MANNKIND CORP
Form S-1/A
July 27, 2004

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As filed with the Securities and Exchange Commission on July 27, 2004

Registration No. 333-115020

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4
to

Form S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**13-3607736**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

28903 North Avenue Paine

Valencia, California 91355
(661) 775-5300
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Alfred E. Mann
Chief Executive Officer and Chairman
MannKind Corporation
28903 North Avenue Paine
Valencia, California 91355
(661) 775-5300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:
o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:
o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:
o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box: o

Calculation of Registration Fee

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, par value $0.01 per share	$94,875,000	$12,021[(2)]

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes $12,375,000 of shares that the underwriters have the option to purchase to cover over-allotments.
(2) Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Filed pursuant to Rule 424A
Registration No. 333-115020

PRELIMINARY PROSPECTUS Subject to completion July 27, 2004

5,500,000 Shares

MannKind Corporation

Common Stock

This is the initial public offering of our common stock. No public market currently exists for our common stock. We are offering all of the 5,500,000 shares of our common stock offered by this prospectus. We expect the public offering price to be between $13.00 and $15.00 per share.

Our common stock has been approved for quotation on The Nasdaq National Market under the symbol MNKD.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common stock in Risk factors beginning on page 9 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	$	$
Underwriting discounts and commissions	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also purchase up to an additional 825,000 shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be $ and our total proceeds, before expenses, will be $.

The underwriters are offering the common stock as set forth under Underwriting. Delivery of the shares will be made on or about , 2004.

UBS Investment Bank

Piper Jaffray

Wachovia Securities

Jefferies & Company, Inc.

Harris Nesbitt

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The Technosphere Insulin System, including both the Technosphere dry-powder formulation of insulin and the MedTone inhaler, is restricted by United States law to investigational use only and is not approved for commercial sale.

You should rely only on the information provided in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock.

Through and including , 2004 (the 25th day after the date of this prospectus), federal securities laws may require all dealers that effect transactions in our common stock, whether or not participating in this offering, to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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Technosphere® is our registered trademark and we have applied to register MedTone™ with the US Patent and Trademark office. We have also applied for or registered company trademarks in other jurisdictions, including Europe and Japan. This prospectus also contains trademarks and service marks of other companies that are the property of their respective owners.

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Prospectus summary

This summary highlights selected information appearing elsewhere in this prospectus and may not contain all of the information that is important to you. This prospectus includes information about the shares we are offering as well as information regarding our business and detailed financial data. You should read this prospectus in its entirety. Unless the context requires otherwise, the words MannKind, we, company, us and our refer to MannKind Corporation and its subsidiary.

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. On the basis of our clinical findings to date and our understanding of current diabetes therapy, 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 have discovered and developed the majority of our technology, including the technology associated with our Technosphere Insulin System and our cancer therapy. Currently, our operations encompass research, preclinical and clinical development as well as pharmaceutical manufacturing. We currently outsource the manufacture of our MedTone inhaler. As our products mature, we intend to either enter into sales and marketing collaborations with other companies, if available on commercially reasonable terms, or develop these capabilities ourselves.

According to the American Diabetes Association, in the United States diabetes is estimated to cost society over $132 billion each year and is currently the fifth leading cause of death by disease. The United States Centers for Disease Control, or CDC, estimated that as of 2002 approximately 18.2 million people in the United States, or 6.3% of the population, suffered from type 1 or type 2 diabetes. The CDC further estimated that 13 million cases were diagnosed and under treatment as of 2002 and that 1.3 million new cases would be diagnosed per year beyond that date. According to the CDC, type 2 diabetes is the more prevalent form of the disease, affecting approximately 90% to 95% of people diagnosed with diabetes.

Typically, the treatment of type 2 diabetes starts with management by diet and exercise and progresses to treatment with various non-insulin oral medications and then to treatment with insulin. Treatment through diet and exercise has not been an effective long-term solution for the vast majority of patients with type 2 diabetes. Non-insulin oral medications, which act by increasing the amount of insulin produced by the pancreas or by increasing the sensitivity of insulin-sensitive cells, generally have significant adverse effects and are limited in their ability to manage the disease effectively. Insulin therapy usually involves administering several subcutaneous injections of insulin each day. However, this treatment regimen is inadequate for many reasons, including the inconvenience and pain associated with injections that lead patients not to comply adequately with the prescribed treatment.

Because of the problems associated with the conventional administration of insulin by injection, patients and their physicians have sought alternative methods for the delivery of insulin. One alternative to conventional insulin therapy being pursued by a number of pharmaceutical and biotechnology companies is the inhalation of an insulin formulation into the deep lung, where it can be absorbed directly into the bloodstream. Delivering insulin through the pulmonary route is less invasive than administering it by injection, which, we believe, should increase patient compliance. We anticipate that the first pulmonary insulin product developed by another pharmaceutical company may be ready for commercial sale as early as 2005. However, we believe this product, as well as other pulmonary insulin products in development of which we are aware, will not address a significant shortcoming of conventional insulin therapy. In particular, based on several published reports,

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including a 2004 review article published in *Diabetes Care*, it would appear that these pulmonary insulin products, if and when approved, may not deliver insulin to the bloodstream rapidly enough to approximate the so-called first-phase insulin release spike that is observed in healthy individuals.

The first-phase insulin release spike occurs when a healthy person begins to eat a meal. At the beginning of the meal, the body responds with a sharp spike of insulin release that acts as a signal to the liver to shut off its release of glucose into the bloodstream. This signal turns off the source of glucose that fuels the body between meals at a time when glucose is being supplied from food. Individuals with diabetes cannot produce a first-phase insulin release spike, so their liver continues to release glucose while they absorb additional glucose from the meal. As a result, these individuals develop abnormally high levels of blood glucose, which predisposes them to serious, adverse health consequences.

