



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**  
(State or other jurisdiction of incorporation  
or organization)

**13-3607736**  
(I.R.S. Employer Identification No.)

**28903 North Avenue Paine**  
**Valencia, California**  
(Address of principal executive offices)

**91355**  
(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.

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

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**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)
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
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	
<b>TOTAL</b>	<b>\$ 125,876</b>	<b>\$ 110,778</b>	
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
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	
<b>COMMITMENTS AND CONTINGENCIES</b>			
<b>SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK,</b> \$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	
<b>STOCKHOLDERS' EQUITY:</b>			
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, \$0.01 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
<b>TOTAL</b>	<b>\$ 125,876</b>	<b>\$ 110,778</b>	

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	<u>13,224</u>	<u>18,382</u>	<u>33,594</u>	<u>34,950</u>	<u>407,208</u>
Loss from operations	<u>(13,224)</u>	<u>(18,382)</u>	<u>(33,594)</u>	<u>(34,950)</u>	<u>(404,350)</u>
Interest income	119	123	204	221	4,799
Other income (expense)	17	14	(33)	75	(2,060)
Loss before provision for income taxes	<u>(13,088)</u>	<u>(18,245)</u>	<u>(33,423)</u>	<u>(34,654)</u>	<u>(401,611)</u>
Income taxes	—	—	—	—	(14)
Net loss	<u>(13,088)</u>	<u>(18,245)</u>	<u>(33,423)</u>	<u>(34,654)</u>	<u>(401,625)</u>
Deemed dividend related to beneficial conversion feature of convertible preferred stock	(875)	—	(875)	(612)	(3,050)
Accretion on redeemable preferred stock	<u>(63)</u>	<u>4</u>	<u>(123)</u>	<u>(60)</u>	<u>(952)</u>
Net loss applicable to common stockholders	<u><u>\$(14,026)</u></u>	<u><u>\$(18,241)</u></u>	<u><u>\$(34,421)</u></u>	<u><u>\$(35,326)</u></u>	<u><u>\$(405,627)</u></u>
Net loss per share:					
Basic and diluted	<u><u>\$ (0.79)</u></u>	<u><u>\$ (0.91)</u></u>	<u><u>\$ (2.01)</u></u>	<u><u>\$ (1.77)</u></u>	
Basic and diluted – pro forma		<u><u>\$ (0.73)</u></u>		<u><u>\$ (1.44)</u></u>	
Shares used to compute net loss per share:					
Basic and diluted	<u>17,760</u>	<u>19,975</u>	<u>17,117</u>	<u>19,975</u>	
Basic and diluted – pro forma		<u>24,907</u>		<u>24,562</u>	

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	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
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	<u>(27,715)</u>	<u>(28,866)</u>	<u>(181,908)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
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	<u>4,990</u>	<u>(4,632)</u>	<u>(92,813)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
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

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	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



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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,	
	2003	2004	2003	2004
(in thousands, except per share data)				
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	<u>\$(14,685)</u>	<u>\$(19,075)</u>	<u>\$(35,533)</u>	<u>\$(37,061)</u>

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2004	2003	2004
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:

(in thousands)	As of:	
	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.

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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

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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,



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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.

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### **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

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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):

Contractual obligations	Payments due in				After 2006
	Total	2004	2005	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;

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- 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

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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

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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;



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- 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

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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;

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- 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

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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

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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),

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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

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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

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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

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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

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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)

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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:

<b>Exhibit Number</b>	<b>Exhibit Description</b>
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)

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<b>Exhibit Number</b>	<b>Exhibit Description</b>
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)*

MANNKIND CORPORATION  
2004 EQUITY INCENTIVE PLAN

ORIGINALLY ADOPTED AS THE 2001 STOCK AWARDS PLAN ON OCTOBER 7, 2001  
ORIGINALLY APPROVED BY STOCKHOLDERS ON OCTOBER 7, 2001  
AMENDED AND RESTATED ON MARCH 23, 2004  
APPROVED BY STOCKHOLDERS ON MARCH 23, 2004  
TERMINATION DATE: MARCH 22, 2014

1. PURPOSES.

(a) AMENDMENT AND RESTATEMENT. The Plan amends and restates the MannKind Corporation 2001 Stock Awards Plan adopted October 7, 2001 (the "PRIOR PLAN"). All outstanding awards granted under the Prior Plan shall remain subject to the terms of the Prior Plan. All options granted subsequent to the effective date of this Plan shall be subject to the terms of this Plan.

(b) ELIGIBLE STOCK AWARD RECIPIENTS. The persons eligible to receive Stock Awards are Employees, Directors and Consultants.

(c) AVAILABLE STOCK AWARDS. The purpose of the Plan is to provide a means by which eligible recipients of Stock Awards may be given an opportunity to benefit from increases in value of the Common Stock through the granting of the following Stock Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Restricted Stock Awards, (iv) Stock Appreciation Rights, (v) Phantom Stock Awards and (vi) Other Stock Awards.

(d) GENERAL PURPOSE. The Company, by means of the Plan, seeks to retain the services of the group of persons eligible to receive Stock Awards, to secure and retain the services of new members of this group and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Affiliates.

2. DEFINITIONS.

(a) "AFFILIATE" means any parent corporation or subsidiary corporation of the Company, whether now or hereafter existing, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(b) "BOARD" means the Board of Directors of the Company.

(c) "CAPITALIZATION ADJUSTMENT" has the meaning ascribed to that term in Section 11(a).

