# 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 March 31, 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**<br>**Valencia, California** | **91355** |
| (Address of principal executive offices) | (Zip Code) |

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

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

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

As of May 10, 2005, there were 32,778,404 shares of the registrant's common stock, $.01 par value per share, outstanding.

**MANNKIND CORPORATION**
**Form 10-Q**
**For the Quarterly Period Ended March 31, 2005**

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MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

**CONSOLIDATED BALANCE SHEETS**
(In thousands except share data)

| | March 31, 2005 (unaudited) | December 31, 2004 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 22,089 | $ 78,987 |
| Marketable securities | 44,958 | 11,546 |
| Restricted cash | 585 | 583 |
| State research and development credit exchange receivable | 1,500 | 1,500 |
| Prepaid expenses and other current assets | 3,027 | 3,265 |
| Total current assets | 72,159 | 95,881 |
| PROPERTY, PLANT AND EQUIPMENT – net | 67,999 | 66,511 |
| STATE RESEARCH AND DEVELOPMENT CREDIT EXCHANGE RECEIVABLE – net of current portion | 1,396 | 1,030 |
| OTHER ASSETS | 203 | 61 |
| TOTAL | $ 141,757 | $ 163,483 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 5,095 | $ 3,477 |
| Accrued expenses and other current liabilities | 7,618 | 8,194 |
| Deferred compensation | 1,373 | 1,373 |
| Total current liabilities | 14,086 | 13,044 |
| OTHER LIABILITIES | 48 | 76 |
| Total liabilities | 14,134 | 13,120 |
| STOCKHOLDERS' EQUITY: | | |
| Undesignated preferred stock, $0.01 par value-10,000,000 shares authorized; no shares issued or outstanding at March 31, 2005 and December 31, 2004 | — | — |
| Common stock, $0.01 par value-90,000,000 shares authorized; 32,769,058 and 32,756,237 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively | 327 | 327 |
| Additional paid-in capital | 592,414 | 592,999 |
| Accumulated other comprehensive income | 7 | — |
| Deficit accumulated during the development stage | (465,125) | (442,963) |
| Total stockholders' equity | 127,623 | 150,363 |
| TOTAL | $ 141,757 | $ 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 | | Cumulative period from February 14, 1991 (date of inception) to March 31, 2005 |
|---|---|---|---|
| | March 31, 2005 | March 31, 2004 | |
| Revenue | $ — | $ — | $ 2,858 |
| Operating expenses: | | | |
| Research and development | 18,696 | 12,799 | 221,609 |
| General and administrative | 3,951 | 3,769 | 79,291 |
| In-process research and development costs | — | — | 19,726 |
| Goodwill impairment | — | — | 151,428 |
| Total operating expenses | 22,647 | 16,568 | 472,054 |
| Loss from operations | (22,647) | (16,568) | (469,196) |
| Other income (expense) | 14 | 54 | (1,956) |
| Interest income | 472 | 105 | 6,043 |
| Loss before provision for income taxes | (22,161) | (16,409) | (465,109) |
| Income taxes | (1) | — | (16) |
| Net loss | (22,162) | (16,409) | (465,125) |
| Deemed dividend related to beneficial conversion feature of convertible preferred stock | — | (612) | (22,260) |
| Accretion on redeemable preferred stock | — | (64) | (952) |
| Net loss applicable to common stockholders | $ (22,162) | $ (17,085) | $ (488,337) |
| Net loss per share: | | | |
| Basic and diluted | $ (0.68) | $ (0.86) | |
| Shares used to compute basic and diluted net loss per share: | | | |
| Basic and diluted | 32,764 | 19,975 | |

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)