In contrast, we have observed in our clinical trials to date that our Technosphere Insulin System produces a profile of insulin levels in the bloodstream that does approximate the natural first-phase insulin release spike. In particular, inhalation of Technosphere Insulin generally produces a rapid increase in blood insulin levels that peaks within 10-14 minutes. As illustrated by the charts on page 52, the time-to-peak blood insulin levels produced by the Technosphere Insulin System approximates the rapid rise that has been demonstrated for first-phase insulin release in healthy individuals, which generally occurs within six minutes after food reaches the digestive system.

To date, we have conducted multiple Phase I and Phase II clinical trials of our Technosphere Insulin System involving more than 200 individuals in Europe and the United States. We are currently conducting late Phase II clinical trials to determine dosage tolerance and optimal dosing, which, when fully-enrolled, will involve approximately 325 individuals with type 2 diabetes in Europe and the United States. We expect results from some of these clinical trials to be available in the fourth quarter of 2004 with additional data to follow in early 2005. We intend to initiate Phase III clinical trials in the United States in the first half of 2005, subject to acceptance of our Phase III protocols by the United States Food and Drug Administration, or FDA. Because our studies involved a fairly small number of participants, we cannot be certain that we will be able to repeat and validate our results until we have completed larger studies of efficacy and longer-term safety.

FEATURES OF OUR DIABETES THERAPY

We believe that our Technosphere Insulin System has a number of attractive performance characteristics, including:

Approximates natural first-phase insulin release spike. Typically, regular insulin delivered by subcutaneous injection results in peak insulin levels in about 120 to 180 minutes. Insulin suppliers have developed rapid-acting insulin analogs, which are variations of insulin that reach peak blood levels in 30 to 90 minutes. Based on our analysis of published reports, including a 2004 review article in *Diabetes Care*, we believe that other pulmonary insulin products in development deliver peak insulin levels in 35 to 90 minutes. In contrast, our clinical trials have shown that our Technosphere Insulin System produces peak insulin levels in 10 to 14 minutes, which approximates the timing of the body s natural first-phase insulin release spike.

Ease of use. Our MedTone inhaler is light, is easy to use and fits in the palm of the patient s hand. To administer a dose, the patient opens the device, inserts a single-dose cartridge of Technosphere Insulin powder into the inhaler, inserts the mouthpiece into the mouth and takes a deep breath, thereby drawing the powder deep into the lungs. Moreover, the optimal time for taking a dose of Technosphere Insulin appears to be at the start of a meal or shortly thereafter, so we believe there would be no need for a user to try to time an injection 15 to 45 minutes before the expected mealtime.

More efficient delivery of pulmonary insulin. Based on our clinical trials of Technosphere Insulin and on our analysis of publicly available information regarding the performance of other

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pulmonary insulin systems in development, we believe that the inhalation of a specified amount of insulin formulated as Technosphere Insulin produces blood insulin levels over a measured period of time that are approximately three times greater than that produced by the same amount of insulin administered via the pulmonary delivery systems being developed by other pharmaceutical companies.

Safety. Based on our clinical trials to date, Technosphere Insulin has not generated any serious, drug-related adverse events in our clinical trials to date, but these results are necessarily preliminary until we have completed long term safety studies.

Because of these advantages, we believe our Technosphere Insulin System will be beneficial in patients that have advanced to the point of requiring conventional insulin therapy, patients that are being treated with non-insulin oral medications as well as patients currently using diet and exercise therapy but who are having difficulty achieving proper blood glucose control. If further clinical trials confirm our observations to date, we believe that our Technosphere Insulin System has the potential to be indicated for the treatment of type 2 diabetes after a patient has failed to respond adequately to diet and exercise alone. The use of insulin earlier in the progression of diabetes would represent a paradigm shift in the treatment of this disease.

OUR STRATEGY FOR DIABETES THERAPY

Commercialize our Technosphere Insulin System for the insulin-using diabetes market. We intend to advance our Technosphere Insulin System into and through Phase III clinical trials and then into commercialization, with the goal of establishing a significant presence for Technosphere Insulin in the insulin-using diabetes market.

Establish our Technosphere Insulin System as the preferred drug therapy within the broader population of people with type 2 diabetes. Our target markets also include patients with type 2 diabetes who are currently using conventional therapies other than insulin, such as management by diet and exercise and by non-insulin oral medications. Given the potential advantages of our product, we believe our Technosphere Insulin System has the potential to become the preferred drug therapy for the broader type 2 diabetes population.

Seek a strategic collaboration for the development, marketing and commercialization of our Technosphere Insulin System. We are actively exploring collaborations with large pharmaceutical companies in the United States, Europe and Japan that would provide marketing, sales and financial resources to develop, commercialize and sell our Technosphere Insulin System. To date, we have not licensed or transferred any of our rights to this product and we believe this will enable us to obtain advantageous terms in potential collaborations. We intend to retain worldwide manufacturing rights for our Technosphere Insulin System.

We expect that our revenues from our Technosphere Insulin System will come from the sale of Technosphere Insulin cartridges and the MedTone inhaler. We expect that our costs will be the expenses to produce Technosphere Insulin cartridges and the inhalers, selling and marketing expenses if we elect to proceed without a collaborator, research expenses to expand our Technosphere platform technology and develop other potential products, as well as general and administrative expenses.

OUR RESEARCH PROGRAMS

We are developing additional applications for our proprietary Technosphere formulation technology by formulating other drugs for pulmonary delivery, primarily for metabolic and immunological diseases. We believe our proprietary Technosphere formulation technology can also be extended to other forms of local administration, such as gastrointestinal delivery, because of its apparent ability to stabilize drugs and facilitate transport across cellular membranes.

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We are also developing therapies for the treatment of solid-tumor cancers. We have conducted initial studies of our cancer therapy in Europe and the United States, including Phase I and II clinical trials in the United States that involved 42 patients who had progressed to late stages of skin cancer. We observed that the delivery of a prototype formulation was well tolerated by patients and produced an appropriate response by their immune system. Although we believe that our clinical data to date have been encouraging, we have continued to refine our cancer therapy program. We have developed several product candidates and expect to begin preclinical safety tests for one of these product candidates later this year, with the goal of commencing clinical trials in 2005.