(d) "CAUSE" means, with respect to a Participant, the occurrence of any of the following: (i) such Participant's conviction of any felony or any crime involving fraud or dishonesty which, in the Board's sole discretion, materially affects the business of the Company; (ii) such Participant's participation (whether by affirmative act or omission) in a fraud, act of dishonesty or other act of misconduct against the Company and/or its Affiliates which, in the

Board's sole discretion, materially affects the business of the Company; (iii) conduct by such Participant which, based upon a good faith and reasonable factual investigation by the Company (or, if such Participant is an Officer, by the Board), demonstrates such Participant's gross unfitness to serve; (iv) such Participant's violation of any statutory or fiduciary duty, or duty of loyalty, owed to the Company and/or its Affiliates; (v) such Participant's breach of any material term of any material contract between such Participant and the Company and/or its Affiliates; and (vi) such Participant's repeated violation of any material Company policy. Notwithstanding the foregoing, such Participant's Disability shall not constitute Cause as set forth herein. The determination that a termination is for Cause shall be by the Committee in its sole and exclusive judgment and discretion.

(e) "CHANGE IN CONTROL" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of an Exchange Act Person as described in Section 2(s) (E) transferring in a single act or series of related acts more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities (1) by gift, (2) for estate planning purposes or (3) to any entity controlled directly or indirectly by such Exchange Act Person, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person from the Company in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (C) solely because the level of Ownership held by any Exchange Act Person (the "SUBJECT PERSON") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "INCUMBENT BOARD") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Stock Awards subject to such agreement (it being understood, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply).

(f) "CODE" means the Internal Revenue Code of 1986, as amended.

(g) "COMMITTEE" means a committee of one or more members of the Board appointed by the Board in accordance with Section 3(c).

(h) "COMMON STOCK" means the common stock of the Company.

(i) "COMPANY" means MannKind Corporation, a Delaware corporation.

(j) "CONSULTANT" means any person, including an advisor, who (i) is engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services or (ii) is serving as a member of the Board of Directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered a "Consultant" for purposes of the Plan.

(k) "CONTINUOUS SERVICE" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, shall not terminate a Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director shall not constitute an interruption of Continuous Service. The Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave. Notwithstanding

the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy or in the written terms of the Participant's leave of absence.

(l) "CORPORATE TRANSACTION" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(m) "COVERED EMPLOYEE" means the chief executive officer and the four (4) other highest compensated officers of the Company for whom total compensation is required to be reported to stockholders under the Exchange Act, as determined for purposes of Section 162(m) of the Code.

(n) "DIRECTOR" means a member of the Board.

(o) "DISABILITY" means the permanent and total disability of a person within the meaning of Section 22(e)(3) of the Code.

(p) "EMPLOYEE" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an "Employee" for purposes of the Plan.

(q) "ENTITY" means a corporation, partnership or other entity.

(r) "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.

(s) "EXCHANGE ACT PERSON" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" shall not include (A) the Company or any Subsidiary of the Company, (B) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (C) an underwriter temporarily holding securities pursuant to an offering of such securities, (D) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (E) any natural person, Entity

or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the effective date of the Plan as set forth in Section 14, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities.

(t) "FAIR MARKET VALUE" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on the Nasdaq National Market or the Nasdaq SmallCap Market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the last market trading day prior to the day of determination, as reported in The Wall Street Journal or such other source as the Board deems reliable.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value shall be determined in good faith by the Board.

(u) "INCENTIVE STOCK OPTION" means an Option intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(v) "IPO DATE" means the closing date of the initial public offering of the Common Stock.

(w) "NON-EMPLOYEE DIRECTOR" means a Director who either (i) is not a current Employee or Officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("REGULATION S-K")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(x) "NONSTATUTORY STOCK OPTION" means an Option not intended to qualify as an Incentive Stock Option.

(y) "OFFICER" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(z) "OPTION" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(aa) "OPTION AGREEMENT" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

(bb) "OPTIONHOLDER" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(cc) "OTHER STOCK AWARD" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 7(d).

(dd) "OTHER STOCK AWARD AGREEMENT" means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(ee) "OUTSIDE DIRECTOR" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation", and does not receive remuneration from the Company or an "affiliated corporation," either directly or indirectly, in any capacity other than as a Director or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(ff) "OWN," "OWNED," "OWNER," "OWNERSHIP" A person or Entity shall be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(gg) "PARTICIPANT" means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(hh) "PHANTOM STOCK AWARD" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 7(b).

(ii) "PHANTOM STOCK AWARD AGREEMENT" means a written agreement between the Company and a holder of a Phantom Stock Award evidencing the terms and conditions of a Phantom Stock Award grant. Each Phantom Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(jj) "PLAN" means this MannKind Corporation 2003 Equity Incentive Plan.

(kk) "RESTRICTED STOCK AWARD" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 7(a).

(ll) "RESTRICTED STOCK AWARD AGREEMENT" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(mm) "RULE 16b-3" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(nn) "SECURITIES ACT" means the Securities Act of 1933, as amended.

(oo) "STOCK APPRECIATION RIGHT" means a right to receive the appreciation of Common Stock that is granted pursuant to the terms and conditions of Section 7(c).

(pp) "STOCK APPRECIATION RIGHT AGREEMENT" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement shall be subject to the terms and conditions of the Plan.

(qq) "STOCK AWARD" means any right granted under the Plan, including an Option, a Restricted Stock Award, a Stock Appreciation Right, a Phantom Stock Award or any Other Stock Award.

(rr) "STOCK AWARD AGREEMENT" means a written agreement between the Company and a holder of a Stock Award Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(ss) "SUBSIDIARY" means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

(tt) "TEN PERCENT STOCKHOLDER" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or of any of its Affiliates.