| | Three months ended March 31, | | Cumulative period from February 14, 1991 (date of inception) to March 31, 2005 |
|---|---|---|---|
| | 2005 | 2004 | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss | $ (22,162) | $ (16,409) | $ (465,125) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,811 | 1,769 | 25,057 |
| In-process research and development | — | — | 19,726 |
| Stock-based compensation expense | (685) | 1,195 | 23,561 |
| Discount on stockholder notes below market rate | — | — | 241 |
| Non-cash compensation to officers | — | — | 70 |
| Loss on sale and abandonment/disposal of property and equipment | (2) | 42 | 3,349 |
| Accrued interest expense on notes payable to stockholders | — | — | 1,538 |
| Accrued interest on notes | — | (26) | (744) |
| Goodwill impairment | — | — | 151,428 |
| (Gain)/loss on available-for-sale securities, net | — | 25 | 229 |
| Changes in assets and liabilities: | | | |
| State research and development credit exchange receivable | (366) | — | (2,896) |
| Prepaid expenses and other current assets | 238 | (58) | (3,027) |
| Restricted cash | (2) | — | (585) |
| Other assets | (142) | 86 | (203) |
| Accounts payable | 1,618 | 404 | 5,095 |
| Accrued expenses and other current liabilities | (576) | 932 | 7,618 |
| Other liabilities | (28) | 42 | 46 |
| Payment of deferred compensation | — | — | 1,373 |
| Net cash used in operating activities | (20,296) | (11,998) | (233,249) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchase of marketable securities | (66,900) | (1,394) | (211,468) |
| Sales of marketable securities | 33,495 | — | 166,290 |
| Purchase of property and equipment | (3,393) | (1,369) | (96,593) |
| Proceeds from sale of property and equipment | 96 | — | 188 |
| Net cash used in investing activities | (36,702) | (2,763) | (141,583) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Cash received for common stock to be issued | — | — | 3,900 |
| Repurchase of common stock | — | — | (1,028) |
| Issuance of common stock for cash | 100 | 5 | 320,671 |

| | Three months ended March 31, 2005 | 2004 | Cumulative period from February 14, 1991 (date of inception) to March 31, 2005 |
|---|---|---|---|
| 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) |
| Payable to stockholder | — | (1,406) | — |
| Issuance of Series B convertible preferred stock for cash | — | — | 15,000 |
| Borrowings on notes payable | — | — | 3,460 |
| Collection of Series C convertible preferred stock subscriptions receivable | — | 18,153 | 50,000 |
| Net cash provided by financing activities | 100 | 16,752 | 396,921 |
| NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS | (56,898) | 1,991 | 22,089 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 78,987 | 47,020 | — |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 22,089 | $ 49,011 | $ 22,089 |
| SUPPLEMENTAL CASH FLOWS DISCLOSURES: | | | |
| Cash paid for income taxes | $ 1 | $ — | $ 16 |
| Interest paid in cash | — | — | 80 |
| Issuance of common stock upon conversion of notes payable | — | — | 3,331 |
| Issuance of common stock for notes receivable | — | — | 2,758 |
| Increase in additional paid-in capital resulting from merger | — | — | 171,154 |
| Put option redemption by stockholder | — | — | 1,921 |
| Accretion on redeemable convertible preferred stock | — | (64) | (952) |
| Issuance of put option by stockholder | — | — | (2,949) |
| Notes receivable by stockholder to officers | — | (75) | 225 |
| Issuance of Series C convertible preferred stock subscriptions | — | — | 50,000 |
| Issuance of Series A redeemable convertible preferred stock | — | — | 4,296 |
| Conversion of Series A redeemable convertible preferred stock | — | — | (5,248) |

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. These 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 months ended March 31, 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 and the valuation of stock-based compensation.

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 March 31, 2005 the Company has reported accumulated net losses of $465.1 million which includes a goodwill impairment charge of $151.4 million. Also, since its inception through March 31, 2005, the Company has reported negative cash flow from operations of $233.2 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 will enable it to continue planned operations through the third quarter of 2005. 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, 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, into 2006.

**2. Initial public offering**

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 gross proceeds of $87.5 million. In connection with the offering, the Company paid $6.1 million in underwriting discounts and commissions to underwriters and incurred $2.2 million in other offering expenses. After deducting the underwriting discounts and commissions and other offering expenses, the Company received net proceeds from the offering of approximately $79.2 million. The Company had granted the underwriters a 30-day option to purchase up to an additional 937,500 shares of common stock from the Company to cover over-allotments, if any. This option was exercised for 307,100 shares on August 28, 2004 and closing occurred 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 unaudited 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 (the "Securities Act"), with the SEC on July 28, 2004.

**3. 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, "Accounting for Stock Issued to Employees," and its interpretations, and has adopted the disclosure-only alternative of 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 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 amounts and fixed exercise prices which, for accounting purposes, are at least equal to the fair value of the Company's common stock at the date of grant. Conversely, when the exercise price for accounting purposes 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, our 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 will be remeasured 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 three months ended March 31, 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 |

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.

