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 June 30, 2004

or

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

For the transition period from _____ to _____.

Commission File Number 000-50865

MannKind Corporation
(Exact name of registrant as specified in its charter)

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

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

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

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

As of September 1, 2004, there were 32,722,476 shares of the registrant's common stock, $.01 par value per share, outstanding.

MANNKIND CORPORATION
Form 10-Q
For the Quarterly Period Ended June 30, 2004

TABLE OF CONTENTS

PART I: FINANCIAL INFORMATION
ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

(In thousands except share data)

	December 31, 2003	June 30, 2004 (unaudited)	Pro forma stockholders' equity at June 30, 2004 (unaudited)
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 54,120	$ 37,373	
Marketable securities	1,825	3,887	
Prepaid expenses and other current assets	1,859	2,653	
Total current assets	57,804	43,913	
PROPERTY, PLANT AND EQUIPMENT – net	67,323	66,235	
RESTRICTED CASH	559	579	
OTHER ASSETS	190	51	
TOTAL	$ 125,876	$ 110,778	
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Accounts payable	$ 1,926	$ 1,840	
Accrued expenses and other current liabilities	4,015	4,835	
Payable to stockholder	1,406	—	
Deferred compensation – current	1,360	1,373	
Total current liabilities	8,707	8,048	
DEFERRED COMPENSATION	284	—	
OTHER LIABILITIES	120	130	
Total liabilities	9,111	8,178	
COMMITMENTS AND CONTINGENCIES			
SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK, $0.01 par value—267,213 shares authorized; 267,212, issued and outstanding at December 31 2003 and June 30, 2004, respectively; aggregate liquidation value, $5,188 as of December 31, 2003 and $5,248 as of June 30, 2004	5,188	5,248	
STOCKHOLDERS' EQUITY:			
Series B convertible preferred stock, $0.01 par value—192,618 shares authorized, issued and outstanding at December 31, 2003 and June 30, 2004, respectively; aggregate liquidation value, $15,000 at December 31, 2003 and June 30, 2004	15,000	15,000	—
Series C convertible preferred stock, $.01 par value — 980,393 shares authorized; 980,392 shares issued and outstanding at June 30, 2004, aggregate liquidation value of $50,000 at June 30, 2004	—	50,000	—
Series C convertible preferred stock issuable	50,000		
Series C convertible preferred stock subscriptions receivable	(18,153)	—	—
Common stock, $0.01 par value—100,000,000 shares authorized; 19,974,727 and 19,975,089 shares issued and outstanding at December 31, 2003 and June 30, 2004, respectively	200	200	261
Additional paid-in capital	433,141	435,240	505,427
Note receivable from stockholders	(1,412)	(1,463)	(1,463)
Note receivable from officers	(228)	—	—
Deficit accumulated during the development stage	(366,971)	(401,625)	(401,625)
Total stockholders' equity	111,577	97,352	$ 102,600
TOTAL	$ 125,876	$ 110,778	

MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)

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

	Three Months Ended		Six Months Ended		Cumulative period from February 14, 1991 (date of inception) to June 30, 2004
	June 30, 2003	June 30, 2004	June 30, 2003	June 30, 2004	
Revenue	$ —	$ —	$ —	$ —	$ 2,858
OPERATING EXPENSES:					
Research & development	9,321	14,311	20,884	27,110	170,757
General & administrative	3,903	4,071	12,710	7,840	65,297
In-process research and development costs	—	—	—	—	19,726
Goodwill impairment	—	—	—	—	151,428
Total operating expenses	13,224	18,382	33,594	34,950	407,208
Loss from operations	(13,224)	(18,382)	(33,594)	(34,950)	(404,350)
Interest income	119	123	204	221	4,799
Other income (expense)	17	14	(33)	75	(2,060)
Loss before provision for income taxes	(13,088)	(18,245)	(33,423)	(34,654)	(401,611)
Income taxes	—	—	—	—	(14)
Net loss	(13,088)	(18,245)	(33,423)	(34,654)	(401,625)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	(875)	—	(875)	(612)	(3,050)
Accretion on redeemable preferred stock	(63)	4	(123)	(60)	(952)
Net loss applicable to common stockholders	$ (14,026)	$(18,241)	$(34,421)	$(35,326)	$(405,627)
Net loss per share:					
Basic and diluted	$ (0.79)	$ (0.91)	$ (2.01)	$ (1.77)	
Basic and diluted – pro forma		$ (0.73)		$ (1.44)	
Shares used to compute net loss per share:					
Basic and diluted	17,760	19,975	17,117	19,975	
Basic and diluted – pro forma		24,907		24,562	