### 3. ADMINISTRATION.

(a) ADMINISTRATION BY BOARD. The Board shall administer the Plan unless and until the Board delegates administration to a Committee, as provided in Section 3(c).

(b) POWERS OF BOARD. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time which of the persons eligible under the Plan shall be granted Stock Awards; when and how each Stock Award shall be granted; what type or combination of types of Stock Award shall be granted; the provisions of each Stock Award granted (which need not be identical), including the time or times when a person shall be permitted to receive Common Stock pursuant to a Stock Award; and the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person.



(ii) To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(iii) To effect, at any time and from time to time, with the consent of any adversely affected Optionholder, (1) the reduction of the exercise price of any outstanding Option under the Plan, (2) the cancellation of any outstanding Option under the Plan and the grant in substitution therefor of (A) a new Option under the Plan or another equity plan of the Company covering the same or a different number of shares of Common Stock, (B) a Restricted Stock Award (including a stock bonus), (C) a Stock Appreciation Right, (D) a Phantom Stock Award (E) an Other Stock Award, (F) cash and/or (G) other valuable consideration (as determined by the Board, in its sole discretion), or (3) any other action that is treated as a repricing under generally accepted accounting principles.

(iv) To amend the Plan or a Stock Award as provided in Section 12.

(v) To terminate or suspend the Plan as provided in Section 13.

(vi) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan.

(vii) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees who are foreign nationals or employed outside the United States.

(c) DELEGATION TO COMMITTEE.

(i) GENERAL. The Board may delegate administration of the Plan to a Committee or Committees of one or more members of the Board, and the term "COMMITTEE" shall apply to any person or persons to whom such authority has been delegated. If administration is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may abolish the Committee at any time and revest in the Board the administration of the Plan.

(ii) SECTION 162(m) AND RULE 16b-3 COMPLIANCE. In the discretion of the Board, the Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, and/or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3. In addition, the Board or the Committee, in its sole discretion, may (1) delegate to a committee of one or more members of the Board who need not be Outside Directors the authority to grant Stock Awards to eligible persons who are either (a) not then Covered Employees and are not expected to be Covered Employees at the time of recognition of

income resulting from such Stock Award, or (b) not persons with respect to whom the Company wishes to comply with Section 162(m) of the Code, and/or (2) delegate to a committee of one or more members of the Board who need not be Non-Employee Directors the authority to grant Stock Awards to eligible persons who are not then subject to Section 16 of the Exchange Act.

(d) DELEGATION TO AN OFFICER. The Board may delegate to one or more Officers of the Company the authority to do one or both of the following (i) designate Officers and Employees of the Company or any of its Subsidiaries to be recipients of Stock Awards and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Officers and Employees of the Company; provided, however, that the Board resolutions regarding such delegation shall specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Notwithstanding anything to the contrary in this Section 3(d), the Board may not delegate to an Officer authority to determine the Fair Market Value of the Common Stock pursuant to Section 2(t)(ii) above.

(e) EFFECT OF BOARD'S DECISION. All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

#### 4. SHARES SUBJECT TO THE PLAN.

(a) SHARE RESERVE. Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, the shares of Common Stock that may be issued pursuant to Stock Awards shall not exceed in the aggregate five million (5,000,000) shares of Common Stock.

(b) REVERSION OF SHARES TO THE SHARE RESERVE. If any Stock Award shall for any reason expire or otherwise terminate, in whole or in part, without having been exercised in full, or if any shares of Common Stock issued to a Participant pursuant to a Stock Award are forfeited to or repurchased by the Company, including, but not limited to, any repurchase or forfeiture caused by the failure to meet a contingency or condition required for the vesting of such shares, then the shares of Common Stock not issued under such Stock Award, or forfeited to or repurchased by the Company, shall revert to and again become available for issuance under the Plan. If any shares subject to a Stock Award are not delivered to a Participant because such shares are withheld for the payment of taxes or the Stock Award is exercised through a reduction of shares subject to the Stock Award (i.e., "net exercised"), the number of shares that are not delivered to the Participant shall remain available for issuance under the Plan. If the exercise price of any Stock Award is satisfied by tendering shares of Common Stock held by the Participant (either by actual delivery or attestation), then the number of shares so tendered shall remain available for issuance under the Plan. Notwithstanding anything to the contrary in this Section 4(b), subject to the provisions of Section 11(a) relating to Capitalization Adjustments the aggregate maximum number of shares of Common Stock that may be issued as Incentive Stock Options shall be seven million (7,000,000) shares of Common Stock.

(c) SOURCE OF SHARES. The shares of Common Stock subject to the Plan may be unissued shares or reacquired shares, bought on the market or otherwise.

5. ELIGIBILITY.

(a) ELIGIBILITY FOR SPECIFIC STOCK AWARDS. Incentive Stock Options may be granted only to Employees. Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants.

(b) TEN PERCENT STOCKHOLDERS. A Ten Percent Stockholder shall not be granted an Incentive Stock Option unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value of the Common Stock on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

(c) SECTION 162(m) LIMITATION ON ANNUAL GRANTS. Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, no Employee shall be eligible to be granted Options or Stock Appreciation Rights covering more than two million (2,000,000) shares of Common Stock during any calendar year.

(d) CONSULTANTS. A Consultant shall not be eligible for the grant of a Stock Award if, at the time of grant, a Form S-8 Registration Statement under the Securities Act ("FORM S-8") is not available to register either the offer or the sale of the Company's securities to such Consultant because of the nature of the services that the Consultant is providing to the Company, because the Consultant is not a natural person, or because of any other rule governing the use of Form S-8.