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 Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-based Compensation," pro forma net loss and net loss per share would have been as follows:

| (in thousands, except per share data) | Three Months Ended March 31, 2005 | 2004 |
|---|---|---|
| Net loss — as reported | $ (22,162) | $ (16,409) |
| Add: Stock-based employee compensation expense (benefit) included in reported net loss | (720) | 1,195 |
| Deduct: Stock-based compensation expense determined under fair value method | (3,341) | (2,150) |
| Net loss — pro forma | (26,223) | (17,364) |
| Deemed dividend related to beneficial conversion features of convertible preferred stock | — | (612) |
| Accretion on redeemable preferred stock | — | (64) |
| Net loss applicable to common stockholders | $ (26,223) | $ (18,040) |
| Net loss per common share (basic and diluted): | | |
| As reported | $ (0.68) | $ (0.86) |
| Pro forma | $ (0.80) | $ (0.90) |

**4. 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 redeemable convertible preferred stock, convertible preferred stock, stock options and warrants that are not included in the diluted net loss per share calculation, consisted of an aggregate of 4,517,093 shares and 7,256,463 shares as of March 31, 2005 and 2004, respectively.

**5. 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 foregoing 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 $4.0 million through the year ended December 31, 2004 and an additional $0.4 million for the three months ended March 31, 2005 related to this research and development credit exchange program. Of these amounts, approximately $1.5 million consisted of cash received during 2004 and $1.5 million was received in April 2005.

**6. Property and equipment**

Property and equipment consist of the following:

| | As of: | |
|---|---|---|
| **(in thousands)** | **March 31, 2005** | **December 31, 2004** |
| Land | $ 5,273 | $ 5,273 |
| Buildings | 9,566 | 9,566 |
| Building improvements | 38,292 | 37,397 |
| Machinery and equipment | 18,915 | 18,080 |
| Computer equipment and software | 3,640 | 3,308 |
| Furniture, fixtures and office equipment | 2,445 | 2,391 |
| Leasehold improvements | 672 | 627 |
| Construction in progress | 4,252 | 3,326 |
| Deposits on equipment | 5,911 | 5,911 |
| | 88,966 | 85,879 |
| Less accumulated depreciation and amortization | (20,967) | (19,368) |
| Property and equipment, net | $ 67,999 | $ 66,511 |

**7. Common and preferred stock**

The Company is authorized to issue 90,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company's board of directors. No other class of capital stock is authorized. As of December 31, 2004 and March 31, 2005, 32,756,237 and 32,769,058 shares of common stock, respectively, were issued and outstanding. No shares of preferred stock were issued and outstanding at December 31, 2004 and March 31, 2005.

**8. Recently issued accounting pronouncements**

In December 2004, the Financial Accounting Standard Board (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 the Company currently follows. In April 2005, the SEC deferred the effective date of SFAS No. 123R, and 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.

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". In September 2004, the FASB issued a proposed Staff Position ("FSP") EITF Issue No. 03-1a, "Implementation Guidance for the Application of Paragraph 16 of EITF 03-1". The proposed FSP will provide measurement and recognition guidance with respect to debt securities that are impaired solely due to interest rates and/or sector spreads. The FSP has delayed the effective date until such time that the FASB issues the final standard. Management has not determined what impact the adoption of the measurement and recognition guidance in EITF Issue No. 03-1 will have on the Company's financial statements.

**9. 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 may be 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, bear interest at fixed rates, and are payable in October 2005. The notes-for-stock transactions are being accounted for as in-substance stock option grants to non-employees. On November 10, 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 its majority 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 Company is in discussion with the borrowers and has concluded that the matter does not have any financial statement impact as of March 31, 2005. 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.

Further, 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 March 31, 2005 is experiencing financial difficulties. The vendor has indicated it intends to supply the equipment against which the deposits were made. The vendor and its parent company are located in France, and the Company has engaged counsel in France to assist it in evaluating the matter. The Company has assessed this matter in accordance with SFAS No. 5 and concluded that, based on currently available information, a loss accrual is not warranted.

## 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 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 commenced Phase 3 clinical trials in Europe of our lead product, the Technosphere Insulin System, to study its potential for 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 MedTone inhaler. We believe that the performance characteristics, unique kinetics, convenience and ease of use of the Technosphere Insulin System may have the potential to change the way diabetes is treated.