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)

	Six months ended June 30,		Cumulative period from February 14, 1991 (date of inception) to June 30, 2004
	2003	2004	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (33,423)	$ (34,654)	$ (401,625)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,855	3,564	19,631
In-process research and development	—	—	19,726
Stock-based compensation expense	3,150	2,377	19,066
Discount on stockholder notes below market rate	—	—	241
Non-cash compensation to officers	70	—	70
Stock issued for services	—	—	747
Loss on sale and abandonment/disposal of property and equipment	740	42	2,865
Accrued interest expense on notes payable to stockholders	—	—	1,538
Accrued interest on notes	(51)	(51)	(691)
Goodwill impairment	—	—	151,428
Loss on available-for-sale securities, net	9	52	195
Changes in assets and liabilities:			
Prepaid expenses and other current assets	280	(794)	(2,653)
Restricted cash	(559)	(20)	(579)
Other assets	7	139	(51)
Accounts payable	(2,194)	(86)	1,840
Accrued expenses and other current liabilities	774	820	4,835
Other liabilities	(153)	16	136
Payment of deferred compensation	(220)	(271)	1,373
Net cash used in operating activities	(27,715)	(28,866)	(181,908)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	(16,338)	(2,614)	(123,729)
Sales of marketable securities	25,229	500	119,647
Purchase of property and equipment	(3,974)	(2,518)	(88,823)
Proceeds from sale of property and equipment	73	—	92
Net cash provided by (used in) investing activities	4,990	(4,632)	(92,813)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Repurchase of common stock	(1,028)	—	(1,028)
Issuance of common stock for cash	40,000	4	235,844
Cash received for common stock to be issued	—	—	3,900

	Six months ended June 30,		Cumulative period from February 14, 1991 (date of inception) to June 30, 2004
	2003	2004	
Put shares sold to majority stockholder	—	—	623
Borrowings under lines of credit	—	—	4,220
Proceeds from notes receivables	—	—	1,742
Principal payments on notes payable	—	—	(1,667)
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	38,972	16,751	312,094
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	16,247	(16,747)	37,373
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	19,917	54,120	—
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 36,164	$ 37,373	$ 37,373
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$ —	$ —	$ 14
Interest paid in cash	—	—	75
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	(123)	(60)	(952)
Issuance of put option by stockholder	—	—	(2,949)
Notes receivable by stockholder to officers	225	(225)	—
Issuance of Series C convertible preferred stock subscriptions	—	—	50,000
Issuance of Series A redeemable convertible preferred stock	—	—	4,296

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, 2003 are included in the Prospectus (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 in connection with the Company's initial public offering.

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

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and six months ended June 30, 2004 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 June 30, 2004 the Company has reported accumulated net losses of $401.6 million which include a goodwill impairment charge of $151.4 million, and negative cash flow from operations of $181.9 million. Substantial funding will be needed by the Company to develop therapeutic products and conduct clinical trials for these products. Based upon the Company's current expectations, management believes the Company's cash, cash equivalents and marketable securities at June 30, 2004 together with $79.6 million of proceeds from the initial public offering completed on August 2, 2004 will enable it to continue planned operations through at least June 30, 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.

2. Subsequent event – 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 an estimated $1.8 million in other offering expenses. After deducting the underwriting discounts and commissions and estimated offering expenses, the Company received net proceeds from the offering of approximately $79.6 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 approximately $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. Because the offering closed

after June 30, 2004, the results of the offering are not reflected in the accompanying unaudited consolidated financial statements. A summary of the terms of the offering can be found in the Prospectus.

3. Accounting for stock-based compensation

The Company's employee stock option plans are accounted for using the intrinsic-value method of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. 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 ratably over the term of the option vesting period in an amount equal to the difference between the value calculated using the exercise price and the fair value. The Company uses the fair-value method to account for non-employee stock-based compensation.

Stock options granted during the six months ended June 30, 2004 are as follows:

	Number of Shares	Exercise Price Per Share	Weighted Average Exercise Price Per Share
For the three months ended:			
March 31, 2004	74,333	$7.95 - $9.18	$ 8.61
June 30, 2004	—	—	—

There were no stock options granted during the three months ended June 30, 2004.

