	1,373
Total current liabilities	18,960	13,044
OTHER LIABILITIES	36	76
Total liabilities	18,996	13,120
STOCKHOLDERS' EQUITY:		
Undesignated preferred stock, $0.01 par value—10,000,000 shares authorized; no shares issued or outstanding at September 30, 2005 and December 31, 2004	—	—
Common stock, $0.01 par value—90,000,000 shares authorized; 50,205,534 and 32,756,237 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	501	327
Additional paid-in capital	764,529	592,999
Accumulated other comprehensive income	8	—
Deficit accumulated during the development stage	(524,010)	(442,963)
Total stockholders' equity	241,028	150,363
TOTAL	$ 260,024	$ 163,483

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, 2005
	2005	2004	2005	2004	
Revenue	$ —	$ —	$ —	$ —	$ 2,858
Operating expenses:					
Research and development	24,466	11,790	66,758	38,901	269,671
General and administrative	8,396	8,713	16,318	16,552	91,658
In-process research and development costs	—	—	—	—	19,726
Goodwill impairment	—	—	—	—	151,428
Total operating expenses	32,862	20,503	83,076	55,453	532,483
Loss from operations	(32,862)	(20,503)	(83,076)	(55,453)	(529,625)
Other income (expense)	(29)	37	(8)	112	(1,978)
Interest income	1,161	278	2,038	499	7,609
Loss before provision for income taxes	(31,730)	(20,188)	(81,046)	(54,842)	(523,994)
Income taxes	—	—	(1)	—	(16)
Net loss	(31,730)	(20,188)	(81,047)	(54,842)	(524,010)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	—	(19,210)	—	(19,822)	(22,260)
Accretion on redeemable preferred stock	—	—	—	(60)	(952)
Net loss applicable to common stockholders	$ (31,730)	$ (39,398)	$ (81,047)	$ (74,724)	$ (547,222)
Net loss per share applicable to common stockholders – basic and diluted	$ (0.73)	$ (1.40)	$ (2.23)	$ (3.29)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	43,460	28,051	36,373	22,687	

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, 2005
	2005	2004	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (81,047)	$ (54,842)	$ (524,010)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,463	5,370	28,709
Stock-based compensation expense (benefit)	(587)	9,381	23,659
Loss/(gain) on sale and abandonment/disposal of property and equipment	(1)	365	3,350
Accrued interest on investments, net of amortization of premiums	(107)	—	(107)
Loss on available-for-sale securities	—	94	229
Accrued interest on notes	—	(78)	(744)
Goodwill impairment	—	—	151,428
In-process research and development	—	—	19,726
Accrued interest expense on notes payable to stockholders	—	—	1,538
Discount on stockholder notes below market rate	—	—	241
Non-cash compensation expense of officer resulting from stockholder contribution	—	—	70
Changes in assets and liabilities:			
State R&D credit exchange receivable	48	(4,026)	(2,482)
Prepaid expenses and other current assets	(186)	(187)	(3,451)
Other assets	(221)	140	(282)
Accounts payable	1,930	(497)	5,407
Accrued expenses and other current liabilities	5,359	2,367	13,553
Other liabilities	(40)	(62)	34
Payment of deferred compensation	(1,373)	(271)	—
Net cash used in operating activities	(70,762)	(42,246)	(283,132)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	(216,200)	(4,999)	(360,768)
Sales of marketable securities	114,695	1,730	247,490
Purchase of property and equipment	(10,428)	(4,632)	(103,628)
Proceeds from sale of property and equipment	90	—	182
Restricted cash	565	(22)	(18)
Net cash used in investing activities	(111,278)	(7,923)	(216,742)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants for cash	172,291	83,173	492,862
Collection of Series C convertible preferred stock subscriptions receivable	—	18,153	50,000
Payable to stockholder	—	(1,406)	—

	Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30, 2005
	2005	2004	
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)
Cash received for common stock to be issued	—	—	3,900
Repurchase of common stock	—	—	(1,028)
Issuance of Series B convertible preferred stock for cash	—	—	15,000
Borrowings on notes payable	—	—	3,460
Net cash provided by financing activities	172,291	99,920	569,112
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(9,749)	49,751	69,238
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	78,987	47,020	—
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 69,238	$ 96,771	$ 69,238
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$ 1	$ —	$ 16
Notes receivable by stockholder issued to officers	—	(225)	—
Accretion on redeemable convertible preferred stock	—	(60)	(952)
Increase in additional paid-in capital resulting from merger	—	—	171,154
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	—	(5,188)	(5,248)
Issuance of common stock upon conversion of notes payable	—	—	3,331
Issuance of common stock for notes receivable	—	—	2,758
Issuance of put option by stockholder	—	—	(2,949)
Put option redemption by stockholder	—	—	1,921
Interest paid in cash	—	—	80

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, 2004 are included in the annual report on Form 10-K for the fiscal year ended December 31, 2004 filed with the SEC on March 16, 2005.

On July 22, 2004, the Company effected a one-for-three reverse stock split of its common stock. All share and per share amounts included in these unaudited consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

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, 2005 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.

Reclassification — Auction rate securities amounting to $7.1 million previously included in cash and cash equivalents as of December 31, 2003 have been reclassified to marketable securities resulting in a reduction in cash equivalents for the beginning of the nine months ended September 30, 2004 in the accompanying consolidated statements of cash flows.

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, 2005 the Company has reported accumulated net losses of $524.0 million which includes a goodwill impairment charge of $151.4 million. Also, since its inception through September 30, 2005, the Company has reported negative cash flow from operations of $283.1 million. It is costly to develop therapeutic products and conduct clinical trials for these products. Based upon the Company's current expectations, management believes the Company's existing capital resources, including the net proceeds of approximately $170.2 million from its private placement in August 2005, will enable it to continue planned operations into the third quarter of 2006. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. If planned operating results are not achieved or the Company is not successful in raising additional equity financing or entering into a collaborative agreement, management believes that planned expenditures could be reduced substantially, extending the time period over which the Company's currently available capital resources will be adequate to fund the Company's operations, on a reduced basis, through 2006.