6. OPTION PROVISIONS.

Each Option shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates shall be issued for shares of Common Stock purchased on exercise of each type of Option. The provisions of separate Options need not be identical, but each Option shall include (through incorporation of provisions hereof by reference in the Option or otherwise) the substance of each of the following provisions:

(a) TERM. The Board shall determine the term of an Option; provided however that, subject to the provisions of Section 5(b) regarding Ten Percent Stockholders, no Incentive Stock Option shall be exercisable after the expiration of ten (10) years from the date on which it was granted.

(b) EXERCISE PRICE OF AN INCENTIVE STOCK OPTION. Subject to the provisions of Section 5(b) regarding Ten Percent Stockholders, the exercise price of each Incentive Stock Option shall be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option on the date the Option is granted. Notwithstanding the foregoing, an Incentive Stock Option may be granted with an exercise price lower than that set forth in the preceding sentence if such Option is granted pursuant to an assumption or substitution for another option in a manner satisfying the provisions of Section 424(a) of the Code.

(c) EXERCISE PRICE OF A NONSTATUTORY STOCK OPTION. The Board, in its discretion, shall determine the exercise price of each Nonstatutory Stock Option.

(d) CONSIDERATION. The purchase price of Common Stock acquired pursuant to an Option shall be paid, to the extent permitted by applicable law, either (i) in cash at the time the Option is exercised or (ii) at the discretion of the Board at the time of the grant of the Option (or subsequently in the case of a Nonstatutory Stock Option) (1) by delivery to the Company (either by actual delivery or attestation) of other Common Stock at the time the Option is exercised, (2) according to a deferred payment or other similar arrangement with the Optionholder, (3) by a "net exercise" of the Option (as further described below), (4) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds or (5) in any other form of legal consideration that may be acceptable to the Board. Unless otherwise specifically provided in the Option, the purchase price of Common Stock acquired pursuant to an Option that is paid by delivery to the Company of other Common Stock acquired, directly or indirectly from the Company, shall be paid only by shares of the Common Stock of the Company that have been held for more than six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes). At any time that the Company is incorporated in Delaware, payment of the Common Stock's "par value," as defined in the Delaware General Corporation Law, shall not be made by deferred payment.

In the case of any deferred payment arrangement, interest shall be compounded at least annually and shall be charged at the minimum rate of interest necessary to avoid (1) the treatment as interest, under any applicable provisions of the Code, of any amounts other than amounts stated to be interest under the deferred payment arrangement and (2) the treatment of the Option as a variable award for financial accounting purposes.

In the case of a "net exercise" of an Option, the Company will not require a payment of the exercise price of the Option from the Participant but will reduce the number of shares of Common Stock issued upon the exercise by the largest number of whole shares that has a Fair Market Value that does not exceed the aggregate exercise price. With respect to any remaining balance of the aggregate exercise price, the Company shall accept a cash payment from the Participant. Shares of Common Stock will no longer be outstanding under an Option (and will therefore not thereafter be exercisable) following the exercise of such Option to the extent of (i) shares used to pay the exercise price of an Option under the "net exercise", (ii) shares actually delivered to the Participant as a result of such exercise and (iii) shares withheld for purposes of tax withholding.

(e) TRANSFERABILITY OF AN INCENTIVE STOCK OPTION. An Incentive Stock Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder. Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be entitled to exercise the Option.

(f) TRANSFERABILITY OF A NONSTATUTORY STOCK OPTION. A Nonstatutory Stock Option shall be transferable to the extent provided in the Option Agreement. If the Nonstatutory Stock Option does not provide for transferability, then the Nonstatutory Stock Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder. Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be entitled to exercise the Option.

(g) VESTING GENERALLY. The total number of shares of Common Stock subject to an Option may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The Option may be subject to such other terms and conditions on the time or times when it may be exercised (which may be based on performance or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options may vary. The provisions of this Section 6(g) are subject to any Option provisions governing the minimum number of shares of Common Stock as to which an Option may be exercised.

(h) TERMINATION OF CONTINUOUS SERVICE. In the event that an Optionholder's Continuous Service terminates (for reasons other than Cause or upon the Optionholder's death or Disability), the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Optionholder's Continuous Service (or such longer or shorter period specified in the Option Agreement or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise his or her Option within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate.

(i) EXTENSION OF TERMINATION DATE. An Optionholder's Option Agreement may also provide that if the exercise of the Option following the termination of the Optionholder's Continuous Service (for reasons other than Cause or upon the Optionholder's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option shall terminate on the earlier of (i) the expiration of the term of the Option set forth in the Option Agreement or (ii) the expiration of a period of three (3) months after the termination of the Optionholder's Continuous Service during which the exercise of the Option would not be in violation of such registration requirements.

(j) DISABILITY OF OPTIONHOLDER. In the event that an Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination (or such longer or shorter period specified in the Option Agreement or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise his or her Option within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate.

(k) DEATH OF OPTIONHOLDER. In the event that (i) an Optionholder's Continuous Service terminates as a result of the Optionholder's death or (ii) the Optionholder dies within the period (if any) specified in the Option Agreement after the termination of the Optionholder's Continuous Service for a reason other than death, then the Option may be exercised (to the extent the Optionholder was entitled to exercise such Option as of the date of death) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the option upon the Optionholder's death pursuant to Section 6(e) or 6(f), but only within the period ending on the earlier of (1) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Option Agreement or (2) the expiration of the term of such Option as set forth in the Option Agreement. If, after the Optionholder's death, the Option is not exercised within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate.