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except per share data)	2003	2004	2003	2004
Net loss applicable to common stockholders - as reported	$ (14,026)	$ (18,241)	$ (34,421)	$ (35,326)
Add: Stock-based compensation expense included in reported net loss	166	1,182	3,150	2,377
Deduct: Stock-based compensation expense determined under fair value method	(825)	(2,016)	(4,262)	(4,112)
Net loss applicable to common stockholders - pro forma	$ (14,685)	$ (19,075)	$ (35,533)	$ (37,061)
Net loss per common share (basic and diluted):				
As reported	$ (0.79)	$ (0.91)	$ (2.01)	$ (1.77)
Pro forma	$ (0.83)	$ (0.95)	$ (2.08)	$ (1.86)

4. Net loss per common share, pro forma net loss per common share and pro forma stockholders' equity

Basic and diluted net loss per common share is calculated by dividing the net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, because the effects of potentially dilutive securities are antidilutive for all periods presented. 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 3,870,016 shares and 7,236,452 shares as of June 30, 2003 and 2004, respectively.

The pro forma net loss per share for the three months and six months ended June 30, 2004 is computed using the weighted average number of common shares outstanding during the respective periods, including the pro forma effects of the pro forma conversion of the Company's Series A, B and C convertible preferred stock into shares of the Company's common stock upon the closing of the Company's initial public offering. Conversion of the Series A, B and C convertible preferred stock reflects the weighted average effective conversion prices of the securities during the periods presented. Conversion of the Series A and B preferred stock is assumed

to have occurred as of January 1, 2003. Conversion of the Series C preferred stock is assumed to have occurred as of January 19, 2004, the date the Series C preferred stock was issued.

The following table summarizes the components of the pro forma net loss per share.

(in thousands, except share and per share data)	Three Months Ended June 30, 2004	Six Months Ended June 30, 2004
Net loss	$ (18,245)	$ (34,654)
Deemed dividend related to beneficial conversion features of convertible preferred stock	—	(612)
Accretion to preferred stockholders	4	(60)
Net loss attributable to common stockholders	$ (18,241)	$ (35,326)
Weighted average shares used in computing basic and diluted net loss per share	19,975,254	19,975,033
Adjusted to reflect the effect of the pro forma conversion of convertible preferred stock	4,931,303	4,587,404
Weighted average shares used in computing pro forma basic and diluted net loss per share	24,906,557	24,562,437
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (0.73)	$ (1.44)

The pro forma stockholders' equity at June 30, 2004 reflects the conversion, upon the closing of the Company's initial public offering, all 267,212 shares of the Company's Series A redeemable convertible preferred stock, all 192,618 shares of the Company's Series B convertible preferred stock and all 980,392 shares of the Company's Series C convertible preferred stock outstanding as of June 30, 2004, at the initial public offering price of $14.00 per share, into an aggregate of 6,166,372 shares of common stock.

5. Property and equipment

Property and equipment at cost consist of the following:

	As of:	
(in thousands)	December 31, 2003	June 30, 2004
Land	$ 5,273	$ 5,273
Buildings	9,566	9,566
Building improvements	36,296	36,653
Machinery and equipment	16,530	17,525
Computer equipment and software	3,048	3,123
Furniture, fixtures and office equipment	2,234	2,353
Leasehold improvements	627	627
Construction in progress	789	1,702
Deposits on equipment	5,656	5,656
	80,019	82,478
Less accumulated depreciation and amortization	(12,696)	(16,243)
Property and equipment, net	$ 67,323	$ 66,235

6. Stockholders' equity

On April 30, 2004, the Company filed a registration statement on Form S-1 with the SEC for an initial public offering of its common stock. Upon the closing of the Company's initial public offering, which occurred on August 2, 2004, 1,440,222 shares of the Company's Series A, B and C convertible preferred stock were converted into an aggregate of 6,166,372 shares of common stock. These conversions were based upon the conversion ratios then applicable for each series of preferred stock.

In March 2004, the Company's board of directors approved the 2004 Equity Incentive Plan, the 2004 Employee Stock Purchase Plan and the 2004 Non-Employee Directors' Stock Option Plan, each to become effective upon the closing of the Company's initial public offering. The aggregate number of shares of common stock which may be issued under the 2004 Equity Incentive Plan and the 2004 Non-Employee Directors' Stock Option Plan is 5,000,000 shares and 800,000 shares, respectively. The aggregate number of shares which may be sold under the 2004 Employee Stock Purchase Plan is 2,000,000 shares of common stock.

Upon the closing of the Company's initial public offering, the Company's authorized capital stock consisted of 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.