2. Financings

On August 2, 2004, the Company completed an initial public offering of its common stock at a price to the public of $14.00 per share. The Company sold 6,250,000 shares of common stock in the offering resulting in net proceeds of $79.2 million. In connection with this offering, the underwriters exercised an option to purchase 307,100 shares which closed on September 1, 2004 with net proceeds to the Company of $4.0 million. Additionally, in connection with the initial public offering, all of the outstanding shares of the Company's preferred stock were converted into shares of its common stock. Accordingly, the automatic conversion of preferred stock

on August 2, 2004 into common stock is reflected in the accompanying consolidated financial statements. A summary of the terms of the offering can be found in the Prospectus filed by the Company pursuant to Rule 424(b) under the Securities Act of 1933, as amended with the SEC on July 28, 2004.

On August 5, 2005, the Company closed a $175.0 million private placement of newly issued shares of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock to accredited investors including the principal stockholder who purchased $87.3 million of the private placement. The Company sold 17,132,000 shares of common stock in the private placement, together with warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share. In connection with this private placement, the Company paid $4.5 million in commissions to the placements agents and incurred $0.3 million in other offering expenses which resulted in net proceeds of approximately $170.2 million.

3. Investment in securities

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

	As of September 30, 2005		As of December 31, 2004	
(in thousands)	Cost basis	Fair value	Cost basis	Fair value
US government securities	$ —	$ —	$ 1,443	$ 1,443
Corporate debt instruments	—	—	2,353	2,353
Auction rate municipal bonds	113,158	113,166	7,750	7,750
	$ 113,158	$ 113,166	$ 11,546	$ 11,546

The net proceeds from the private placement, which closed in August 2005, have been invested in marketable securities and cash equivalents in accordance with the Company's investment policy which requires the average maturity of the portfolio not to exceed 12 months.

4. Accounting for stock-based compensation

The Company accounts 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 its interpretations, and has adopted the disclosure-only alternative of Statement of Financial Accounting Standards ("SFAS") No. 123 ("SFAS No. 123"), "Accounting for Stock-based Compensation". Stock options issued to consultants are accounted for in accordance with the provisions of Emerging Issues Task Force Issue ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and Financial Accounting Standard Board ("FASB") Interpretation No. 28 ("FIN 28"), "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans". Accordingly, no compensation expense is recorded for options issued to employees with fixed share amounts and fixed exercise prices which are at least equal to the fair value of the Company's common stock at the date of grant. Conversely, when the exercise price is below fair value of the Company's common stock on the date of grant, a non-cash charge to compensation expense is recorded for the amount equal to the difference between the exercise price and the fair value ratably over the term of the option vesting period. On October 7, 2003, the Company's board of directors approved a repricing program for certain outstanding options to purchase shares of our common stock granted under each of our stock plans. Compensation cost for all options repriced under the repricing program is measured on a quarterly basis until the options expire or are exercised or canceled. The Company uses the fair-value method to account for non-employee stock-based compensation.

Stock options granted during the nine months ended September 30, 2005 are as follows:

	Number of Shares	Exercise Price Per Share	Weighted Average Exercise Price Per Share
For the three months ended:			
March 31, 2005	342,616	$13.02-$14.72	$13.85
June 30, 2005	348,000	$12.52	$12.52
September 30, 2005	329,650	$11.60	$11.60

On January 31, 2005, the Company's board of directors approved stock option grants to the Chief Executive Officer and the President

and Chief Operating Officer to purchase an aggregate of 185,000 shares of common stock which vest annually over four years at an exercise price of $13.39 per share.

On February 14, 2005, the Company's board of directors approved new hire stock option grants to purchase 127,616 shares of common stock which vest annually over four years at an exercise price of $14.72 per share.

Pursuant to the 2004 Non-Employee Directors' Stock Option Plan, a stock option grant to purchase 30,000 shares of common stock at an exercise price of $13.02 was awarded to a non-employee director in March 2005 upon his acceptance of an appointment to the Company's board of directors. This option vests in three equal annual installments.

On May 24, 2005, the Company's board of directors approved new hire and promotion stock option grants to purchase 290,500 shares of common stock which vest annually over four years at an exercise price of $12.52 per share. Additionally, options to purchase 57,500 shares of common stock were automatically granted on May 24, 2005, the day of the annual stockholders meeting, to non-employee directors pursuant to the 2004 Non-Employee Directors Stock Option Plan.

On August 16, 2005, the Company's board of directors approved new hire and promotion stock option grants to purchase 329,650 shares of common stock which vest annually over four years at an exercise price of $11.60 per share.

If the Company had determined compensation cost for grants issued during the current and prior periods based on the fair-value approach in accordance with SFAS No. 123, pro forma net loss and net loss per share would have been as follows:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands, except per share data)	2005	2004	2005	2004
Net loss applicable to common stockholders — as reported	$ (31,730)	$ (39,398)	$ (81,047)	$ (74,724)
Add (deduct): Stock-based employee compensation expense (benefit) included in reported net loss	2,296	6,969	(885)	9,349
Deduct: Stock-based compensation expense determined under fair value method	(3,548)	(2,642)	(10,588)	(6,751)
Net loss applicable to common stockholders — pro forma	$ (32,982)	$ (35,071)	$ (92,520)	$ (72,126)
Net loss per share applicable to common stockholders (basic and diluted):				
As reported	$ (0.73)	$ (1.40)	$ (2.23)	$ (3.29)
Pro forma	$ (0.76)	$ (1.25)	$ (2.54)	$ (3.18)