We were incorporated in February 1991 under the laws of the State of Delaware as Pharmaceutical Discovery Corporation, or PDC. On December 12, 2001, AlleCure and CTL merged with wholly-owned subsidiaries of PDC. Pursuant to the merger, all of the outstanding shares of capital stock of AlleCure and CTL were exchanged for shares of capital stock of PDC, and AlleCure and CTL became wholly-owned subsidiaries of PDC. In connection with the merger, PDC changed its name to MannKind Corporation. On December 31, 2002, AlleCure and CTL merged with and into MannKind and ceased to be separate entities.

To date, we have not generated any revenues, and except for our recently completed initial public offering, we have funded our operations primarily through private placements of equity securities. We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of March 31, 2005, we have incurred a cumulative net loss of $465.1 million which includes a goodwill impairment charge of $151.4 million. We do not anticipate receiving revenues from the sales of any product prior to regulatory approval and commercialization of our Technosphere Insulin System. 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 and quality systems to meet our currently anticipated commercial production needs as we advance the Technosphere Insulin System through Phase 3 clinical trials and into commercialization;
- expand our other research, discovery and development programs focused primarily on the development of therapies for cancer;
- expand our proprietary Technosphere formulation technology and develop additional applications for the 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.

We have a limited history of operations with our current management team. To date, we have not generated any revenues from sales of any product. We currently do not 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.

Since 1991, we have been successful in completing several rounds of private equity financing. In 2003, we raised $100.0 million through private placements of our equity securities, comprised of 3,493,194 shares of common stock sold at a weighted average price of $14.31 per share and 980,392 shares of Series C convertible preferred stock that were subscribed for in 2003 at a price of $51.00

per share. Of the $50.0 million of Series C convertible preferred stock subscribed for in 2003, $31.8 million, representing the purchase price for 624,449 shares of Series C convertible preferred stock, was received in 2003 and $18.2 million, representing the purchase price of the remaining 355,943 shares of Series C convertible preferred stock, was received in the first quarter of 2004. On August 2, 2004, we sold 6,250,000 shares of common stock in an initial public offering for aggregate gross proceeds of $87.5 million. The underwriters exercised 307,100 shares of the over-allotment option on August 28, 2004, and the closing occurred on September 1, 2004 for aggregate gross proceeds of $4.3 million. After deducting the underwriters' commission and offering expenses, we received aggregate net proceeds of $83.2 million.

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, 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 and manufacturing and related activities. This staff is divided between our facilities in Valencia, California, Elmsford, New York, 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 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 and the initiation of new clinical trials, the resulting manufacturing costs associated with producing materials for these clinical trials, and the expansion, qualification and validation of our commercial manufacturing processes.

**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 significantly, in part due to increased (non-cash) stock compensation expense resulting in part from the anticipated adoption of Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-based Payment: an Amendment of FASB Statement 123 and 95*. See "Note 3 — Accounting for stock-based compensation" in the footnotes to our financial statements. Also, we became a public company in July 2004. As a public company, we expect our general and administrative expenses to increase significantly in such areas as audit and legal fees, internal control compliance and insurance. A significant portion of these increases will be paid directly to third parties; most of the remainder will be related to increased staffing in these areas.

## CRITICAL ACCOUNTING POLICIES

We have based our discussion and analysis of our financial condition and results of operations on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making estimates of expenses such as stock option expenses and judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. The significant accounting policies that are critical to the judgments and estimates used in the preparation of our financial statements are described in more detail below.

### Goodwill, intangibles and other long-lived assets

Assessing goodwill, intangibles and other long-lived assets for impairment requires us to make assumptions and judgments regarding the carrying value of these assets. Goodwill and intangible assets with indefinite lives are tested for impairment annually, or on an interim basis if events or circumstances indicate that the fair value of the asset has decreased below its carrying value. Other long-lived assets are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

- significant changes in our strategic business objectives and utilization of the assets;
- a determination that the carrying value of such assets can not be recovered through undiscounted cash flows;
- loss of legal ownership or title to the assets; or
- the impact of significant negative industry or economic trends.

If we believe that one of our assets is impaired, the impairment we recognize is the amount by which the carrying value of the asset exceeds the fair value of the asset. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the useful lives of the assets. If a change were to occur in any of the above-mentioned factors or estimates, our reported results could materially change.

To date, we have had recurring operating losses, and the recoverability of our long-lived assets is contingent upon executing our business plan. If we are unable to execute our business plan, we may be required to write down the value of our long-lived assets in future periods.