(l) RETIREMENT. Notwithstanding the foregoing, if at the time of termination of an Optionholder's Continuous Service for any reason other than Cause, the Optionholder is at least fifty five (55) years old, then the Optionholder (or such person or person(s) as may be entitled to exercise such Option pursuant to Section 6(k) in the event of the Optionholder's death) may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination) within such period of time ending on the earlier of (i) the date twenty four (24) months following such termination or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination, the Option is not exercised within the time specified herein, the Option shall terminate.

(m) TERMINATION FOR CAUSE. In the event an Optionholder's Continuous Service is terminated for Cause, the Option shall terminate upon the termination date of such Optionholder's Continuous Service and the Optionholder shall be prohibited from exercising his or her Option from and after the time of such termination of Continuous Service.

(n) EARLY EXERCISE. The Option may, but need not, include a provision whereby the Optionholder may elect at any time before the Optionholder's Continuous Service terminates to exercise the Option as to any part or all of the shares of Common Stock subject to the Option prior to the full vesting of the Option. Any unvested shares of Common Stock so purchased may be subject to a repurchase option in favor of the Company or to any other restriction the Board determines to be appropriate. The Company shall not be required to exercise its repurchase option until at least six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes) have elapsed following exercise of the Option unless the Board otherwise specifically provides in the Option.

## 7. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS.

(a) RESTRICTED STOCK AWARDS. Each Restricted Stock Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. At the Board's election, shares of Common Stock may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate shall be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements

need not be identical, provided, however, that each Restricted Stock Award Agreement shall include (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) PURCHASE PRICE. At the time of the grant of a Restricted Stock Award, the Board will determine the price to be paid by the Participant for each share subject to the Restricted Stock Award. To the extent required by applicable law, the price to be paid by the Participant for each share of the Restricted Stock Award will not be less than the par value of a share of Common Stock. A Restricted Stock Award may be awarded as a stock bonus (i.e., with no cash purchase price to be paid) to the extent permissible under applicable law.

(ii) CONSIDERATION. At the time of the grant of a Restricted Stock Award, the Board will determine the consideration permissible for the payment of the purchase price of the Restricted Stock Award. The purchase price of Common Stock acquired pursuant to the Restricted Stock Award shall be paid in one of the following ways: (i) in cash at the time of purchase; (ii) at the discretion of the Board, according to a deferred payment or other similar arrangement with the Participant; (iii) by services previously rendered to the Company in the case of a stock bonus; or (iv) in any other form of legal consideration that may be acceptable to the Board and permissible under the Delaware Corporation Law.

(iii) VESTING. Shares of Common Stock acquired under a Restricted Stock Award may, but need not, be (i) subject to a share repurchase right or option in favor of the Company or (ii) subject to a forfeiture right in favor of the Company, each in accordance with a vesting schedule to be determined by the Board.

(iv) TERMINATION OF PARTICIPANT'S CONTINUOUS SERVICE. In the event that a Participant's Continuous Service terminates, the Company shall have the right, but not the obligation, to repurchase, otherwise reacquire or receive by a forfeiture right, any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination under the terms of the Restricted Stock Award Agreement. At the Board's election, the repurchase right may be at the least of: (i) the Fair Market Value on the relevant date; (ii) the Participant's original cost; or (iii) if the Participant paid the purchase price for the shares of Common Stock with services rendered, then for no consideration. The Company shall not be required to exercise its repurchase option until at least six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes) have elapsed following the purchase of the restricted stock unless otherwise determined by the Board or provided in the Restricted Stock Award Agreement.

(v) TRANSFERABILITY. Rights to purchase or receive shares of Common Stock granted under a Restricted Stock Award shall be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board shall determine in its discretion, and so long as Common Stock awarded under the Restricted Stock Award remains subject to the terms of the Restricted Stock Award Agreement.

(b) PHANTOM STOCK. Each Phantom Stock Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Phantom Stock Award Agreements may change from time to time, and the terms

and conditions of separate Phantom Stock Award Agreements need not be identical, provided, however, that each Phantom Stock Award Agreement shall include (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) CONSIDERATION. At the time of grant of a Phantom Stock Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Phantom Stock Award. To the extent required by applicable law, the consideration to be paid by the Participant for each share of Common Stock subject to a Phantom Stock Award will not be less than the par value of a share of Common Stock. Such consideration may be paid in any form permitted under applicable law.

(ii) VESTING. At the time of the grant of a Phantom Stock Award, the Board may impose such restrictions or conditions to the vesting of the Phantom Stock Award as it, in its absolute discretion, deems appropriate.

(iii) PAYMENT. A Phantom Stock Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration as determined by the Board and contained in the Phantom Stock Award Agreement.

(iv) ADDITIONAL RESTRICTIONS. At the time of the grant of a Phantom Stock Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Phantom Stock Award after the vesting of such Phantom Stock Award.

(v) DIVIDEND EQUIVALENTS. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Phantom Stock Award, as determined by the Board and contained in the Phantom Stock Award Agreement. At the discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Phantom Stock Award in such manner as determined by the Board. Any additional shares covered by the Phantom Stock Award credited by reason of such dividend equivalents will be subject to all the terms and conditions of the underlying Phantom Stock Award Agreement to which they relate.

(vi) TERMINATION OF PARTICIPANT'S CONTINUOUS SERVICE. Except as otherwise provided in the applicable Phantom Stock Award Agreement, such portion of the Phantom Stock Award that has not vested will be forfeited upon the Participant's termination of Continuous Service for any reason.