Pro forma information regarding net loss applicable to common stockholders and net loss per share applicable to common stockholders required by SFAS No. 123 was estimated at the date of grant using a Black-Scholes option valuation model with the following weighted-average assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Risk-free interest rate	4.12%	3.48%	3.80%	3.45%
Dividend yield	0%	0%	0%	0%
Volatility factor	100%	100%	100%	100%
Weighted average expected life	4 years	4 years	4 years	4 years

5. Net loss per common share

Basic net loss per common share excludes dilution for potentially dilutive securities and is computed by dividing the loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period. Common shares outstanding during the period include shares of common stock issued in exchange for notes receivable, including those that are being accounted for as in-substance stock options. Diluted net loss per common 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 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 and warrants, that are not included in the diluted net loss per share calculation consisted of an aggregate of 7,916,772 shares and 4,038,091 shares as of September 30, 2005 and 2004, respectively.

6. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income 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. The Company has recorded an offset to research and development expenses of $5.5 million through the nine months ended September 30, 2004 and $1.1 million for the nine months ended September 30, 2005 related to this research and development credit exchange program. The three months ended September 30, 2004 was the first period in which the Company was able to recognize the benefit of these credits for financial reporting purposes, and thus $4.3 million of the $5.5 million recognized as an offset to research and development expenses during that period was attributable to research and development expenditures in prior periods. Of these amounts, approximately $1.5 million consisted of cash received during 2004 and $1.5 million received in April 2005.

7. Property and equipment

Property and equipment consist of the following:

	As of:	
(in thousands)	**September 30, 2005**	**December 31, 2004**
Land	$ 5,273	$ 5,273
Buildings	9,565	9,566
Building improvements	39,448	37,397
Machinery and equipment	21,948	18,080
Computer equipment and software	4,201	3,308
Furniture, fixtures and office equipment	2,451	2,391
Leasehold improvements	633	627
Construction in progress	5,734	3,326
Deposits on equipment	6,411	5,911
	95,664	85,879
Less accumulated depreciation and amortization	(24,277)	(19,368)
Property and equipment, net	$ 71,387	$ 66,511

8. 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 December 31, 2004 and September 30, 2005, 32,756,237 and 50,205,534 shares of common stock, respectively, were issued and outstanding. No shares of preferred stock were issued and outstanding at December 31, 2004 and September 30, 2005.

9. 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. During the second quarter ended June 30, 2005, warrants to purchase 110,888 shares of common stock were exchanged for 24,210 shares of common stock resulting in stock-based compensation expense of $245,000 based on a fair market value of the common stock of $10.12 per share. As of September 30, 2005, the remaining warrants to purchase 20,740 shares of common stock 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. See also Note 2 - Financings.

10. Recently issued accounting pronouncements

In May 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections” (“SFAS No. 154”), which replaces APB Opinion No. 20, “Accounting Changes” and SFAS No. 3, “Reporting Accounting Changes in Interim Financial Statements – An Amendment of APB Opinion No. 28”. SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company believes that the adoption of this statement will not have a material effect on its financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 123R, “Share-based Payment: an Amendment of FASB Statements No. 123 and 95” (“SFAS No. 123R”). The statement requires companies to expense share-based payments to employees, including stock options, based on the fair value of the award at the grant date. The statement also eliminates the intrinsic value method of accounting for stock options permitted by APB No. 25, which the Company currently follows. The Company is required to adopt the standard for the quarter that begins January 1, 2006. While the fair value method under SFAS No. 123R is very similar to the fair value method under SFAS No. 123 with regards to measurement and recognition of stock-based compensation, management is currently evaluating the impact of several of the key differences between the two standards on the Company’s financial statements. For example, SFAS No. 123 permits recognition of forfeitures as they occur while SFAS No. 123R will require estimating future forfeitures and adjusting estimates on a quarterly basis. SFAS No. 123R will also require a classification change in the statement of cash flows, whereby a portion of any tax benefit from stock options will move from operating cash flows to financing cash flows (total cash flows will remain unchanged). While the Company continues to evaluate the impact of SFAS No. 123R on its financial statements, management believes that the expensing of stock-based compensation will have an impact on the Company’s Statements of Operations similar to the pro forma disclosure under SFAS No. 123. See also Note 4 — Accounting for stock-based compensation.

In March 2004, the FASB ratified the measurement and recognition guidance and certain disclosure requirements for impaired securities as described in EITF Issue No. 03-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments”. On November 3, 2005, the FASB issued FASB Staff Position (“FSP”) Nos. FAS 115-1 and FAS 124-1 which addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, “Accounting for Certain Investments in Debt and Equity Securities”, and No. 124, “Accounting for Certain Investments Held by Not-for-Profit Organizations” and APB Opinion No. 18, “The Equity Method of Accounting for Investments in Common Stock”. The FSP is effective for reporting periods beginning after December 15, 2005. Management has not determined what impact the adoption of the measurement and recognition guidance in EITF Issue No. 03-1 and the FSP will have on the Company’s financial statements.

11. Commitments and contingencies

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.

Additionally, 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.