RISKS ASSOCIATED WITH OUR BUSINESS

We face a number of challenges in bringing the Technosphere Insulin System to market. We have not received regulatory approval for this product, nor do we expect to be the first company to bring a pulmonary insulin product to market. In order to complete the clinical trials for our Technosphere Insulin System and develop the sales and marketing capabilities necessary to commercialize the product, we will need to raise additional capital or enter into a collaborative agreement with a pharmaceutical company or both.

We are subject to a number of risks, which you should be aware of before you decide to buy our common stock. These risks are discussed more fully in Risk factors. We are a development stage company with no commercial products. We have not received commercial revenues from any of our product candidates. It is possible that we may never successfully commercialize any of our product candidates. As of March 31, 2004, we had an accumulated deficit of $383.4 million. We expect to continue to incur losses over at least the next several years, and we may never become profitable. Since our inception, we have funded our operations principally through the sale of equity securities, and we expect that we will need to secure additional funding or raise additional capital to enable us to continue to develop and commercialize our Technosphere Insulin System and other product candidates and for other reasons. We cannot assure you that we will be able to obtain additional financing on acceptable terms, or at all.

CORPORATE INFORMATION

We were incorporated in the State of Delaware on February 14, 1991. Our principal executive offices are located at 28903 North Avenue Paine, Valencia, California 91355, and our telephone number at that address is (661) 775-5300. Our website address is http://www.mannkindcorp.com. The information contained in, and that can be accessed through, our website is not incorporated into and does not form a part of this prospectus.

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The offering

Common stock offered by us	5,500,000 shares
Common stock to be outstanding after this offering	31,641,461 shares
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $69.8 million, or approximately $80.6 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of $14.00 per share. We intend to use the net proceeds from this offering to continue the development and prepare for the commercialization of our Technosphere Insulin System, to expand our Technosphere Insulin System manufacturing operations and quality systems, to expand our other product development programs, to fund operations, to provide working capital and for other general corporate purposes. See Use of proceeds.
Nasdaq National Market symbol	MNKD

The number of shares of our common stock shown in the table above to be outstanding after the closing of this offering is based on approximately 26,141,461 shares of our common stock outstanding as of May 31, 2004 and excludes:

- 2,132,922 shares of our common stock issuable upon exercise of options outstanding as of May 31, 2004, with a weighted average exercise price of $10.18 per share, of which options to purchase 790,250 shares were exercisable as of that date at a weighted average exercise price of $11.09 per share;
- 175,227 shares of our common stock issuable upon exercise of warrants outstanding as of May 31, 2004, with a weighted average exercise price of $12.54 per share, all of which were exercisable as of that date;
- 3,659,926 shares of our common stock reserved for future issuance under our 2004 Equity Incentive Plan effective as of the completion of this offering; and
- 2,800,000 shares of our common stock reserved for future issuance under our 2004 Non-Employee Directors Stock Option Plan and 2004 Employee Stock Purchase Plan, which we have adopted effective upon the completion of this offering.

Unless otherwise indicated, all information in this prospectus assumes:

- a one-for-three reverse split of our common stock that occurred on July 22, 2004;
- the conversion, upon the closing of this offering, of all 267,212 shares of our Series A redeemable convertible preferred stock, all 192,618 shares of our Series B convertible preferred stock and all 980,392 shares of our Series C convertible preferred stock, each outstanding as of May 31, 2004, into an aggregate of 6,166,372 shares of our common stock, based on an assumed initial public offering price of $14.00 per share; and
- that the underwriters do not exercise their option to purchase up to 825,000 shares of our common stock to cover over-allotments, if any.

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Summary financial data

We were incorporated in February 1991 under the laws of the State of Delaware as Pharmaceutical Discovery Corporation, or PDC. On December 12, 2001, AlleCure Corp., or AlleCure, and CTL ImmunoTherapies Corp., or 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. For periods prior to January 1, 2002, the results of operations have been presented on a combined basis. For periods subsequent to December 31, 2001, the financial statements of MannKind and its wholly-owned subsidiaries have been presented on a consolidated basis.

The following statements of operations data for the years ended December 31, 1999 and 2000 are unaudited. The following statement of operations data for the years ended December 31, 2001, 2002 and 2003 were derived from our financial statements, which have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, and are included elsewhere in this prospectus. The balance sheet data as of March 31, 2004 and the statement of operation data for each of the three months ended March 31, 2003 and 2004 and for the period from inception (February 14, 1991) through March 31, 2004 have been derived from our unaudited financial statements, which include, in the opinion of management, all adjustments necessary to present fairly the data for such periods. The historical results are not necessarily indicative of results to be expected in any future period. See the notes to the audited financial statements included elsewhere in this prospectus for an explanation of the method used to determine the number of shares used in computing historical and pro forma basic and diluted net loss per share.

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The following financial data is only a summary and should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus and Management s discussion and analysis of financial condition and results of operations. The following selected financial data is not intended to replace our financial statements included elsewhere in this prospectus.