(c) STOCK APPRECIATION RIGHTS. Each Stock Appreciation Right Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Stock Appreciation Right Agreements may change from time to time, and the terms and conditions of separate Stock Appreciation Right Agreements need not be identical, provided, however, that each Stock Appreciation Right Agreement shall include (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:



(i) STRIKE PRICE AND CALCULATION OF APPRECIATION. Each Stock Appreciation Right will be denominated in share of Common Stock equivalents. The appreciation distribution payable on the exercise of a Stock Appreciation Right will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the Stock Appreciation Right) of a number of shares of Common Stock equal to the number of share of Common Stock equivalents in which the Participant is vested under such Stock Appreciation Right, and with respect to which the Participant is exercising the Stock Appreciation Right on such date, over (B) an amount (the strike price) that will be determined by the Board at the time of grant of the Stock Appreciation Right.

(ii) VESTING. At the time of the grant of a Stock Appreciation Right, the Board may impose such restrictions or conditions to the vesting of such Stock Appreciation Right as it, in its absolute discretion, deems appropriate.

(iii) EXERCISE. To exercise any outstanding Stock Appreciation Right, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

(iv) PAYMENT. The appreciation distribution in respect to a Stock Appreciation Right may be paid in Common Stock, in cash, in any combination thereof or in any other form of consideration as determined by the Board and contained in the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

(v) TERMINATION OF CONTINUOUS SERVICE. In the event that a Participant's Continuous Service terminates, the Participant may exercise his or her Stock Appreciation Right (to the extent that the Participant was entitled to exercise such Stock Appreciation Right as of the date of termination) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the Stock Appreciation Right Agreement) or (ii) the expiration of the term of the Stock Appreciation Right as set forth in the Stock Appreciation Right Agreement. If, after termination, the Participant does not exercise his or her Stock Appreciation Right within the time specified herein or in the Stock Appreciation Right Agreement (as applicable), the Stock Appreciation Right shall terminate.

(d) OTHER STOCK AWARDS. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock may be granted either alone or in addition to Stock Awards provided for under Section 6 and the preceding provisions of this Section 7. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

8. COVENANTS OF THE COMPANY.

(a) AVAILABILITY OF SHARES. During the terms of the Stock Awards, the Company shall keep available at all times the number of shares of Common Stock required to satisfy such Stock Awards.

(b) SECURITIES LAW COMPLIANCE. The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; provided, however, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority which counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained.

9. USE OF PROCEEDS FROM STOCK.

Proceeds from the sale of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

10. MISCELLANEOUS.

(a) ACCELERATION OF EXERCISABILITY AND VESTING. The Board shall have the power to accelerate the time at which a Stock Award may first be exercised or the time during which a Stock Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Stock Award stating the time at which it may first be exercised or the time during which it will vest.

(b) STOCKHOLDER RIGHTS. No Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until such Participant has satisfied all requirements for exercise of the Stock Award pursuant to its terms.

(c) NO EMPLOYMENT OR OTHER SERVICE RIGHTS. Nothing in the Plan or any instrument executed or Stock Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(d) INCENTIVE STOCK OPTION \$100,000 LIMITATION. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any

calendar year (under all plans of the Company and its Affiliates) exceeds one hundred thousand dollars (\$100,000), the Options or portions thereof that exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(e) INVESTMENT ASSURANCES. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (1) the issuance of the shares of Common Stock upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act or (2) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(f) WITHHOLDING OBLIGATIONS. To the extent provided by the terms of a Stock Award Agreement, the Company may in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to a Stock Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Participant by the Company) or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; or (iii) by such other method as may be set forth in the Stock Award Agreement.

#### 11. ADJUSTMENTS UPON CHANGES IN STOCK.

(a) CAPITALIZATION ADJUSTMENTS. If any change is made in, or other event occurs with respect to, the Common Stock subject to the Plan or subject to any Stock Award without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company (each a "CAPITALIZATION ADJUSTMENT"), the Plan will be appropriately adjusted in the class(es) and maximum number of securities subject to the Plan pursuant to Sections 4(a) and 4(b) and the maximum number of securities subject to award to any person pursuant to Section 5(c), and the outstanding Stock Awards will be appropriately adjusted in the class(es) and number of securities and price per share of Common Stock subject to such outstanding Stock Awards. The

Board shall make such adjustments, and its determination shall be final, binding and conclusive. (Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a transaction "without receipt of consideration" by the Company.)

(b) DISSOLUTION OR LIQUIDATION. In the event of a dissolution or liquidation of the Company, then all outstanding Stock Awards shall terminate immediately prior to the completion of such dissolution or liquidation.

(c) CORPORATE TRANSACTION. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation may assume or continue any or all Stock Awards outstanding under the Plan or may substitute similar stock awards for Stock Awards outstanding under the Plan (including, but not limited to, awards to acquire the same consideration paid to the stockholders of the Company, as the case may be, pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Stock Awards may be assigned by the Company to the successor of the Company (or the successor's parent company), if any, in connection with such Corporate Transaction. In the event that any surviving corporation or acquiring corporation does not assume or continue all such outstanding Stock Awards or substitute similar stock awards for all such outstanding Stock Awards, then with respect to Stock Awards that have been not assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction, the vesting of such Stock Awards (and, if applicable, the time at which such Stock Awards may be exercised) shall (contingent upon the effectiveness of the Corporate Transaction) be accelerated in full to a date prior to the effective time of such Corporate Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), and such Stock Awards shall terminate if not exercised (if applicable) at or prior to such effective time, and any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall (contingent upon the effectiveness of the Corporate Transaction) lapse. With respect to any other Stock Awards outstanding under the Plan that have not been assumed, continued or substituted, the vesting of such Stock Awards (and, if applicable, the time at which such Stock Award may be exercised) shall not be accelerated, unless otherwise provided in a written agreement between the Company or any Affiliate and the holder of such Stock Award, and such Stock Awards shall terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction.