### Clinical trial expenses

Our clinical trial accrual process seeks to account for expenses resulting from our obligations under contract with vendors, consultants, and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in uneven payment flows. Our objective is to reflect the appropriate trial expenses in our financial statements by matching period expenses with period services and efforts expended. We account for these expenses according to the progress of the trial as measured by patient enrollment and the timing of various aspects of the trial. We determine accrual estimates through discussions with internal clinical personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Service provider status is then compared to the contractually obligated fee to be paid for such services. During the course of a clinical trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. In the event that we do not identify certain costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our reported expenses for a period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of the services are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

**Stock-based compensation**

We have recorded compensation expense related to options to purchase our common stock issued to employees and consultants. We have elected to follow Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for our stock-options issued to employees, and we have adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, we have recorded stock-based compensation expense in connection with the grant of common stock options to employees based on the intrinsic-value method provided for under APB No. 25 rather than the alternative fair-value method provided for under SFAS No. 123. The intrinsic value of an employee stock option under APB No. 25 is equal to the difference between the exercise price of the option and the estimated fair value of the stock, on the measurement date, of the common stock purchasable with the option. In the notes to our financial statements, we provide pro forma disclosures that indicate the effect on our net income as if we had applied the fair-value method.

The measurement date for stock-based compensation, if any, in connection with an employee stock option is generally the option grant date. However, modifying option terms subsequent to the grant date can result in a remeasurement of stock option compensation on the modification date and subsequently under certain circumstances. On October 7, 2003, our 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. Under the repricing program, each holder of outstanding options granted under the stock plans who was an employee of ours on November 5, 2003 could elect to exchange up to all of his or her outstanding options that had an exercise price greater than $7.95 for repriced stock options with an exercise price of $7.95 per share and a term of four years. The option repricing became effective on November 5, 2003. Each replacement option vested 50% in November 2004 and then monthly thereafter until fully vested in November 2005. Employees who voluntarily resigned in the 12-month period beginning November 5, 2003 forfeited their repriced options. Employees who were involuntarily terminated in the 12-month period beginning November 5, 2003 vested 50% upon termination and forfeited the remaining portions of their options. Compensation cost for all options repriced under the repricing program will be remeasured on a quarterly basis until the options expire or are exercised or canceled.

Stock options issued to consultants are accounted for in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.* Under SFAS No. 123, stock-based compensation for stock options granted to non-employees is equal to the fair value of the stock options rather than the intrinsic value under APB No. 25. We determine the fair value of options granted to non-employees using the Black-Scholes option valuation model, which was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. The Black-Scholes option valuation model requires the input of highly subjective assumptions, including the expected volatility of our stock price. Stock-based compensation related to options granted to consultants is generally remeasured periodically as the underlying options vest.

Stock-based compensation expense includes amounts attributable to certain issuances of common stock for notes receivable that we have accounted for as in-substance stock options and are further described in the notes to our annual financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2004. Stock-based compensation expense is assigned to operating expense categories in our statements of operations according to nature of the services rendered by the employee or consultant to whom the expense applies.

In future periods, we are required to remeasure stock-based compensation cost for all employee options repriced under the repricing program that remain outstanding and to periodically remeasure the stock-based compensation cost of options we have granted to consultants. Since the amount of compensation cost attributable to the repriced options and consultant options is dependent on the fair value of our common stock underlying the options on the future remeasurement dates, the amount of stock-based compensation recognized in any given future period cannot be predicted and may have a material impact on our results of operations.

In December 2004, the Financial Accounting Standard Board (“FASB”) issued 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 we currently follow. In April 2005, the SEC deferred the effective date of SFAS No. 123R, and 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 our financial statements. For example, SFAS No. 123 permits recognizing 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 benefits 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 our pro forma disclosure under SFAS No. 123.

**Accounting for income taxes**

We must make significant management judgments when determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. As of March 31, 2005, we established a full valuation allowance against our gross deferred tax asset balance due to uncertainties related to our deferred tax assets as a result of our history of operating losses. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to change the valuation allowance, which could materially impact our financial position and results of operations.

**Results of Operations**

**Three Months Ended March 31, 2005 and 2004**

**Revenues**

No revenues were recorded for the three months ended March 31, 2005 or 2004. We do not anticipate receiving revenues from the sales of any product prior to regulatory approval and commercialization of our Technosphere Insulin System.