Statement of operations data:	Year ended December 31,					Three months ended March 31,		Cumulative period from February 14, 1991 (date of inception) to
	1999	2000	2001	2002	2003	2003	2004	March 31, 2004
	(in thousands, except per share data)							
Revenue	$ 74	$ 154	$ 326	$	$	$	$	$ 2,858
Operating expenses:								
Research and development	3,994	20,542	19,763	42,724	45,613	11,564	12,799	156,446
General and administrative	1,654	4,854	10,629	13,215	20,699	8,807	3,769	61,226
In-process research and development costs			19,726					19,726
Goodwill impairment				151,428				151,428
Total operating expenses	5,648	25,396	50,118	207,367	66,312	20,371	16,568	388,826
Loss from operations	(5,574)	(25,242)	(49,792)	(207,367)	(66,312)	(20,371)	(16,568)	(385,968)
Other income (expense)	50	204	288	487	(25)	(51)	54	(2,142)
Interest income (expense)	(155)	379	1,261	617	459	86	105	4,744
Loss before provision for income taxes	(5,679)	(24,659)	(48,243)	(206, 263)	(65,878)	(20,336)	(16,409)	(383,366)
Income taxes		(2)	(2)	(2)	(1)			(14)
Net loss	(5,679)	(24,661)	(48,245)	(206,265)	(65,879)	(20,336)	(16,409)	(383,380)
Deemed dividend related to beneficial conversion feature of convertible preferred stock				(1,421)	(1,017)		(612)	(3,050)
Accretion on redeemable preferred stock		(149)	(239)	(251)	(253)	(60)	(64)	(956)
Net loss applicable to common stockholders	$(5,679)	$(24,810)	$(48,484)	$ (207,937)	$(67,149)	$(20,396)	$(17,085)	$(387,386)
Basic and diluted net loss per share:								
Historical	$ (1.38)	$ (3.95)	$ (4.60)	$ (15.43)	$ (3.63)	$ (1.24)	$ (0.86)	
Pro forma(1)					$ (3.34)		$ (0.71)	
Shares used to compute basic and diluted net loss per share:								
Historical	4,125	6,278	10,534	13,472	18,488	16,466	19,975	
Pro forma(1)					20,107		24,218	

(1)

The pro forma basic and diluted net loss per share reflects the weighted effect of the assumed conversion of convertible preferred stock at the conversion prices in effect during the periods presented. See Note 2 to our financial statements for information regarding computation of basic and diluted net loss per share and pro forma basic and diluted net loss per share.

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Balance sheet data:	As of March 31, 2004		
	Actual	Pro forma(1)	Pro forma as adjusted(2)
		(in thousands)	
Cash, cash equivalents and marketable securities	$ 59,305	$ 59,305	$ 129,115
Working capital	52,586	52,586	122,396
Total assets	128,766	128,766	198,576
Deferred compensation and other liabilities	447	447	447
Redeemable convertible preferred stock	5,252		
Deficit accumulated during the development stage	(383,380)	(383,380)	(383,380)
Total stockholders equity	114,431	119,683	189,493

(1) Pro forma to give effect to the conversion, upon the closing of this offering, of all 267,212 shares of our Series A redeemable convertible preferred stock, all 192,618 shares of our Series B convertible preferred stock and all 980,392 shares of our Series C convertible preferred stock, each outstanding as of March 31, 2004, at an assumed initial public offering price of $14.00 per share, into 6,166,372 shares of our common stock.

(2) Pro forma as adjusted to give further effect to the sale of 5,500,000 shares we are offering pursuant to this prospectus and the receipt of the estimated net proceeds therefrom.

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Risk factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below and the other information in this prospectus, including the financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In this event, the market price of our common stock could decline, and you could lose part or all of your investment.

RISKS RELATED TO OUR BUSINESS

We have a history of operating losses, we expect to continue to incur losses, and we may never become profitable.

We are a development stage company with no commercial products. All of our product candidates are still being developed, and all but our Technosphere Insulin System are still in early stages of development. Our product candidates will require significant additional development, clinical trials, regulatory clearances and additional investment before they can be commercialized. We anticipate that our Technosphere Insulin System will not be commercially available for several years, if at all.

We have never been profitable, and, as of March 31, 2004, we had an accumulated deficit of $383.4 million and a net loss of $65.9 million for the year ended December 31, 2003 and $16.4 million for the three months ended March 31, 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 of this offering, will enable us to continue planned operations into the second quarter of 2005, even if we do not enter into a collaborative agreement. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Accordingly, we expect that we will need to raise additional capital, either through a strategic business collaboration, the sale of equity and/or debt securities or the establishment of other funding facilities, in order to continue the development and commercialization of our Technosphere Insulin System and other product candidates and to support

our other ongoing activities. The amount of additional funds we need will depend on a number of factors, including:

- the rate of progress and costs of our clinical trials and research and development activities, including costs of procuring clinical materials and expanding our own manufacturing facilities;
- actions taken by the FDA and other regulatory authorities;
- our success in establishing strategic business collaborations;
- the timing and amount of milestone or other payments we might receive from potential third parties;
- the timing and amount of payments we might receive from potential licenses;
- the costs of discontinuing projects and technologies or decommissioning existing facilities, if we undertake those activities;
- our degree of success in commercializing our Technosphere Insulin System or our other product candidates;
- the emergence of competing technologies and products and other adverse market developments; and
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others.

We have raised capital in the past primarily through the private placement of equity securities. We intend to raise additional capital through strategic business collaborations. In addition, we may in the future pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact your rights as a holder of our common stock, may dilute your ownership percentage and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments.

We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. We cannot assure you, however, that any strategic collaborations, sales of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, licensing arrangements, sales of securities and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including our Technosphere Insulin System development activities, or further reduction of costs for facilities and administration.

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

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

generate revenues will depend solely on the successful development and commercialization of our Technosphere Insulin System.

We have expended significant time, money and effort in the development of our lead product candidate, the Technosphere Insulin System, which has not yet received regulatory approval and which may never be commercialized. Before we can market and sell our Technosphere Insulin System, we will need to advance our Technosphere Insulin System to Phase III clinical trials and demonstrate in these trials that our Technosphere Insulin System is safe and effective. We currently anticipate conducting several pivotal Phase III clinical trials as well as several special population studies involving, in total, several thousand patients, which will require the expenditure of additional time and resources. We must also receive the necessary approvals from the FDA and similar foreign regulatory agencies before this product can be marketed in the United States or elsewhere. Even if we were to receive regulatory approval, we ultimately may be unable to gain market acceptance of our Technosphere Insulin System for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and cost effectiveness. If we fail to commercialize our Technosphere Insulin System, our business, financial condition and results of operations will be materially and adversely affected.