During the year ended December 31, 2000, the Company issued an aggregate 699,972 shares of common stock to three consultants in exchange for notes receivable aggregating approximately $10,891,000. The notes are collateralized by the underlying common stock and bear interest at fixed rates. The notes-for-stock transactions have been accounted for as in-substance stock option grants to non-

employees. In November 2004, the borrowers notified the Company that they believed that they had entered into an agreement in October 2001 with the Company's principal stockholder under which the stockholder would purchase from the borrowers some of the common stock, with the proceeds to be paid to the Company to pay down the notes. The borrowers informed the Company that they believe both the Company and the stockholder are in breach of certain agreements related to the transaction and indicated they intend to seek alleged damages arising from any failure of the agreement to be performed. The borrowers have not commenced any legal proceedings against the stockholder or the Company. On October 19, 2005, the principal and interest on the notes aggregating $14,637,000 became due and payable to the Company. As of September 30, 2005, the aggregate 699,972 shares of common stock issued for the notes receivable had a market value aggregating approximately $9,583,000. The Company is pursuing collection and has not deemed the notes uncollectible. As the notes-for-stock transactions were accounted for as in-substance stock option grants to non-employees, there is no impairment to assess for financial reporting purposes. While the outcome of this matter is uncertain, any modification to the terms of the notes could result in additional stock compensation being ascribed to the in-substance options. The amount of any additional stock compensation could have a material impact on the Company's results of operations in the period of modification.

In November 2004, the Company learned that the parent company of a vendor with whom the Company has equipment deposits in the amount of $2.9 million as of September 30, 2005 was experiencing financial difficulties. On September 28, 2005, the parent company emerged from its bankruptcy proceedings. The Company assessed this matter in accordance with SFAS No. 5 and concluded that, based on currently available information, a loss accrual is not warranted.

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 intends to vigorously defend 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 motion to strike the Company's 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 the Company's cross-complaint. On November 4, 2005, Dr. Cheatham filed a notice of appeal of the Court's ruling denying his motion to strike. Discovery as to Dr. Cheatham's claims against the Company is proceeding, and this case is scheduled for trial to commence in July 2006. 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.

In September and October 2005, the principal and interest totaling $1,598,000 on notes issued in exchange for 78,010 shares of common stock to a former executive of the Company became due and payable to the Company. On September 30, 2005, the 78,010 shares of common stock issued in exchange for the notes receivable had a market value of approximately $1,068,000. The Company is pursuing collection and has not deemed the notes uncollectible. As the notes-for-stock transactions were accounted for as in-substance stock option grants, there is no impairment to assess for financial reporting purposes. 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.

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 under the caption "Risk Factors" and elsewhere in this quarterly report on Form 10-Q. 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 thereto for the year ended December 31, 2004 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 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

We are a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. We are currently in Phase 3 clinical trials in the United States and Europe of our lead product, the Technosphere Insulin System, to study its safety and efficacy in the treatment of diabetes. This therapy consists of a proprietary dry powder Technosphere formulation of insulin that is inhaled into the deep lung using our proprietary MedTone inhaler. We believe that the combination of the unique performance characteristics associated with the Technosphere Insulin System, including the rapid transfer of the insulin into the blood, the significantly higher bioavailability, and the convenience and ease of use may result in the potential to change the way diabetes is treated. We are developing additional applications for our proprietary Technosphere platform technology by formulating other drugs for pulmonary delivery, primarily for metabolic and immunological diseases. We are also developing therapies for the treatment of solid-tumor cancers. Our other product-candidates are in research and pre-clinical development.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2005, we have incurred a cumulative net loss of $524.0 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities. On August 5, 2005, we completed a private placement of securities for aggregate net proceeds of $170.2 million.

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 such 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.

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 divided between 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 type 1 and type 2 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.

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 to increase slightly, except for the effects of (non-cash) stock compensation expense resulting from the adoption of Statement of Financial Accounting Standards (“SFAS”) No. 123R, “Share-based Payment: an Amendment of FASB Statement 123 and 95” effective as of January 1, 2006. See “Note 4 — Accounting for stock-based compensation” in the footnotes to our financial statements.

CRITICAL ACCOUNTING POLICIES

There have been no material changes to our critical accounting policies as described in Item 7 to our annual report on Form 10-K for the year ended December 31, 2004.

Results of Operations

The discussion and analysis of our financial condition and results of operations for the three and nine month periods ended September 30, 2005 and 2004 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

No revenues were recorded for the three and nine month periods ended September 30, 2005 or 2004. 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 month periods ended September 30, 2005 and 2004 (dollars in thousands):

	Three months ended September 30,			
	2005	2004	$ Change	% Change
Clinical	$ 12,973	$ 6,585	$ 6,388	97%
Manufacturing	5,609	4,212	1,397	33%
Research	6,217	4,496	1,721	38%
Research and development tax credit	(823)	(5,526)	4,703	(85)%
Stock-based compensation expense	490	2,023	(1,533)	(76)%
Research and development expenses	$ 24,466	$ 11,790	$ 12,676	108%

	Nine months ended September 30,			
	2005	2004	$ Change	% Change
Clinical	$ 34,568	$ 15,326	$ 19,242	126%
Manufacturing	16,878	13,534	3,344	25%
Research	16,474	12,784	3,690	29%
Research and development tax credit	(1,142)	(5,526)	4,384	(79)%
Stock-based compensation expense	(20)	2,783	(2,803)	(101)%
Research and development expenses	$ 66,758	$ 38,901	$ 27,857	72%

The increase in research and development expenses for the three and nine month periods ended September 30, 2005, as compared to the same periods in 2004 was primarily due to ongoing expenses related to the clinical development of our Technosphere Insulin System. Continuation of preclinical and clinical studies in 2005 increased our clinical research expenditures, which also resulted in increased manufacturing costs to supply clinical trial materials and to continue qualification and validation of our manufacturing system. Additionally, research activity related to 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 increase

significantly. 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 research and development tax credit recognized for the three and nine month periods ended September 30, 2005 and 2004 partially offsets our research and development expenses. The State of Connecticut provides an opportunity to exchange certain research and development tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development credits. The three months ended September 30, 2004 was the first period in which we were able to recognize the benefit of these credits for financial reporting purposes, and thus $4.3 million of the $5.5 million recognized as an offset to research and development expenses during that period was attributable to research and development expenditures in prior periods. For the nine months ended September 30, 2005, the Company recognized a $1.1 million research and development credit exchange receivable that was primarily related to 2005 research and development expenditures.