7. Recently issued accounting pronouncements

In December 2002, the Financial Accounting Standard Board ("FASB") issued SFAS No. 148, "Accounting for Stock-based Compensation — Transition and Disclosure, an Amendment of FASB Statement No. 123," to provide alternative methods of transition for a voluntary change to the fair-value based method of accounting for stock-based compensation. The Company has adopted the disclosure requirements of this statement. In March 2004, the FASB issued a proposed SFAS - "Share-based Payment: an Amendment of FASB Statements No. 123 and 95." The proposed statement would require companies to expense share-based payments to employees, including stock options, based on the fair value of the award at the grant date. The proposed statement also would eliminate the intrinsic value method of accounting for stock options permitted by APB No. 25, "Accounting for Stock Issued to Employees," which the Company currently follows. The Company will continue to monitor the actions of the FASB and assess the impact, if any, on its consolidated financial statements.

In March 2004, the FASB approved the consensus reached on the Emerging Issues Task Force ("EITF") Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of EITF Issue No. 03-1 is to provide guidance for identifying impaired investments. EITF Issue No. 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. The accounting provisions of EITF Issue No. 03-1 are effective for all reporting periods beginning after June 15, 2004, while the disclosure requirements are effective only for annual periods ending after June 15, 2004. The Company has evaluated the impact of the adoption of EITF 03-1 and does not believe the impact will be significant to the Company's overall results of operations or financial position.

8. 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.

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, 2003 and the related Management's discussion and analysis of financial condition and results of operations, both of which are contained in our Prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act"), with the SEC on July 28, 2004. 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, cancer, inflammatory and autoimmune diseases. Our lead product, the Technosphere Insulin System, which is currently in late Phase II clinical trials for the treatment of diabetes, consists of our dry powder Technosphere formulation of insulin and our MedTone inhaler through which the powder is inhaled into the deep lung. We believe the performance characteristics, convenience and ease of use of our proprietary Technosphere Insulin System 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 ("PDC"). On December 12, 2001, AlleCure Corp. ("Allecure") and CTL ImmunoTherapies Corp. ("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.

From our inception in 1991 through June 30, 2004, we have incurred a cumulative net loss of $401.6 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 expenditures and to incur additional operating losses for at least the next several years as we:

• continue the development and commercialization of our Technosphere Insulin System for the treatment of diabetes, currently in late Phase II clinical trials;

• expand our proprietary Technosphere formulation technology and develop additional applications for the delivery of other drugs;

• expand our other research, discovery and development programs focused on the development of therapies for cancer, inflammation and autoimmune disorders;

• expand our manufacturing operations and quality systems to meet our currently anticipated commercial production needs as we advance the Technosphere Insulin System through Phase III clinical trials and into commercialization; 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 and we have not generated any revenues from sales of any product to date. 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.

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.

We have funded our operations primarily through private placements of equity securities. 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 preferred 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. The remaining $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.

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.

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 located at our facilities in Valencia, California and Danbury, Connecticut. We expense research and development costs as we incur them.

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 results of our current Phase II trials, discussions with the U.S. Food and Drug Administration (the "FDA") on their requirements, the length of our clinical trials and the cost and efficiency of our manufacturing process. However, we expect our research and development costs to increase as we continue to develop new applications for our proprietary therapeutics and drug-delivery technologies, refine our manufacturing processes and move our other product candidates through preclinical and clinical trials.

Clinical development timelines, likelihood of success and total costs vary widely. We are currently focused primarily on advancing the Technosphere Insulin System through continuing Phase II and into and through Phase III clinical trials. We plan to commercialize our lead product as a treatment for diabetes. Based on the results of preclinical studies, we also 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.

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.

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.

Accrued expenses

As part of the process of preparing consolidated financial statements we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of services performed and the associated cost incurred for these services as of each balance sheet date in our consolidated financial statements. Examples of estimated expenses for which we accrue include professional service fees, such as lawyers and accountants fees, and contract service fees such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, as well as fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with these service fees, our estimates are primarily affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by our service providers. The majority of our service providers invoice us monthly in arrears for services performed. 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, respectively. 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 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 Opinion 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 Opinion No. 25 is equal to the difference between the exercise price of the option and the estimated fair value, 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 vests 50% in November 2004 and the remaining 50% vests monthly until fully vested in November 2005. Employees who voluntarily resign in the 12-month period beginning November 5, 2003 will forfeit their repriced options. Employees who are involuntarily terminated in the 12-month period beginning November 5, 2003 will vest 50% upon termination and forfeit 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 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 consultants 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 consultants 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 the Prospectus. 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.

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 June 30, 2004, we recorded a full valuation allowance against our gross deferred tax assets 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.