We are seeking to develop and expand our portfolio of product candidates through our internal research programs and through licensing or otherwise acquiring the rights to therapeutics in the areas of cancer and immunology. All of these product candidates will require additional research and development and significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for many years, if at all.

A significant portion of the research that we are conducting involves new and unproven compounds and technologies, including our Technosphere Insulin System, Technosphere formulation technology and immunotherapy product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. Even if our research programs identify candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective drugs or therapeutics. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to successfully complete the development and commercialization of our Technosphere Insulin System or develop or expand our other product candidates, or are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

If we fail to enter into a strategic collaboration with respect to our Technosphere Insulin System, our most clinically advanced program, we may not be able to execute on our business model.

Our current strategy for developing, manufacturing and commercializing our product candidates includes securing collaborations with pharmaceutical and biotechnology companies at some point in the drug development process and for these collaborators to undertake the advanced clinical development and commercialization of our product candidates. It may be difficult for us to find third parties that are willing to enter into collaborations on economic terms that are favorable to us, or at all.

If we are not able to enter into collaborations for our products, we could be required to undertake and fund product development, clinical trials, manufacturing and marketing activities solely at our own expense. For example, we are currently seeking to enter into a collaboration with respect to our Technosphere Insulin System. If we are not able to enter into a collaboration prior to the commencement of Phase III clinical trials, upon successful completion of our Phase II clinical trials we

intend to fund the initial Phase III clinical trials ourselves from the proceeds of this offering. We estimate that the cost of a Phase III program over the next 24 to 30 months would be approximately $70 to $80 million. Failure to enter into a collaboration with respect to our Technosphere Insulin System following initial Phase III clinical trials or for any other product candidate would substantially increase our requirements for capital, which might not be available on favorable terms, or at all. Alternatively, we would have to substantially reduce our development efforts, which would delay or otherwise impede the commercialization of our product candidates.

If testing of a particular product candidate does not yield successful results, we will be unable to commercialize that product candidate.

Our research and development programs are designed to test the safety and efficacy of our product candidates through extensive preclinical and clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our Technosphere Insulin System or any of our other product candidates, including the following:

- safety and efficacy results obtained in our preclinical and initial clinical testing may be inconclusive or may not be predictive of results obtained in later-stage clinical trials or following long-term use and we may be forced to stop developing product candidates that we currently believe are important to our future;
- the data collected from clinical trials of our product candidates may not be sufficient to support FDA or other regulatory approval;
- after reviewing test results, we or any potential collaborators may abandon projects that we previously believed were promising; and
- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

The long-term safety studies of our Technosphere Insulin system are designed to evaluate a number of safety issues, including pulmonary function. Our Technosphere Insulin System is intended for multiple uses per day. Due to the size and time frame over which the clinical trials are conducted, the results of clinical trials may not be indicative of the effects of long-term use. If long-term use of our product results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell our Technosphere Insulin System, may narrow the approved indications for use or otherwise require restrictive product labeling, or may require further clinical trials, which may be time-consuming and expensive, and may not produce favorable results.

As a result of any of these events, the FDA, other regulatory authorities, our collaborators or we may suspend or terminate clinical trials or marketing of our Technosphere Insulin System at any time. Any suspension or termination of our clinical trials or marketing activities may harm our business and results of operations and the market price of our common stock may decline.

If third-party payors do not reimburse customers for our products, they might not be used or purchased, which would adversely affect our revenues.

Our revenues and profitability may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing or profitability of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any healthcare reform proposals or legislation.

Such reforms may make it difficult to complete the development and testing of our product candidates, and therefore may limit our ability to generate revenues from sales of our product candidates and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of other companies that are prospective collaborators for some of our product candidates, our ability to commercialize our product candidates under development may be adversely affected.

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. In addition, because each third-party payor individually approves reimbursement, obtaining these approvals is a time-consuming and costly process that will require us to provide scientific and clinical support for the use of each of our products to each third-party payor separately with no assurance that approval will be obtained. This process could delay the market acceptance of new products and could have a negative effect on our revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that these products will be considered cost-effective or that reimbursement to the consumer will be available, in which case our business and results of operations will be harmed and the market price of our common stock may decline.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of the achievement of these milestones can vary dramatically compared to our estimates in many cases for reasons beyond our control depending on numerous factors, including:

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

In addition, if we do not obtain sufficient additional funds through strategic collaborations, sales of securities or the sale or license of our assets on a timely basis, we may be required to reduce expenses by delaying, reducing or curtailing our Technosphere Insulin System or other product development activities, which may impact our ability to meet milestones. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development goals in the timeframes we announce and expect, our business and results of operations will be harmed and the market price of our common stock may decline.

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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, or cGMP. The supply of all of these materials may be limited or the manufacturer may not meet relevant regulatory requirements, and if we are unable to obtain these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we should encounter delays or difficulties in our relationships with manufacturers or suppliers, our development or manufacturing may be delayed. Any such events would delay the submission of our product candidates for regulatory approval or market introduction and subsequent sales and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

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

A broad base of physicians and specialists treat patients with diabetes. A large sales force will be required in order to educate and support these physicians and specialists. Therefore, we plan to enter into collaborations with one or more pharmaceutical companies to sell, market and distribute our Technosphere Insulin System. If we fail to enter into collaborations, we will be required to establish our own direct sales, marketing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and we estimate that establishing a specialty sales force would cost more than $20 million. Because of our size, we would be at a disadvantage to our potential competitors, all of which have collaborated with large pharmaceutical companies that have substantially more resources than we do. As a result, we would not initially be able to field a sales force as large as our competitors or provide the same degree of market research or marketing support. In addition, our competitors would have a greater ability to devote research resources toward expansion of the indications for their products. We cannot assure you that we will succeed in entering into acceptable collaborations, that any such collaboration will be successful or, if not, that we will successfully develop our own sales, marketing and distribution capabilities.

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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. See Business Competition.

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 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 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 has entered into an agreement to be 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.