(d) CHANGE IN CONTROL. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur.

## 12. AMENDMENT OF THE PLAN AND STOCK AWARDS.

(a) AMENDMENT OF PLAN. Subject to the limitations, if any, of applicable law, the Board at any time, and from time to time, may amend the Plan. However, except as provided in Section 11(a) relating to Capitalization Adjustments, no amendment shall be effective unless

approved by the stockholders of the Company to the extent stockholder approval is necessary to satisfy applicable law.

(b) STOCKHOLDER APPROVAL. The Board, in its sole discretion, may submit any other amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Section 162(m) of the Code and the regulations thereunder regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees.

(c) CONTEMPLATED AMENDMENTS. It is expressly contemplated that the Board may amend the Plan in any respect the Board deems necessary or advisable to provide eligible Employees with the maximum benefits provided or to be provided under the provisions of the Code and the regulations promulgated thereunder relating to Incentive Stock Options and/or to bring the Plan and/or Incentive Stock Options granted under it into compliance therewith.

(d) NO IMPAIRMENT OF RIGHTS. Rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (i) the Company requests the consent of the Participant and (ii) the Participant consents in writing.

(e) AMENDMENT OF STOCK AWARDS. The Board at any time, and from time to time, may amend the terms of any one or more Stock Awards, including, but not limited to, amendments to provide terms more favorable than previously provided in the agreement evidencing a Stock Award, subject to any specified limits in the Plan that are not subject to Board discretion; provided, however, that the rights under any Stock Award shall not be impaired by any such amendment unless (i) the Company requests the consent of the Participant and (ii) the Participant consents in writing.

#### 13. TERMINATION OR SUSPENSION OF THE PLAN.

(a) PLAN TERM. The Board may suspend or terminate the Plan at any time. Unless sooner terminated, the Plan shall terminate on the day before the tenth (10th) anniversary of the date the Plan is adopted by the Board or approved by the stockholders of the Company, whichever is earlier. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) NO IMPAIRMENT OF RIGHTS. Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the Participant.

#### 14. EFFECTIVE DATE OF PLAN.

The Plan shall become effective on the IPO Date, but no Stock Award shall be exercised (or, in the case of a stock bonus, shall be granted) unless and until the Plan has been approved by the stockholders of the Company, which approval shall be within twelve (12) months before or after the date the Plan is adopted by the Board.

15. CHOICE OF LAW.

The laws of the State of California shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to such state's conflict of laws rules.

MANNKIND CORPORATION  
2004 EQUITY INCENTIVE PLAN

STOCK OPTION AGREEMENT  
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice ("GRANT NOTICE") and this Stock Option Agreement, MannKind Corporation (the "COMPANY") has granted you an option under its 2004 Equity Incentive Plan (the "PLAN") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Defined terms not explicitly defined in this Stock Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option are as follows:

1. VESTING. Subject to the limitations contained herein, your option will vest as provided in your Grant Notice, provided that vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. EXERCISE PRIOR TO VESTING ("EARLY EXERCISE"). If permitted in your Grant Notice (i.e., the "EXERCISE SCHEDULE" indicates that "EARLY EXERCISE" of your option is permitted) and subject to the provisions of your option, you may elect at any time that is both (i) during the period of your Continuous Service and (ii) during the term of your option, to exercise all or part of your option, including the nonvested portion of your option; provided, however, that:

a. a partial exercise of your option shall be deemed to cover first vested shares of Common Stock and then the earliest vesting installment of unvested shares of Common Stock;

b. any shares of Common Stock so purchased from installments that have not vested as of the date of exercise shall be subject to the purchase option in favor of the Company as described in the Company's form of Early Exercise Stock Purchase Agreement;

c. you shall enter into the Company's form of Early Exercise Stock Purchase Agreement with a vesting schedule that will result in the same vesting as if no early exercise had occurred; and

d. if your option is an Incentive Stock Option, then, to the extent that the aggregate Fair Market Value (determined at the time of grant) of the shares of Common Stock with respect to which your option plus all other Incentive Stock Options you hold are exercisable for the first time by you during any calendar year (under all plans of the Company and its Affiliates) exceeds one hundred thousand dollars (\$100,000), your option(s) or portions thereof

that exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options.

4. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your option. You may elect to make payment of the exercise price in cash or by check or in any other manner PERMITTED BY YOUR GRANT NOTICE, which may include one or more of the following:

a. In the Company's sole discretion at the time your option is exercised and provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in The Wall Street Journal, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. Payment of the exercise price pursuant to this Section 5(a) must comply with applicable law, including the Sarbanes-Oxley Act of 2002.

b. Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in The Wall Street Journal, by delivery of already-owned shares of Common Stock either that you have held for the period required to avoid a charge to the Company's reported earnings (generally six (6) months) or that you did not acquire, directly or indirectly from the Company, that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "DELIVERY" for these purposes, in the sole discretion of the Company at the time you exercise your option, shall include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your option by tender to the Company of Common Stock to the extent such tender would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

c. Pursuant to the following deferred payment alternative:

1) Not less than one hundred percent (100%) of the aggregate exercise price, plus accrued interest, shall be due four (4) years from date of exercise or, at the Company's election, upon termination of your Continuous Service.