Accretion of dividends and offering costs on convertible preferred stock

Accretion of dividends and offering costs on convertible preferred stock primarily consists of dividends on convertible preferred stock. Prior to the conversion of our convertible preferred stock into shares of our common stock that occurred on August 2, 2004 upon the completion of our initial public offering, our convertible preferred stock was entitled to accretion of dividends. The amount of the accretion of dividends decreased the amount of stockholders' equity available to our common stockholders and effectively increased the loss per share of our common stock. After August 2, 2004, no existing convertible preferred stock was outstanding, and accordingly there will be no further accretion of dividends and offering costs on these shares. All preferred stock dividends which were accreted before August 2, 2004 were forfeited by the preferred stockholders on that date in connection with the conversion of these preferred shares to common stock.

Results of Operations

Three Months Ended June 30, 2004 and 2003

Revenues

No revenues were recorded for the three months ended June 30, 2004 or 2003. 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 $5.0 million to $14.3 million for the three months ended June 30, 2004 compared to $9.3 million for the three months ended June 30, 2003, an increase of 53.6%. The increase was primarily due to ongoing expenditures in 2004 related to our Technosphere Insulin System. Initiation of preclinical and clinical studies in 2004 increased research expenditures by $2.6 million, which also resulted in increased manufacturing costs of $2.7 million to supply clinical trial materials and our continued validation of our manufacturing system. The increased costs were offset by a decrease of $0.3 million in research and development costs resulting from the termination of AlleCure product development programs and the redesign of CTL product development programs which was initiated in the first quarter of 2003. 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. Additionally, we continue to advance our efforts in developing additional applications for our proprietary Technosphere formulation technology and developing therapies for the treatment of solid-tumor cancers.

General and Administrative Expense

General and administrative expenses increased by $0.2 million to $4.1 million for the three months ended June 30, 2004 compared to $3.9 million for the three months ended June 30, 2003, an increase of 5.1%. The increase was primarily due to stock-based compensation expense of $0.9 million in 2004 resulting primarily from the repricing of employee stock options in 2003, which was approved by our board of directors in October 2003, as compared to $0.1 million in stock-based compensation expense recognized in 2003. The increase in costs were offset by a decrease of $0.6 million in various general and administrative expenses resulting from the consolidation of our California operations and reductions in workforce initiated in the first quarter of 2003.

Interest Income

Interest income increased by $4,000 to $123,000 for the three months ended June 30, 2004 compared to $119,000 for the three months ended June 30, 2003, an increase of 3.4%. The increase was primarily due to higher levels of marketable securities available for investment during 2004 compared to 2003.

Other Income (Expense)

Other income of $14,000 and $17,000 for the three months ended June 30, 2004 and 2003, respectively, relates primarily to dividend income from available-for-sale securities.

Six Months Ended June 30, 2004 and 2003

Revenues

No revenues were recorded for the six months ended June 30, 2004 or 2003.

Research and Development Expense

Research and development expenses increased by $6.2 million to $27.1 million for the six months ended June 30, 2004 compared to $20.9 million for the six months ended June 30, 2003, an increase of 29.7%. The increase was primarily due to ongoing expenditures in 2004 related to our Technosphere Insulin System. Initiation of preclinical studies in 2004 increased research expenditures by $2.8 million, which also resulted in increased manufacturing costs of $4.3 million to supply clinical trial materials and our continued validation of our manufacturing system. The increased costs were offset by a decrease of $0.9 million in research and development costs resulting from the termination of AlleCure product development programs and the redesign of CTL product development programs initiated in the first quarter of 2003.

General and Administrative Expense

General and administrative expenses decreased by $4.9 million to $7.8 million for the six months ended June 30, 2004 compared to $12.7 million for the six months ended June 30, 2003, a decrease of 38.6%. The decrease was primarily due to the consolidation of California operations into our Valencia, California facility and reduction of our California workforce, which resulted in transition and

severance expenses of $3.2 million in the six months ended June 30, 2003. Additionally, we recognized stock-based compensation expense of $3.2 million in 2003 resulting primarily from the modification of certain employee stock options as compared to $2.4 million in 2004.

Interest Income

Interest income increased by $17,000 to $221,000 for the six months ended June 30, 2004 compared to $204,000 for the six months ended June 30, 2003, an increase of 8.3%. The increase was primarily due to higher levels of cash and marketable securities available for investment during 2004 compared to 2003.

Other Income (Expense)

Other income of $75,000 for the six months ended June 30, 2004 relates primarily to investment income and the receipt of $10,000 in rental income related to leasing a portion of our facility to a third party. In 2003, we fully reserved the recorded rental income receivable related to the facility lease due to non-payment by the lessee, which resulted in other expense of $33,000.

Liquidity and Capital Resources

Historically, we have 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 as of June 30, 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 an 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 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.