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The requirements governing the conduct of clinical trials and manufacturing and marketing of our product candidates, including our Technosphere Insulin System, outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. To our knowledge, no pulmonary insulin product has yet been approved for marketing and we are not aware of any precedent for the successful commercialization of products based on our technology or technologies similar to ours. The FDA likely will regulate our Technosphere Insulin System as a combination product because of the complex nature of the system that includes the combination of a new drug (Technosphere Insulin) and a new medical device (the MedTone inhaler used to administer the insulin). There have been some indications from the FDA that the review of a future marketing application for our Technosphere Insulin System will involve three separate review groups of the FDA: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health within the FDA that reviews medical devices. We currently understand that the Metabolic and Endocrine Drug Products Division will be the lead group and will obtain consulting reviews from the other two FDA groups. The FDA has not made an official final decision in this regard, however, and we can make no assurances at this time about what impact FDA review by multiple groups will have on the review and approval of our product or whether we are correct in our understanding of how the Technosphere Insulin System will be reviewed.

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

We are developing our Technosphere Insulin System as a new treatment for diabetes utilizing unique, proprietary components. The FDA advised us that the Technosphere Insulin System must be tested as an entire system and that changes to either the MedTone inhaler, the Technosphere material or the insulin could result in FDA requirements to repeat clinical studies because the agency will not permit bridging studies. Bridging studies are traditionally performed on investigational medical products to demonstrate relevance of data obtained on older generation products to newer changed products. Our product candidates that are currently in development for the treatment of cancer and autoimmune and inflammatory diseases also face similar obstacles and costs.

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

We will not be able to commercialize our Technosphere Insulin System and other product candidates until we have obtained regulatory approval, and any delay in obtaining, or inability to obtain, regulatory approval could harm our business. In addition, regulatory authorities may also limit the segments of the diabetes population to which we or others may market our Technosphere Insulin System or limit the target population for our other product candidates.

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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 QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. If our facilities, or the facilities of our manufacturers or suppliers, cannot pass a preapproval plant inspection, the FDA will not approve the marketing of our product candidates. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e.g., recalls), establishment registration, device listing, promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business and results of operations.

Our insulin supplier does not yet supply human recombinant insulin for an FDA-approved product and will likely be subject to an FDA preapproval inspection before the agency will approve a future marketing application for our Technosphere Insulin System.

We can make no assurances that our insulin supplier will be acceptable to the FDA. If we were required to find a new or additional supplier of insulin, we would be required to evaluate the new supplier s ability to provide insulin that meets our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of our Technosphere Insulin System. We also depend on suppliers for other materials that comprise our Technosphere Insulin System, including our MedTone inhaler and cartridges. We must rely on our MedTone inhaler and cartridge supplier to comply with relevant regulatory requirements including Quality System Regulations, or 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

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Technosphere Insulin System. At the present time our supplier is certified to the ISO9001:2000 Standard. There can be no assurance, however, that if the FDA were to conduct a preapproval inspection of our 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, or USPTO.

We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

If we become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, we would be required to devote substantial time and resources to prosecute or defend such proceedings.

Competitors may infringe our patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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

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

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

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

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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

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operations and cause the market price of our common stock to decline. See Business Intellectual Property and Proprietary Technology.

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

We have not selected trade names for some of our products and product candidates; therefore, we have not filed trademark registrations for our potential trade names for those products in any jurisdiction, including the United States. Although we intend to defend any opposition to our trademark registrations, no assurance can be given that any of our trademarks will be registered in the United States or elsewhere or that the use of any of our trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO THIS OFFERING

Our stock price may be volatile and, as a result, you could lose some or all of your investment.

Following this offering, the market price for our common stock is likely to be volatile, in part because our shares have not been traded publicly. In addition, there has been a history of significant volatility in the market prices of securities of biotechnology and biopharmaceutical companies. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- the progress and results of our clinical trials;
- announcements by us or our competitors concerning their clinical trial results, acquisitions, strategic alliances, technological innovations and newly approved commercial products;
- the availability of critical materials used in developing and manufacturing our Technosphere Insulin System or other product candidates;
- developments concerning our patents, proprietary rights and potential infringement claims;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- changes in securities analysts estimates of our financial and operating performance;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders; and
- discussion of our Technosphere Insulin System, our other product candidates, competitors products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms.

Any of these risks, as well as other factors, could cause the market price of our common stock to decline and may result in a loss of some or all of your investment.

If other biotechnology and biopharmaceutical companies or the securities markets in general encounter problems, the market price of our common stock could be adversely affected.

Public companies in general and companies included on The Nasdaq National Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market

prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

In the past, following periods of large price declines in the public market price of a company s securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management s attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Alfred E. Mann, our Chairman, Chief Executive Officer and principal stockholder, can individually control our direction and policies, and his interests may be adverse to the interests of our other stockholders. After his death, his stock will be left to his funding foundations for distribution to various charities, and we cannot assure you of the manner in which those entities will manage their holdings.

Mr. Mann has been our primary source of financing to date. As of May 31, 2004, Mr. Mann owned or controlled approximately 61.8% of our outstanding shares of capital stock and will own or control approximately 50.2% of our outstanding shares of common stock immediately following this offering. By virtue of his holdings, he is and will be able to individually elect 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 date of this prospectus. See Underwriting.

You should not consider Mr. Mann s other businesses in deciding whether to purchase our stock.

Mr. Mann has been and continues to be involved in the formation, financing and operation of many businesses unrelated to our business. These businesses have included, among others, Advanced Bionics Corporation, a company focused on the development of cochlear implants that was acquired by Boston Scientific Corporation; Second Sight LLC, a privately held company developing a visual prosthesis to restore a degree of sight to the blind; MiniMed, Inc., a company focused on diabetes

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therapy and microinfusion drug delivery that was acquired by Medtronic, Inc. in 2001; Medical Research Group, Inc., a company involved in the development of an artificial pancreas that was also acquired by Medtronic, Inc. in 2001; and Pacesetter Systems and its successor, Siemens Pacesetter, a manufacturer of cardiac pacemakers that is now part of St. Jude Medical. Mr. Mann is also involved in numerous charitable organizations. You should not consider any of these businesses or activities and should only rely on the information provided in this prospectus in deciding whether or not to purchase our stock.