The decrease in stock-based compensation expense for the three and nine month periods ended September 30, 2005 and 2004 primarily results from the effect of the decrease of our stock price since December 31, 2004. A significant portion of the compensation expense is tied to the stock options that were repriced in November 2003 as the compensation cost for all options repriced is measured on a quarterly basis until the options expire or are exercised or canceled.

General and Administrative Expense

The following table provides a comparison of the general and administrative expense categories for the three and nine month periods ended September 30, 2005 and 2004 (dollars in thousands):

	Three months ended September 30,			
	2005	2004	$ Change	% Change
Salaries, employee related and other general expenses	$ 6,571	$ 3,732	$ 2,839	76%
Stock-based compensation expense	1,825	4,981	(3,156)	(63)%
General and administrative expenses	$ 8,396	$ 8,713	$ (317)	(4)%

	Nine months ended September 30,			
	2005	2004	$ Change	% Change
Salaries, employee related and other general expenses	$ 16,884	$ 9,954	$ 6,930	70%
Stock-based compensation expense	(566)	6,598	(7,164)	(109)%
General and administrative expenses	$ 16,318	$ 16,552	$ (234)	1%

General and administrative expenses for the three and nine month periods ended September 30, 2005 decreased as compared to the same periods in 2004. Salaries, other employee related expenses and various other general and administrative expenses, such as insurance, accounting and legal fees increased as a result of operating as a public company. Offsetting increases to general and administrative expenses for these periods was a decrease in stock compensation expense resulting from the effect of the fluctuation of our stock price on the valuation of stock options that were repriced in November 2003. We expect general and administrative expenses to increase slightly, except for the effects of (non-cash) stock compensation expense resulting from the adoption of SFAS No. 123R. See “Note 4 — Accounting for stock-based compensation” in the footnotes to our financial statements.

Deemed Dividend

Deemed dividend for the three and nine month periods ended September 30, 2004 represents the beneficial conversion charge to common stockholders related to the downward adjustment of the Series B and C preferred stock conversion price. All outstanding preferred stock automatically converted into common stock at the close of the initial public offering in the third quarter of 2004, and no further deemed dividend has been or will be recognized.

Interest Income

Interest income for the three and nine month periods ended September 30, 2005 increased compared to the same periods in 2004 primarily due to higher levels of cash equivalents and marketable securities available for investment throughout 2005 compared to 2004.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity securities. On August 5, 2005, we closed a $175.0 million private placement of newly issued shares of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock to accredited investors including our principal stockholder who purchased approximately $87.3 million. We sold 17,132,000 shares of our common stock in the private placement, together with warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share. In connection with this private placement, we paid $4.5 million in commissions to our placements agents and incurred $0.3 million in other offering expenses which resulted in net proceeds of approximately $170.2 million.

During the nine months ended September 30, 2005, operating activities used $70.8 million of cash, primarily due to a net loss of $81.0 million, which included depreciation and amortization of $5.5 million and $1.4 million recognized as research and development credit exchange receivable. Additionally, accounts payable and accrued expenses increased by an aggregate of $7.3 million. Deferred compensation of $1.4 million was repaid in May 2005 and $1.5 million was received in April 2005 related to the Connecticut research and development tax credit exchange. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of our Technosphere Insulin System.

During the nine months ended September 30, 2005, investing activities used $111.3 million of cash. Cash used in investing activities was primarily from net purchases of marketable securities of $101.5 million and $10.4 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.

During the nine months ended September 30, 2005, financing activities provided $172.3 million in cash primarily from the private placement in August 2005 and the exercise of stock options.

As of September 30, 2005, we had $182.4 million in cash, cash equivalents and marketable securities. Although we believe our existing cash resources will be sufficient to fund our anticipated cash requirements into the third quarter of 2006, we will require significant additional financing in the future to fund our operations. If adequate funds are not available, we may be required to delay, reduce or eliminate expenditures for certain of our programs, including our Technosphere Insulin System development activities. Because the majority of our anticipated expenses in the near term can be reduced or eliminated in a relatively short period, we believe that if we are unable to obtain additional capital we can continue activities, on a reduced basis, through the end of 2006.

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.

If we enter into a strategic business collaboration with a pharmaceutical or biotechnology company, we would expect, as part of the transaction, to receive additional capital and share a portion of the costs associated with the development, manufacture and commercialization of our Technosphere Insulin System. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

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, 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, 2005, we did not have any off-balance sheet arrangements as defined under Item 303(a)(4)(ii) of SEC Regulation S-K.

Contractual Obligations

There have been no material changes to our contractual obligations disclosed in Item 7 to our annual report on Form 10-K for the year ended December 31, 2004 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.

Recently Issued Accounting Pronouncements

In May 2005, the FASB issued SFAS No. 154, “Accounting Changes and Error Corrections” (“SFAS No. 154”), which replaces APB Opinion No. 20, “Accounting Changes” and SFAS No. 3, “Reporting Accounting Changes in Interim Financial Statements – An Amendment of APB Opinion No. 28.” SFAS No. 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We believe that the adoption of this statement will not have a material effect on our financial condition or results of operations.