As of June 30, 2004, we had $41.3 million in cash, cash equivalents and marketable securities.

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 and the aggregate price of the offering registered on our behalf was $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, 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 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 an estimated $1.8 million in other offering expenses. After deducting the underwriting discounts and commissions and estimated offering expenses, we received net proceeds from the initial public offering, including the over-allotment, of approximately $83.6 million. These proceeds and the conversion of our preferred stock to common stock are not reflected in the accompanying consolidated financial statements as of June 30, 2004.

During the six months ended June 30, 2004, operating activities used $28.9 million of cash. Net cash used by operating activities during this period resulted primarily from a net loss of $34.7 million, which included non-cash stock-based compensation of $2.4 million and depreciation of $3.6 million. We expect our negative operating cash flow to continue for several years.

During the six months ended June 30, 2004, investing activities used $4.6 million of cash. This use of cash was solely for purchases of equipment of $2.5 million and marketable securities of $2.1 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 six months ended June 30, 2004, financing activities provided $16.8 million in cash primarily from the collection of $18.2 million in preferred stock subscriptions receivable in the first quarter of 2004, offset by $1.4 million returned to a stockholder due to the oversubscribed sale of our Series C convertible preferred stock.

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, a portion of our capital resources will be devoted to expanding our other product development programs for the treatment of solid-tumor cancers and a variety of inflammatory and autoimmune diseases. We also intend to use our capital resources for general corporate purposes, which may include in-licensing or acquiring additional technologies.

We intend to raise additional capital through strategic business collaborations. In addition, 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 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.

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.

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 June 30, 2004. The amounts due for deferred compensation are non-interest-bearing with no repayment terms. Our other obligations are included in the table below.

At June 30, 2004, our total capital lease commitments were not material. Future payments under our operating lease obligations and open purchase commitments consist of the following at June 30, 2004 (in thousands):

	Payments due in				
Contractual obligations	**Total**	**2004**	**2005**	**2006**	**After 2006**
Open purchase order commitments (1)	$ 4,735	$ 3,085	$ 1,100	$ 550	—
Operating lease obligations	295	184	69	42	—
Total contractual obligations	$ 5,030	$ 3,269	$ 1,169	$ 592	—

_____

(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 2002, FASB issued SFAS No. 148, "Accounting for Stock-based Compensation — Transition and Disclosure, an Amendment of FASB Statement No. 123," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. We have adopted the disclosure requirements of this statement. In March 2004, the FASB issued a proposed SFAS - "Share-based Payment: an Amendment of FASB Statements No. 123 and 95." The proposed standard would require companies to expense share-based payments to employees, including stock options, based on the fair value of the award at the grant date. The proposed statement would eliminate the intrinsic value method of accounting for stock options permitted by APB No. 25, "Accounting for Stock Issued to Employees," which we currently follow. We will continue to monitor the actions of the FASB and assess the impact, if any, on our consolidated financial statements.

In March 2004, the FASB approved the consensus reached on EITF Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of Issue No. 03-1 is to provide guidance for identifying impaired investments. Issue No. 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. The accounting provisions of Issue No. 03-1 are effective for all reporting periods beginning after June 15, 2004, while the disclosure requirements are effective only for annual periods ending after June 15, 2004. We have evaluated the impact of the adoption of Issue No. 03-1 and do not believe the impact will be significant to our overall results of operations or financial position.

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 June 30, 2004, we had an accumulated deficit of $401.6 million and a net loss of $65.9 million for the year ended December 31, 2003 and $34.7 million for the six months ended June 30, 2004. The accumulated deficit has resulted principally from the write-off of goodwill, costs incurred in our research and development programs 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, including the proceeds from our initial public offering, will enable us to continue planned operations through at least the second quarter of 2005, even if we do not enter into a collaborative agreement. 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 a strategic business collaboration, the sale of equity and/or debt securities 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;
- 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 licenses;
- 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 private placement of equity securities. We intend to raise additional capital through strategic business collaborations. In addition, 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 to Phase III clinical trials and demonstrate in these trials that our Technosphere Insulin System is safe and effective. We currently anticipate conducting several pivotal Phase III clinical trials as well as several special population studies involving, in total, several thousand 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 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 securing collaborations 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 collaborations 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 seeking to enter into a collaboration with respect to our Technosphere Insulin System. If we are not able to enter into a collaboration prior to the commencement of Phase III clinical trials, upon successful completion of our Phase II clinical trials we intend to fund the initial Phase III clinical trials ourselves from the proceeds of the initial public offering. We estimate that the cost of a Phase III program over the next 24 to 30 months would be approximately $70 to $80 million. Failure to enter into a collaboration with respect to our Technosphere Insulin System following initial Phase III clinical trials or for any other product candidate would substantially increase our requirements for capital, which might not be available on favorable terms, or 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 testing of a particular product candidate does not yield successful results, we will 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 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.