**Research and Development Expense**

Research and development expenses increased by $5.9 million to $18.7 million for the three months ended March 31, 2005 compared to $12.8 million for the three months ended March 31, 2004, an increase of 46.1%. The increase was primarily due to ongoing expenses in 2005 related to our Technosphere Insulin System. Continuation of preclinical and clinical studies in 2005 increased research expenditures by $5.1 million, which also resulted in increased manufacturing costs of $0.9 million to supply clinical trial materials and our continued validation of our manufacturing system. Offsetting the total increase in research and development expenses of $6.3 million was the recognition of an estimated $0.4 million receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash. We anticipate that our research and development expenses will increase significantly with the continuation of existing, and initiation of new, clinical trials and the resulting manufacturing costs associated with producing materials for these clinical trials.

**General and Administrative Expense**

General and administrative expenses increased by $0.2 million to $4.0 million for the three months ended March 31, 2005 compared to $3.8 million for the three months ended March 31, 2004, an increase of 4.8%. The increase was primarily due to increased salaries and other employee related expenses of $0.9 million and various other general and administrative expenses which increased by $0.7 million, such as insurance, accounting and legal fees as a result of operating as a public company. This increase was offset by a $1.5 million 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.

**Other Income**

Other income of $14,000 and $54,000 for the three months ended March 31, 2005 and 2004, respectively, relates primarily to dividend income from available-for-sale securities.

**Interest Income**

Interest income increased by $367,000 to $472,000 for the three months ended March 31, 2005 compared to $105,000 for the three months ended March 31, 2004, an increase of 349.5%. The increase was primarily due to higher levels of cash equivalents and marketable securities available for investment during 2005 compared to 2004.

**Deemed Dividend**

The deemed dividend of $0.6 million for the three months ended March 31, 2004 represents the beneficial conversion charge to common stockholders related to the downward adjustment of the Series B preferred stock conversion price. No further deemed dividend has been recognized as all outstanding preferred stock automatically converted into common stock at the close of the initial public offering in the third quarter of 2004.

**LIQUIDITY AND CAPITAL RESOURCES**

Prior to our initial public offering, we have historically funded our operations primarily through the private placement of equity securities with our majority stockholder and his affiliated entities, who have invested approximately $228.5 million of the approximately $328.5 million that we have raised prior to the closing of our initial public offering on August 2, 2004. In 2003, we raised $100.0 million through private placements of our equity securities, comprising 3,493,194 shares of common stock sold at a weighted average price of $14.31 per share, and 980,392 shares of Series C convertible preferred stock that were subscribed for in 2003 at a price of $51.00 per preferred share. Of the $50.0 million of Series C convertible preferred stock subscribed for in 2003, $31.8 million, representing the purchase price of 624,449 shares of Series C convertible preferred stock, was received in 2003 and $18.2 million, representing the purchase price of the remaining 355,943 shares of Series C convertible preferred stock, was received in the first quarter of 2004. All of the shares of our Series C convertible preferred stock were issued in the first quarter of 2004.

On August 2, 2004, we closed our initial public offering at a price to the public of $14.00 per share. We sold 6,250,000 shares of our common stock in the offering for a gross offering price of $87.5 million. We granted the underwriters a 30-day option to purchase up to an additional 937,500 shares of common stock to cover over-allotments. This option was exercised for 307,100 shares on August 28, 2004 and closing occurred on September 1, 2004 with net proceeds to us of approximately $4.0 million. In connection with the initial public offering, we paid $6.4 million in underwriting discounts and commissions to underwriters and incurred $2.2 million in other offering expenses. After deducting the underwriting discounts and commissions and other offering expenses, we received net proceeds from the initial public offering, including the over-allotment, of approximately $83.2 million. These proceeds and the conversion of our preferred stock to common stock are reflected in the accompanying consolidated financial statements as of December 31, 2004 and March 31, 2005.

During the three months ended March 31, 2005, operating activities used $20.3 million of cash. Net cash used by operating activities during this period resulted primarily from a net loss of $22.2 million, which included a credit to non-cash stock-based compensation of $0.7 million and depreciation of $1.8 million. We expect our negative operating cash flow to continue for several years.

During the three months ended March 31, 2005, investing activities used $36.7 million of cash. This use of cash was for purchases of equipment of $3.4 million and net purchases of marketable securities of $33.5 million. Our efforts with respect to our Technosphere Insulin System include expansion of our manufacturing operations and quality systems. Accordingly, we expect to make significant purchases of equipment in the foreseeable future.