In December 2004, the FASB issued SFAS No. 123R, “Share-based Payment: an Amendment of FASB Statements No. 123 and 95”. The statement requires companies to expense share-based payments to employees, including stock options, based on the fair value of the award at the grant date. The statement also eliminates the intrinsic value method of accounting for stock options permitted by APB No. 25, which we currently follow. We are required to adopt the standard for the quarter that begins January 1, 2006. While the fair value method under SFAS No. 123R is very similar to the fair value method under SFAS No. 123 with regards to measurement and recognition of stock-based compensation, we are currently evaluating the impact of several of the key differences between the two standards on our financial statements. For example, SFAS No. 123 permits recognition of forfeitures as they occur while SFAS No. 123R will require estimating future forfeitures and adjusting estimates on a quarterly basis. SFAS No. 123R will also require a classification change in the statement of cash flows, whereby a portion of any tax benefit from stock options will move from operating cash flows to financing cash flows (total cash flows will remain unchanged). While we continue to evaluate the impact of SFAS No. 123R on our financial statements, we believe that the expensing of stock-based compensation will have an impact on our Statements of Operations similar to the pro forma disclosure under SFAS No. 123.

In March 2004, the FASB ratified the measurement and recognition guidance and certain disclosure requirements for impaired securities as described in EITF Issue No. 03-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments”. On November 3, 2005, the FASB issued FASB Staff Position (“FSP”) Nos. FAS 115-1 and FAS 124-1 which addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. This FSP also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The guidance in this FSP amends FASB Statements No. 115, “Accounting for Certain Investments in Debt and Equity Securities”, and No. 124, “Accounting for Certain Investments Held by Not-for-Profit Organizations” and APB Opinion No. 18, “The Equity Method of Accounting for Investments in Common Stock”. The FSP is effective for reporting periods beginning after December 15, 2005. We have not determined what impact the adoption of the measurement and recognition guidance in EITF Issue No. 03-1 and the FSP will have on our financial statements.

RISK FACTORS

You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. 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, 2005, we had an accumulated deficit of $524.0 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 will 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.

Based upon our current expectations, we believe that our existing capital resources, including the net proceeds from our private placement in August 2005, will enable us to continue planned operations into the third quarter of 2006. 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 expect that we will need 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. 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;
- actions taken by the FDA and other regulatory authorities affecting our products and competitive products;
- our success in establishing strategic business collaborations;
- the timing and amount of milestone or other payments we might receive from potential commercial partnerships;
- the timing and amount of payments we might receive from potential licensees;

- 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 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 currently anticipate conducting several pivotal Phase 3 clinical trials as well as several special population studies involving, in total, more than 3,000 patients, which will require the expenditure of additional time and 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 immunology. 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, the commercialization of our product candidates may be delayed and our business harmed.

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;
- 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;
- other actions by regulators;
- 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; and
- the costs of expanding and maintaining manufacturing operations, as necessary.

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. Pfizer, Inc. and sanofi-aventis, in collaboration with Nektar Therapeutics, have been conducting Phase 3 clinical trials for the Exubera product. In September 2005, an FDA advisory committee panel recommended approval of Exubera for the treatment of adults with type 1 and type 2 diabetes. In October 2005, the Committee for Medicinal Products for Human Use of the European Medicines Evaluation Agency issued a positive opinion recommending approval of Exubera. Novo Nordisk A.S. has a pulmonary insulin product in development. In July 2005, Eli Lilly and Company, in collaboration with Alkermes, Inc., initiated a Phase 3 clinical trial required for registration of their inhaled insulin system and to define the safety and efficacy of the Lilly/Alkermes product. In addition, a number of established pharmaceutical companies have or are developing proprietary technologies or have entered into arrangements with, or acquired, companies with 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 would render our technology and our Technosphere Insulin System less competitive, uneconomical or obsolete. The fact that another company will likely be the first to commercialize a pulmonary insulin system may give that company an advantage in terms of being able to gain reputation and market share as well as set parameters for the pulmonary insulin market such as pricing. 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, our most clinically advanced program, we may not be able to execute on our business model.

Our current strategy for developing, manufacturing and commercializing our 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.

If we are not able to enter into a collaboration on terms that are favorable to us for our products, we could be required to undertake and fund product development, clinical trials, manufacturing and marketing activities solely at our own expense. For example, we are currently evaluating potential collaborations with respect to our Technosphere Insulin System. We currently estimate that the cost to continue the development of the Technosphere Insulin System over the next 12 months would be in the range of $175 to $200 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 following initial Phase 3 clinical trials or with respect to any other product candidate 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 product candidates.

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 product candidates 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 product candidates, including 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 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 a particular 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 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 the second of our Phase 3 studies, a pivotal safety study of our Technosphere Insulin System, primarily to evaluate pulmonary function during long term use. Our Technosphere Insulin System is intended for multiple uses per day. Due to the size and time frame over which the clinical trials are conducted, the results of clinical trials may not be indicative of the effects of long-term use. If long-term use of our product 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 third-party payors do not reimburse customers for our products, they might not be used or purchased, which would adversely affect our revenues.

Our revenues and 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 or profitability 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 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 that will require us to provide scientific and clinical support for the use of each of our products to each third-party payor separately with no assurance that approval will be obtained. This process could delay the market acceptance of new products and could have a negative effect on our revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that these products will be considered cost-effective or that reimbursement to the consumer will be available, in which case our business and results of operations will be harmed 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 will suffer.

We are reaching a critical juncture in our development, transitioning from an early-stage development company to one with multiple Phase 3 clinical trials moving toward commercializing a product. Phase 3 development of the Technosphere Insulin System will be 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. We are in the process of implementing the following measures, among others, to accommodate our transition and successfully implement our commercialization strategy for our Technosphere Insulin System:

- add a significant number of new personnel, particularly in clinical development, regulatory and manufacturing production, including personnel with significant Phase 3-to-commercialization experience;
- expand our manufacturing capabilities;
- develop comprehensive and detailed commercialization, clinical development and regulatory plans;
- implement standard operating procedures, including those for protocol development; and
- align our management structure to accommodate the increasing complexity of our operations.

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.

We have never manufactured any of our product candidates in commercial quantities, and if we fail to develop an effective manufacturing capability for our product candidates or to engage third-party manufacturers with this capability, we may be unable to commercialize these products.