The long-term safety studies of our Technosphere Insulin system are 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 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, our collaborators 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 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 may 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;
- 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 strategic collaborations, sales of securities 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 may 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.

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 are seeking to 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.

If we are unable to manage growth in connection with our transition from an early-stage development company to a company that commercializes therapeutics, our operations will suffer.

We will need to add a significant number of new personnel, broaden our areas of expertise, and expand our manufacturing capabilities in order to successfully implement our commercialization strategy for our Technosphere Insulin System. Over the next two years, we estimate that we will need to recruit at least 65 new employees, principally in the clinical development and manufacturing production areas. Organizational growth and expansion of operations could strain our existing managerial, operational, financial and other resources.

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. We are in the process of qualifying a third-party manufacturer to supply us with commercial quantities of the raw Technosphere material. We are currently negotiating a long-term supply agreement with a third party to manufacture our MedTone inhaler and the unfilled cartridges as well as the related molds.

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, which is currently our sole supplier for insulin. We are aware of at least five other suppliers of bulk insulin. We are currently negotiating a long-term supply agreement with 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 Good Manufacturing Practices ("cGMP"). 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.

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 Aventis, in collaboration with Nektar Therapeutics, have been conducting Phase III clinical trials for the Exubera product and in March 2004 filed a submission seeking regulatory approval in Europe. Novo Nordisk A.S., in collaboration with Aradigm Corporation, has a pulmonary insulin product in Phase III clinical trials, and Eli Lilly and Company, in collaboration with Alkermes, Inc., is also developing a pulmonary insulin product, which is currently in Phase II clinical trials. In addition, a number of established pharmaceutical companies 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, cancer and inflammatory and autoimmune diseases. 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 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 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 may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. 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 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, insurance coverage in our industry can be very expensive and difficult to obtain and we cannot assure you that we will be able to obtain sufficient coverage at an acceptable cost, if at all. If we are sued for any injury caused by our technology or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

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/$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 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 latter indemnities are limited to the purchase price that we paid for the Danbury facilities. We estimate the cost to complete the soil cleanup plan is $500,000 to $1,500,000 over the next 18 to 24 months. 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 Messrs. Mann, Edstrom, Burns and Anderson and Drs. Cheatham and Thomson, could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are “at will” and we currently do not have employment agreements with any of the principal members of our management or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experience required to develop, gain regulatory approval of and commercialize our product candidates successfully.

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

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

Alfred Mann, our Chairman and Chief Executive Officer, is also serving as the Chairman and Co-Chief Executive Officer of Advanced Bionics Corporation, which was acquired by Boston Scientific Corporation, and 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 be able to 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, 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.

RISKS RELATED TO REGULATORY APPROVALS

Our product candidates must undergo rigorous preclinical and clinical testing and 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 interactions 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. We cannot be certain when or under what conditions we will undertake further clinical trials, including a Phase III program for our Technosphere Insulin System. The clinical trials of our product candidates may not be completed on schedule, and 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. The FDA likely 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). There have been some indications from the FDA that the review of a future 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.

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 an entire system and that changes to either the MedTone inhaler, the Technosphere material or the insulin could result in FDA requirements to repeat clinical studies because the agency will not permit bridging studies. Bridging studies are traditionally performed on investigational medical products to demonstrate relevance of data obtained on older generation products to newer changed products. Our product candidates that are currently in development for the treatment of cancer and autoimmune and inflammatory diseases also face similar obstacles and costs.

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

We will not be able to commercialize our Technosphere Insulin System and other product candidates until we have obtained regulatory approval, and any delay in obtaining, or inability to obtain, regulatory approval could harm our business. In addition, regulatory authorities may also 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.

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, we will be subject to stringent, ongoing government regulation.