The future sale of our common stock could negatively affect our stock price.

After this offering, we will have approximately 31.6 million shares of common stock outstanding, or 32.5 million shares if the underwriters exercise their over-allotment option in full. The shares sold in this offering will be freely tradable without restriction under the federal securities laws unless purchased by our affiliates. The remaining shares of common stock outstanding after this offering will be available for public sale subject in some cases to volume and other limitations. See Shares eligible for future sale. Substantially all of our shares outstanding after this offering (excluding the shares sold in this offering) will be subject to the lock-up agreements with the underwriters described under Underwriting.

If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. After this offering, the holders of approximately 913,015 shares of our common stock and the holders of warrants to purchase 135,328 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registrations rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

If an active, liquid trading market for our common stock does not develop, you may be unable to sell your shares quickly or at the market price.

Prior to this offering, there was no public market for our common stock. An active trading market for our common stock may not develop following this offering. As a result, you may not be able to sell your shares quickly or at the market price if trading in our stock is not active. The initial public offering price may not be indicative of prices that will prevail in the trading market. See Underwriting for more information regarding the factors considered in determining the initial public offering price.

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. See Description of capital stock Amended and restated certificate of incorporation and bylaw provisions.

If we do not effectively use our broad discretion in how we use the proceeds of this offering, our results of operations could suffer and the value of our stock could decline.

Our management will have considerable discretion in the application of the net proceeds of this offering. We have not finalized how we will use these proceeds. We may use the net proceeds for corporate purposes that do not yield a significant return or any return at all for our stockholders. See Use of proceeds.

As a new investor, you will incur substantial dilution as a result of this offering, and as a result, the market price of our common stock may decline.

The historical net tangible book value of our common stock as of March 31, 2004 was approximately $119.7 million, or approximately $5.99 per share, based on 19,975,089 of shares outstanding as of March 31, 2004. We expect the initial public offering price to be substantially higher than $5.99 per share. Therefore, if you purchase shares of our common stock in this offering at an assumed price of $14.00 per share, you will incur immediate and substantial dilution in net tangible book value of $8.01 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed initial public offering price. You may incur additional dilution if the holders of outstanding options or warrants exercise those options or warrants. All purchasers of shares in this offering will contribute 19% of the total amount of the purchase price that has been paid by all stockholders but will own only 17% of shares outstanding after the offering. Additional information regarding the dilution to investors in this offering is included in this prospectus under the heading Dilution.

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

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

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Special note regarding forward-looking statements

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in, but not limited to, the sections entitled Risk factors, Management s discussion and analysis of financial condition and results of operations and Business. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the progress or success of our research, development and clinical programs, the timing of completion of enrollment in our clinical trials, the timing of the interim analyses and the timing or success of the commercialization of our Technosphere Insulin System, or any other products or therapies that we may develop;
- our ability to market, commercialize and achieve market acceptance for our Technosphere Insulin System, or any other products or therapies that we may develop;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our estimates for future performance; and
- our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, ma potential, predicts, projects, should, will, would and similar expressions intended to identify forward-looking statements. Forward-lookin statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. We discuss many of these risks in this prospectus in greater detail under the heading Risk factors. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus forms a part completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we do not undertake any obligation to update or revise any forward-looking statements contained in this prospectus or incorporated herein by reference, whether as a result of new information, future events or otherwise. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this prospectus may not transpire. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those described in the Risk factors section and elsewhere in this prospectus.

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Use of proceeds

We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately $69.8 million ($80.6 million if the underwriters exercise their over-allotment option in full), based upon an assumed initial public offering price of $14.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We estimate that we will use approximately $50 million of the net proceeds of this offering to continue the development of our Technosphere Insulin System, including the continuation of our clinical trial program, and to develop additional applications for our proprietary Technosphere formulation technology. We expect, with these proceeds, to complete Phase II trials on Technosphere Insulin and initiate a Phase III clinical trial. Additionally, our efforts with respect to our Technosphere Insulin System will include expansion of our manufacturing operations and quality systems.

We estimate that we will use approximately $10 million of the net proceeds of this offering to expand our other product development programs, specifically developing therapies for the treatment of solid-tumor cancers and a variety of inflammatory and autoimmune diseases. We expect to begin preclinical safety tests for a cancer product candidate later this year, with the goal of commencing clinical trials in 2005.

We intend to use the balance of the net proceeds of this offering to fund operations, to provide working capital and for other general corporate purposes, which may include in-licensing or acquiring additional technologies. We have no current plans, agreements or commitments with respect to any future acquisitions or in-licensing, and we are not currently engaged in any negotiations with respect to any transactions of that nature.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering. Pending these uses, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that funds are readily available to fund our research and development operations. On December 12, 2003, our board of directors adopted our written investment policy. The investment policy imposes restrictions on our investments in order to ensure that we preserve our principal and maintain our liquidity. Any investment of the net proceeds from this offering will be made in accordance with the terms of our investment policy.