We currently use our Danbury, Connecticut facility to manufacture raw Technosphere material, 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 any of our product candidates 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 will 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 our potential third-party manufacturers fail to deliver the required commercial quantities of our products 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 our products and we would lose potential revenues.

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 will be harmed and the market price of our common stock may 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 source our Technosphere pre-cursor 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 recently 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, our development or manufacturing may be delayed. Any such events would delay the submission of our product candidates 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.

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

A broad base of physicians and specialists treat patients with diabetes. A large sales force will be required in order to educate and support these physicians and specialists. Therefore, we plan to enter into collaborations with one or more pharmaceutical companies to sell, market and distribute our Technosphere Insulin System. If we fail to enter into collaborations, we will 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 $20 million. Because of our size, we would be at a disadvantage to our potential competitors, all of which 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 our products do not become widely accepted by physicians, patients, third-party payors and the healthcare community, we may be unable to generate significant revenue, if any.

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

The degree of market acceptance of our 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 products relative to existing treatment methods;

- the pricing and reimbursement of our products relative to existing treatment therapeutics and methods; and
- marketing and distribution support for our products.

Physicians will not recommend our products until clinical data or other factors demonstrate the safety and efficacy of our products as compared to other treatments. 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, our products may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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 various product candidates, including the Technosphere Insulin System, 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 $5 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 local coverage. We intend to obtain product liability coverage for commercial sales in the future. 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 will be harmed and the market price of our common stock may decline.

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, 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 estimate that the cost to complete the soil cleanup plan for industrial use is $1.5 to $3.0 million over the next 18 to 24 months. 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 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. In October 2005, Dr. Peter Richardson joined us as Corporate Vice President and Chief Scientific Officer. 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, which was acquired by 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. Mr. Mann typically devotes anywhere between 25 and 50 hours a week to our business. 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 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 the Company's cross-complaint. On November 4, 2005, Dr. Cheatham filed a notice of appeal of the Court's ruling denying his motion to strike. Discovery as to Dr. Cheatham's claims against us is proceeding, and this case is scheduled for trial to commence in July 2006.

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. 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.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which, beginning with our fiscal year ending December 31, 2005, will require annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent auditors that both addresses management's assessments and provides for the independent auditor's assessment of the effectiveness of our internal controls. During the course of our testing, we may identify deficiencies which we may not be able to remediate in time to meet the deadline for compliance with Section 404. Testing and maintaining internal controls also involves significant costs and can divert our management's attention from other matters that are important to our business. We may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404, and our independent auditors may not be able or willing to issue a favorable assessment of our conclusions. Failure to achieve and maintain an effective internal control environment could harm our operating results and could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our 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 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 pulmonary 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 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. 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. To our knowledge, no pulmonary insulin product has yet been approved for marketing, and we are not aware of any precedent for the successful commercialization of products based on our technology or technologies similar to ours. However, an application for approval for another pulmonary insulin product candidate was recently filed in the United States, and we believe a decision could be made by the FDA in early 2006. 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, recent events regarding questions about the safety of marketed drugs, 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 or pulmonary insulin products in development, including its approximation of the natural first-phase insulin release spike. 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 recent events regarding questions 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.

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.

For example, in August 2004, an analyst reported that the United Kingdom Committee on the Safety of Medicines had expressed concern that a European application for approval of a drug for the treatment of diabetes was not licensable at the time. Earlier in 2004, sanofi-aventis, on behalf of Pfizer and Nektar, filed for regulatory approval in Europe of Exubera. Although the identity of the drug was not disclosed in the analyst's report, the news nonetheless triggered temporary but sharp declines in the market prices of Nektar's common stock as well as our common stock.

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 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 if we attempt to enforce them and they are challenged in court or in other proceedings, such as oppositions, which may be brought in US or foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the US Patent and Trademark Office, or USPTO.

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. 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 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 a patent and the courts do not always arrive at uniform conclusions.

A third party may claim that we are using inventions covered by such third party’s patents and may go to court to stop us from engaging in our normal operations and activities. These 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 that a court may interpret to restrict our freedom to operate (that is, to cover our products) in the areas of Technosphere formulations, pulmonary insulin delivery and the treatment of cancer. Specifically, 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.

Patent litigation is costly and time-consuming. Among other things, such 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. Although patent and intellectual property disputes in the pharmaceutical area have often been settled for licensing or similar arrangements, associated costs may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business and results of operations and cause the market price of our common stock to decline.

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

We have not selected trade names for some of our products and product candidates; therefore, we have not filed trademark registrations for our potential trade names for those products in any jurisdiction, including the United States. 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

We expect that our stock price will fluctuate significantly.

We completed our initial public offering on August 2, 2004. Prior to that, our stockholders could not buy or sell our common stock publicly. An active public market for our common stock may not continue to develop or be sustained. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks. Since August 2, 2004, the high and low sales price of our common stock has varied significantly, from a low of $8.42 to a high of $24.31. 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;
- 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 National 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. Following the close of the private placement on August 5, 2005, Mr. Mann beneficially owned approximately 48.6% of our outstanding shares of capital stock. Members of Mr. Mann's family beneficially owned at least an additional 1.6% 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 Institute at the University of Southern California, 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, 2005, we had approximately 50.2 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have not used derivative financial instruments for speculation or trading purposes. 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 US money market funds and government and investment-grade corporate 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, 2005, we estimate that the fair value of our investment portfolio would decline by an immaterial amount.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our technology. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our consolidated balance sheet. Due

to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

ITEM 4. 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, 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.

We carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, 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, 2005 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 quarterly report on Form 10-Q for the quarter ended June 30, 2005, in May 2005, our former Chief Medical Officer filed a complaint against us 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 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 intend to vigorously defend 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. On November 4, 2005, Dr. Cheatham filed a notice of appeal of the Court's ruling denying his motion to strike. Discovery as to Dr. Cheatham's claims against us is proceeding, and this case is scheduled for trial to commence in July 2006. We believe that the ultimate resolution of this matter will not have a material impact on our financial position or results of operations.