2) Interest shall be compounded at least annually and shall be charged at the minimum rate of interest necessary to avoid (1) the treatment as interest, under any applicable provisions of the Code, of any amounts other than amounts stated to be interest under the deferred payment arrangement and (2) the treatment of the Option as a variable award for financial accounting purposes.

3) At any time that the Company is incorporated in Delaware, payment of the Common Stock's "par value," as defined in the Delaware General Corporation Law, shall be made in cash and not by deferred payment.

4) In order to elect the deferred payment alternative, you must, as a part of your written notice of exercise, give notice of the election of this payment alternative and,



in order to secure the payment of the deferred exercise price to the Company hereunder, if the Company so requests, you must tender to the Company a promissory note and a pledge agreement covering the purchased shares of Common Stock, both in form and substance satisfactory to the Company, or such other or additional documentation as the Company may request.

5. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

6. SECURITIES LAW COMPLIANCE. Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

7. TERM. You may not exercise your option before the commencement or after the expiration of its term. The term of your option commences on the Date of Grant and expires upon the earliest of the following:

a. if you are less than fifty five (55) years old at the time of such termination of your Continuous Service, three (3) months after the termination of your Continuous Service for any reason other than Cause or upon your Disability or death, provided that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in Section 7, your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;

b. if you are less than fifty five (55) years old at the time of such termination of your Continuous Service, twelve (12) months after the termination of your Continuous Service due to your Disability;

c. if you are less than fifty five (55) years old at the time of such termination of your Continuous Service, eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates;

d. if you are fifty five (55) years or older at the time of termination of your Continuous Service for any reason other than Cause, twenty four (24) months after such termination of your Continuous Service;

e. the Expiration Date indicated in your Grant Notice; or

f. the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times

beginning on the date of grant of your option and ending on the day three (3) months before the date of your option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or your permanent and total disability, as defined in Section 22(e) of the Code. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

8. EXERCISE.

a. You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by delivering a Notice of Exercise (in a form designated by the Company) together with the exercise price to the Secretary of the Company, or to such other person as the Company may designate, during regular business hours, together with such additional documents as the Company may then require.

b. By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (1) the exercise of your option, (2) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (3) the disposition of shares of Common Stock acquired upon such exercise.

c. If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the date of your option grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

9. TRANSFERABILITY. Your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to exercise your option.

10. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option shall obligate the Company or an Affiliate, their respective stockholders, Boards of Directors, Officers or Employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

11. WITHHOLDING OBLIGATIONS.

a. At the time you exercise your option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

b. Upon your request and subject to approval by the Company, in its sole discretion, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid variable award accounting). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

c. You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein unless such obligations are satisfied.

12. NOTICES. Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company.

13. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control.

14. CHANGE IN CONTROL.

a. If a Change in Control occurs and as of, or within thirteen (13) months after, the effective time of such Change in Control your Continuous Service terminates due to an involuntary termination (not including death or Disability) without Cause or due to a voluntary termination with Good Reason, then, as of the date of termination of Continuous Service, the vesting and exercisability of your option shall be accelerated in full.

b. "GOOD REASON" means that one or more of the following are undertaken by the Company without your express written consent: (i) the assignment to you of any duties or responsibilities that results in a material diminution in your function as in effect immediately prior to the effective date of the Change in Control; provided, however, that a change in your title or reporting relationships shall not provide the basis for a voluntary termination with Good Reason; (ii) a material reduction by the Company in your annual base salary, as in effect on the effective date of the Change in Control or as increased thereafter; provided, however, that Good Reason shall not be deemed to have occurred in the event of a reduction in your annual base salary that is pursuant to a salary reduction program affecting substantially all of the employees of the Company and that does not adversely affect you to a greater extent than other similarly situated employees; (iii) any failure by the Company to continue in effect any benefit plan or program, including incentive plans or plans with respect to the receipt of securities of the Company, in which you were participating immediately prior to the effective date of the Change in Control (hereinafter referred to as "BENEFIT PLANS"), or the taking of any action by the Company that would adversely affect your participation in or reduce your benefits under the Benefit Plans or deprive you of any fringe benefit that you enjoyed immediately prior to the effective date of the Change in Control; provided, however, that Good Reason shall not be deemed to have occurred if the Company provides for your participation in benefit plans and programs that, taken as a whole, are comparable to the Benefit Plans; (iv) a relocation of your business office to a location more than fifty (50) miles from the location at which you performed your duties as of the effective date of the Change in Control, except for required travel by you on the Company's business to an extent substantially consistent with your business travel obligations prior to the effective date of the Change in Control; or (v) a material breach by the Company of any provision of the Plan or the Option Agreement or any other material agreement between you and the Company concerning the terms and conditions of your employment.

c. If any payment or benefit you would receive pursuant to a Change in Control from the Company or otherwise ("PAYMENT") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "EXCISE Tax"), then such Payment shall be equal to the Reduced Amount. The "REDUCED AMOUNT" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the following order unless you elect in writing a different order

(provided, however, that such election shall be subject to Company approval if made on or after the effective date of the event that triggers the Payment): reduction of cash payments; cancellation of accelerated vesting of Stock Awards; reduction of employee benefits. In the event that acceleration of vesting of Stock Award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of your Stock Awards (i.e., earliest granted Stock Award cancelled last) unless you elect in writing a different order for cancellation.

The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

The accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a Payment is triggered (if requested at that time by you or the Company) or such other time as requested by you or the Company. If the accounting firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Amount, it shall furnish you and the Company with an opinion reasonably acceptable to you that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon you and the Company.

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

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

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)

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

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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

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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.