During the three months ended March 31, 2005, financing activities provided $0.1 million in cash from the exercise of options to purchase an aggregate of 12,821 shares of common stock at an average exercise price of $7.84 per share.

As of March 31, 2005, we had $67.0 million in cash, cash equivalents and marketable securities. We expect our capital resources and interest income will be sufficient to fund currently planned operations through the third quarter of 2005. We intend to seek additional funding through public or private equity financing, arrangements with corporate partners or other sources. There can be no assurance that we will be able to obtain such additional capital or enter into such relationships with corporate partners on a timely basis, on favorable terms, or at all. 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 development activities. Because the majority of our expenses in 2005 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, into 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 formulation 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 product candidate. 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 March 31, 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**

Our contractual obligations consist of operating leases, purchase obligations, capital lease commitments and deferred compensation. Some of our current and former employees elected to defer part or all of their compensation from 1991 through 1998, resulting in total deferred compensation of $1.4 million at March 31, 2005. The amounts due for deferred compensation are non-interest-bearing with no repayment terms. Our other obligations are included in the table below.

Future payments under our operating lease obligations, including a facility lease executed in March 2005, and open purchase commitments consist of the following at March 31, 2005 (in thousands):

| | Payments due in | | | | |
|---|---|---|---|---|---|
| **Purchase commitments and lease obligations** | **Less than One Year** | **1-3 years** | **3-5 years** | **More than 5 years** | **Total** |
| Open purchase order commitments (1) | $ 18,248 | $ 1,514 | $ — | $ — | $ 19,762 |
| Operating lease obligations | 699 | 960 | 499 | — | 2,158 |
| Total | $ 18,947 | $ 2,474 | $ 499 | $ — | $ 21,920 |

*(1) The amounts included in open purchase order commitments are subject to performance under the purchase order by the supplier of the goods or services and do not become our obligation until such performance is rendered. The amount shown is principally for the purchase of materials for our clinical trials and the acquisition of manufacturing equipment.*

**Recently Issued Accounting Pronouncements**

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. In April 2005, the SEC deferred the effective date of SFAS No. 123R, and 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”. In September 2004, the FASB issued a proposed Staff Position (“FSP”) EITF Issue No. 03-1a, “Implementation Guidance for the Application of Paragraph 16 of EITF 03-1”. The proposed FSP will provide measurement and recognition guidance with respect to debt securities that are impaired solely due to interest rates and/or sector spreads. The FSP has delayed the effective date until such time that the FASB issues the final standard. We have not determined what impact the adoption of the measurement and recognition guidance in EITF Issue No. 03-1 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 March 31, 2005, we had an accumulated deficit of $465.1 million and a net loss of $22.2 million for the three months ended March 31, 2005 and $76.0 million for the year ended December 31, 2004. 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 additional 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 and perform preclinical research 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 will enable us to continue planned operations through the third quarter of 2005. 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 third parties;
- the timing and amount of payments we might receive from potential licensees;

- the costs of discontinuing projects and technologies or decommissioning existing facilities, if we undertake those activities;
- 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; and
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others.

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, 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 assure you, 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 early stages of 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 many 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 formulation 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 drugs or therapeutics. 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 will be 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;
- 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;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent of scheduling conflicts with participating clinicians and clinical institutions; and
- our ability to identify and enroll patients who meet clinical trial eligibility criteria.

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 March 2004, these collaborators filed a submission seeking regulatory approval in Europe, and in March 2005, their new drug application, or NDA, was accepted by the FDA. Novo Nordisk A.S. has a pulmonary insulin product in development. Eli Lilly and Company, in collaboration with Alkermes, Inc., is conducting clinical trials for a pulmonary insulin 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 of a self-funded Phase 3 program over the next 12 months would be in the range of $110 to $140 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 hospitals and clinical research organizations 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 assure you 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 one of several long-term safety studies of our Technosphere Insulin System designed to evaluate a number of safety issues, including pulmonary function. 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 products. 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-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 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:

- launch and 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 assure you 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 its 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 manufacture the raw Technosphere material, but we are in the process of qualifying a secondary manufacturer to supply us with commercial quantities of this raw material. 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. 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, including Alfred Mann, our Chairman and Chief Executive Officer, or Hakan Edstrom, our President and Chief Operating Officer, 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. In May 2005, Wendell Cheatham, M.D., ceased to be an employee of ours. Although Mr. Edstrom has assumed Dr. Cheatham's management responsibilities while we search for a senior executive to lead our development operations, there can be no assurance that we will be able to recruit such an individual with the appropriate skills and experience.