During the year ended December 31, 2000, we issued an aggregate 699,972 shares of common stock to three consultants in exchange for notes receivable aggregating approximately $10,891,000. The notes are collateralized by the underlying common stock and bear interest at fixed rates. The notes-for-stock transactions have been accounted for as in-substance stock option grants to non-employees. On November 10, 2004, the borrowers notified us that they believed that they had entered into an agreement in October 2001 with Alfred E. Mann, our Chairman, Chief Executive Officer and principal stockholder, under which Mr. Mann would purchase from the borrowers some of the common stock, with the proceeds to be paid to us to pay down the notes. The borrowers have informed us that they believe both we and Mr. Mann are in breach of certain agreements related to the transaction and indicated they intend to seek

alleged damages arising from any failure of the agreement to be performed. The borrowers have not commenced any legal proceedings against Mr. Mann or us. On October 19, 2005, the principal and interest on the notes aggregating $14,637,000 became due and payable to us. On September 30, 2005, the aggregate 699,972 shares of common stock issued for the notes receivable had a market value aggregating approximately $9,583,000. We are pursuing collection and have not deemed the notes uncollectible. As the notes-for-stock transactions were accounted for as in-substance stock option grants to non-employees, there is no impairment to assess for financial reporting purposes. While the outcome of this matter is uncertain, any modification to the terms of the notes could result in additional stock compensation being ascribed to the in-substance options. The amount of any additional stock compensation could have a material impact on our results of operations in the period of modification.

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

(b) Use of Proceeds

The initial public offering of our common stock, par value $0.01 per share, was effected through a Registration Statement on Form S-1 (File No. 333-115020) that was declared effective by the SEC on July 27, 2004, and a Registration Statement on Form S-1 (File No. 333-117702) that became effective upon filing with the SEC on July 28, 2004. The Registration Statements covered the offer and sale of up to 7,187,500 shares of our common stock, including an over-allotment option we granted to the underwriters to purchase up to 937,500 shares of our common stock from us, for an aggregate offering price of $100.6 million. Our initial public offering commenced on July 28, 2004. On August 2, 2004, 6,250,000 shares of our common stock were sold for an aggregate offering price of $87.5 million. The managing underwriters in the offering were UBS Investment Bank, Piper Jaffray, Wachovia Securities, Jefferies & Company, Inc. and Harris Nesbitt. The underwriters exercised 307,100 shares of the over-allotment option on August 28, 2004 and the closing occurred on September 1, 2004.

Our initial public offering resulted in aggregate net proceeds to us of approximately $83.2 million, including approximately $4.0 million in proceeds from the exercise of the underwriter’s over-allotment option. In connection with the offering, we paid $6.4 million in underwriting discounts and commissions and offering expenses of approximately $2.2 million.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or person owning ten percent or more of any class of our equity securities or to any other affiliates. All offering expenses were paid directly to others.

As of September 30, 2005, we estimate that we had used approximately $70.6 million of the net proceeds of our initial public offering for operating activities and approximately $8.9 million of the net proceeds for the purchase of manufacturing equipment. The remainder of the net proceeds has been invested into short-term securities and cash equivalents.

The foregoing payments were direct payments made to third parties who were not our directors or officers (or their associates), persons owning ten percent or more of any class of our equity securities or any other affiliate, except that the proceeds used for working capital included regular compensation for officers and directors. The use of proceeds does not represent a material change from the use of proceeds described in the prospectus we filed pursuant to Rule 424(b) of the Securities Act with the SEC on July 28, 2004.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

On September 22, 2005, our Corporate Vice President and General Counsel entered into a 10b5-1 plan pursuant to which he will exercise and sell certain stock options aggregating 59,095 shares over a period of 24 months, commencing in October 2005.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference from Exhibit 3.5 to the Registrant's Registration Statement on Form S-1, File No. 333-115020)
3.2	Amended and Restated Bylaws (incorporated by reference from Exhibit 3.7 to the Registrant's Registration Statement on Form S-1, File No. 333-115020)
4.1	Form of Common Stock Certificate (incorporated by reference from Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, File No. 333-115020)
10.1	Securities Purchase Agreement dated August 2, 2005 by and among MannKind Corporation and the purchasers listed on Exhibit A thereto (incorporated by reference from Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed August 5, 2005)
31.1	Certification of the Chief Executive Officer Pursuant to Rules 13a-14(a) and 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) and 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) and 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)

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 14, 2005

MannKind Corporation

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

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO RULES 13a-14(a) AND 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 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(s) 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)) 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) 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

(c) 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(s) 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 14, 2005

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

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO RULES 13a-14(a) AND 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 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(s) 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)) 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, particularly during the period in which this report is being prepared;

(b) 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

(c) 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(s) 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 14, 2005

/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
RULES 13a-14(b) AND 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)

I, Alfred E. Mann, Chief Executive Officer of MannKind Corporation (the "Company"), certify, pursuant to Rules 13a-14(b) and 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), that to my knowledge:

1. The quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2005 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 14, 2005

/s/ Alfred E. Mann
Alfred E. Mann
Chief Executive Officer

I, Richard L. Anderson, Chief Financial Officer of MannKind Corporation (the "Company"), certify pursuant to Rules 13a-14(b) and 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), that to my knowledge:

1. The quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2005 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 14, 2005

/s/ Richard L. Anderson
Richard L. Anderson
Chief Financial Officer

A signed original of these certifications has been provided to MannKind Corporation and will be retained by MannKind Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

These certifications are being furnished solely to accompany this quarterly report 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 MannKind Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.