Even if regulatory authorities approve any of our product candidates, the manufacture, marketing and sale of these product candidates will be subject to stringent and ongoing government regulation. We also are required to register our establishments 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 Quality System Regulations ("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), establishment registration, device listing, 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. We must rely on our MedTone inhaler and cartridge supplier to comply with relevant regulatory requirements including QSR and other FDA requirements for medical device manufacturers. It also is likely that this supplier will be subject to an FDA preapproval inspection before the agency will approve a future marketing application for our Technosphere Insulin System. At the present time our supplier is certified to the ISO 9001:2000 Standard. There can be no assurance, however, that if the FDA were to conduct a preapproval inspection of our supplier, that the agency would find that the supplier substantially complies with the QSR. If we or any potential third-party manufacturer or supplier fail to comply with these cGMP or QSR requirements, 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 other pharmaceutical companies involving insulin delivery systems. The announcement of adverse results from these clinical trials, particularly trials involving the pulmonary delivery of insulin, as well as the FDA's response to these clinical trials, could negatively impact the timing of our clinical trials, our ability to obtain regulatory approval or the public perception of our products. For example, in 2001, Pfizer and Aventis announced that the planned filing for regulatory approval of their pulmonary insulin product would be delayed, citing two concerns. The first concern was that one patient out of more than 1,000 that had used the inhaled form of insulin had developed pulmonary fibrosis. The incidence of pulmonary fibrosis seen in their Phase III clinical trials was comparable to the general population incidence, so it was unclear that the pulmonary fibrosis was related to the use of inhaled insulin. However, the use of inhaled insulin could not be ruled out as a cause. The second concern was that four times as many patients inhaling their drug developed antibodies against insulin as those who injected insulin, although these antibodies did not appear to inhibit insulin activity. Because of these concerns, Pfizer and Aventis stated that the FDA would likely require more safety data. To date, they have filed for regulatory approval in Europe (in March 2004), but have not filed for regulatory approval in the United States. A review of this long-term safety data by the FDA may result in delays in approvals of any inhaled insulin product, including our Technosphere Insulin System. 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 ("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), be required to obtain a license from the other party in order to continue to commercialize the affected products, or 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, you 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 and may result in a loss of some or all of your investment.

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.

Alfred E. Mann, our Chairman, 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 prior to the initial public offering. As of September 1, 2004, Mr. Mann owned or controlled approximately 48.6% of our outstanding shares of common stock. By virtue of his holdings, he is able to effectively control the election of the members of our board of directors, control our management and 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 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 following the expiration of his lock-up agreement with the underwriters. 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.

Mr. Mann has agreed to certain provisions regarding the disposition of his shares, including a prohibition on the sale of his shares for a period of 180 days following the Prospectus dated July 28, 2004.

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 in excess of 15% of our outstanding voting stock from merging or combining with us. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value 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 an investment portfolio consisting mainly of U.S. money market and government-grade securities, directly or through managed funds, with maturities of one year or less. 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 June 30, 2004, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We currently have the ability to hold our fixed income investments until maturity, and therefore we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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 SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), 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 our most recent fiscal quarter 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

None

ITEM 2. CHANGES IN SECURITIES AND 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 proceeds to us of approximately $83.6 million, including $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 $1.8 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. 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.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

On July 20, 2004, our stockholders acted by written consent to approve and adopt an Amended and Restated Certificate of Incorporation to be filed prior to the effectiveness of our initial public offering to implement a 1-for-3 reverse stock split of our outstanding common stock. Stockholders holding an aggregate of 14,190,507 shares approved the reverse stock split set forth in the action by written consent and stockholders holding approximately 11,950,954 shares did not vote with respect to the reverse stock split.

The above action was effected pursuant to an action by written consent of our stockholders in compliance with Section 228 of the Delaware General Corporation Law.

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) List of exhibits:

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation as currently in effect (filed as Exhibit 3.5 to Registration Statement File No. 333-115020)
3.2	Amended and Restated Bylaws as currently in effect (filed as Exhibit 3.7 to Registration Statement File No. 333-115020)
4.1	Form of Common Stock Certificate (filed as Exhibit 4.1 to Registration Statement 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 (filed as Exhibit 4.2 to Registration Statement File No. 333-115020)
10.1 (a)	Form of Indemnity Agreement (filed as Exhibit 10.1 to Registration Statement File No. 333-115020)
10.2 (a)	2004 Equity Incentive Plan and Form of Stock Option Agreement thereunder
10.3	2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement thereunder (filed as Exhibit 10.3 to Registration Statement No. 333-115020)
10.4 (a)	2004 Employee Stock Purchase Plan and Form of Offering Document thereunder (filed as Exhibit 10.4 to Registration Statement 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

(a) Indicates management contract or compensatory plan.

(b) Reports on Form 8-K:

On September 1, 2004, we furnished with the SEC a Current Report on Form 8-K reporting the public dissemination of a press release announcing our financial results for the quarter ended June 30, 2004.

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 3rd day of September 2004.

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 any 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: September 3, 2004

/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 any 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: September 3, 2004

/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 June 30, 2004 (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: September 3, 2004

/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 June 30, 2004 (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: September 3, 2004

/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.