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.

**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 conduct 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, including a US Phase 3 program for our Technosphere Insulin System. 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. The FDA advised us that the Technosphere Insulin System must be tested 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 approved 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. 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. As of March 31, 2005, Mr. Mann beneficially owned approximately 48.4% of our outstanding shares of capital stock. As of the same date, members of Mr. Mann's family beneficially owned at least an additional 2.4% 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 March 31, 2005, we had approximately 32.8 million shares of common stock outstanding, all of which are available for public sale, subject in some cases to volume and other limitations. 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. The holders of 916,715 shares of our common stock and the holders of warrants to purchase 131,628 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders 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. See "Description of capital stock—Amended and restated certificate of incorporation and bylaw provisions."

**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 March 31, 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 March 31, 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**

We are not currently a party to any material legal proceedings. We may from time to time become a party to legal proceedings arising in the ordinary course of business. 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, bear interest at fixed rates, and are payable in October 2005. 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. To the best of our knowledge, the borrowers have not commenced any legal proceedings against Mr.

Mann or us. We believe that the ultimate resolution of this matter will not have a material impact on our financial position or results of operations.

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

(a) Unregistered Sales of Equity Securities

None.

(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 March 31, 2005, we estimate that we had used approximately $47.8 million of the net proceeds of our initial public offering for operating activities and approximately $6.8 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.

(c) Repurchases

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

No matters were submitted to a vote of our security holders during the quarter ended March 31, 2005.

**ITEM 5. OTHER INFORMATION**

In January 2005, pursuant to our Officers' Incentive Program, the Compensation Committee of our Board of Directors authorized bonus payments for 2004 to our executive officers, including the following bonus payments: Alfred E. Mann, $159,809; Hakan S.

Edstrom, $144,913; Dan R. Burns, $107,300; Richard L. Anderson, $97,093; and Wayman Wendell Cheatham, $78,038. The Officers' Incentive Program is not set forth in a separate document, but a summary of the program follows.

Under the Officers' Incentive Program, each of our executive officers is eligible to earn cash bonus compensation based upon a target bonus amount equal to a predetermined percentage of his or her salary. The actual amount of any bonus is determined by the level of achievement of specified objectives relating to our corporate performance and to each participant's individual performance. The Board of Directors establishes the corporate objectives at the beginning of each fiscal year. The corporate objectives established for 2004 were related to clinical trial milestones, partnership discussions, pipeline developments, financial performance, and organizational development.

Following the end of each fiscal year, the Board of Directors determines the extent to which the corporate objectives were attained and the Compensation Committee determines the extent to which each participant attained his or her individual objectives. Based on these determinations, the Compensation Committee awards each participant a bonus equal to a percentage of the participant's target bonus amount. This percentage can range from zero to 125%.

In February 2005, the Board approved 2005 target bonus amounts for each of the participating executive officers, including the following: Mr. Mann, 50% of his annual salary; Mr. Edstrom, 45%; Mr. Burns, 40%; Mr. Anderson, 35%; and Dr. Cheatham, 35%. The Board also established 2005 corporate goals related to clinical trial milestones, commercialization objectives, manufacturing productivity, pipeline advancement objectives, organizational effectiveness, and financial performance.

In February 2005, the Board of Directors also approved 2005 annual salaries for our executive officers, including the following: Mr. Mann, $356,160; Mr. Edstrom, $356,150; Mr. Burns, $305,000; Mr. Anderson, $300,300; and Dr. Cheatham, $275,000. In May 2005, Dr. Cheatham ceased to be an employee.

**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) |
| 4.2 | Registration Rights Agreement made and entered into as of October 15, 1998 by and among CTL Immunotherapies Corp., Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended (incorporated by reference from Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, File No. 333-115020) |
| 31.1 | Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32 | Certifications of the Chief Executive Officer and Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 |

**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 on this 16th day of May 2005.

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 SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: May 16, 2005

/s/ ALFRED E. MANN

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

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: May 16, 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
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Alfred E. Mann, Chief Executive Officer of MannKind Corporation (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2005 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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: May 16, 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 Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2005 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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: May 16, 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.