Dividend policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business. Accordingly, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

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Capitalization

The following table sets forth our capitalization as of March 31, 2004:

- on an actual basis;
- on a pro forma basis to give effect to the conversion, upon the closing of this offering, of all 267,212 shares of our Series A redeemable convertible preferred stock, all 192,618 shares of our Series B convertible preferred stock and all 980,392 shares of our Series C convertible preferred stock each outstanding as of March 31, 2004, based on an assumed initial public offering price of $14.00 per share, into an aggregate of 6,166,372 shares of our common stock; and
- on a pro forma as adjusted basis to give further effect to the sale in this offering of 5,500,000 shares of our common stock at an assumed initial public offering price of $14.00 per share and the receipt of the estimated net proceeds therefrom, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of March 31, 2004		
	Actual	Pro forma	Pro forma as adjusted
		(in thousands, except share and per share data)	
Cash, cash equivalents and marketable securities	$59,305	$59,305	$ 129,115
Deferred compensation and other liabilities	447	447	447
Series A redeemable convertible preferred stock, $0.01 par value per share; 267,213 shares authorized; 267,212 issued and outstanding, actual; no shares issued and outstanding, pro forma or pro forma as adjusted	5,252		
Stockholders equity:			
Series B convertible preferred stock, $0.01 par value per share; 192,618 shares authorized, issued and outstanding, actual; no shares issued and outstanding, pro forma or pro forma as adjusted	15,000		
Series C convertible preferred stock, $0.01 par value per share; 980,393 authorized; 980,392 issued and outstanding, actual; no shares issued and outstanding, pro forma or pro forma adjusted	50,000		
Common stock, $0.01 par value per share; 100,000,000 shares authorized and 19,975,089 shares issued and outstanding, actual; 100,000,000 and 90,000,000 shares authorized, pro forma and pro forma as adjusted, respectively; 26,141,461 and 31,641,461 shares issued and outstanding, pro forma and pro forma as adjusted, respectively	200	261	316
Additional paid-in capital	434,202	504,393	574,148
Notes receivable from stockholders	(1,438)	(1,438)	(1,438)
Notes receivable from officers	(153)	(153)	(153)
Deficit accumulated during the development stage	(383,380)	(383,380)	(383,380)
Total stockholders equity	114,431	119,683	189,493
Total capitalization	$120,130	$120,130	$ 189,940

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Capitalization

You should read the information in the table above in conjunction with Management s discussion and analysis of financial condition and results of operations and our financial statements and accompanying notes appearing elsewhere in this prospectus.

The number of shares in the table above excludes:

- 2,149,953 shares of our common stock issuable upon exercise of options outstanding as of March 31, 2004, with a weighted average exercise price of $10.20 per share, of which options to purchase 765,464 shares were exercisable as of that date, with a weighted average exercise price of $10.74 per share;

- 175,227 shares of our common stock issuable upon exercise of warrants outstanding as of March 31, 2004, with a weighted average exercise price of $12.54 per share, all of which were exercisable as of that date;

- 3,643,957 shares of our common stock reserved for future issuance under our 2004 Equity Incentive Plan effective as of the completion of this offering; and

- 2,800,000 shares of our common stock reserved for future issuance under our 2004 Non-Employee Directors Stock Option Plan and 2004 Employee Stock Purchase Plan, which we have adopted effective upon the completion of this offering.

We effected a one-for-three reverse split of our common stock on July 22, 2004. All share amounts set forth in the table above give effect to this stock split.

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Dilution

Our historical net tangible book value as of March 31, 2004 was approximately $119.7 million, or $5.99 per share of common stock, based on 19,975,089 shares of common stock outstanding. Historical net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of our common stock outstanding as of March 31, 2004. Our pro forma net tangible book value as of March 31, 2004 was approximately $119.7 million, or $4.58 per share of our common stock. Pro forma net tangible book value per share gives effect to the conversion, upon the closing of this offering, of all then outstanding shares of our preferred stock, based on an assumed initial public offering price of $14.00 per share, into an aggregate of 6,166,372 shares of our common stock.

After giving further effect to the sale of the 5,500,000 shares of our common stock offered by this prospectus at an assumed initial public offering price of $14.00 per share, and after deducting underwriting discounts and commissions and our estimated offering expenses, our pro forma as adjusted net tangible book value as of March 31, 2004 would have been approximately $189.5 million, or $5.99 per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $1.41 per share to existing stockholders and an immediate dilution of $8.01 per share to new investors. The following table illustrates this calculation on a per share basis:

Assumed initial public offering price per share		$14.00
Net tangible book value per share as of March 31, 2004	$ 5.99	
Decrease per share attributable to the conversion of our convertible preferred stock and redeemable convertible preferred stock	(1.41)	
Pro forma net tangible book value as of March 31, 2004	4.58	
Increase per share attributable to the offering	1.41	
Pro forma as adjusted net tangible book value per share after this offering		5.99
Dilution per share to new investors		$ 8.01

If the underwriters exercise their over-allotment option in full, pro forma as adjusted net tangible book value will increase to $6.17 per share, representing an increase to existing stockholders of $1.59 per share, and there will be an immediate dilution of $7.83 per share to new investors.

The following table summarizes, on a pro forma as adjusted basis as of March 31, 2004, after giving effect to this offering and the conversion upon the closing of this offering of all of our shares of convertible preferred stock and redeemable convertible preferred stock outstanding as of that date, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors:

	Total shares		Total consideration		Average price per share
	Number	%	Amount	%	
Existing stockholders	26,141,461	83%	$328,500,000	81%	$12.57
New investors	5,500,000	17	77,000,000	19	14.00
Total	31,641,461	100%	$405,500,000	100%	

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Dilution

If the underwriters exercise their over-allotment option in full, the following will occur:

- the pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately 81% of the pro forma as adjusted total number of shares of our common stock outstanding immediately after this offering; and

- the pro forma as adjusted number of shares of our common stock held by new investors will increase to 6,325,000, or approximately 19% of the total pro forma as adjusted number of shares of our common stock outstanding immediately after this offering.

The tables and calculations above are based on 26,141,461 shares of our common stock outstanding as of March 31, 2004 and exclude:

- 2,149,953 shares of our common stock issuable upon exercise of options outstanding as of March 31, 2004, with a weighted average exercise price of $10.20 per share, of which options to purchase 765,464 shares were exercisable as of that date, with a weighted average exercise price of $10.74 per share;

- 175,227 shares of our common stock issuable upon exercise of warrants outstanding as of March 31, 2004, with a weighted average exercise price of $12.54 per share, all of which were exercisable as of that date;

- 3,643,957 shares of our common stock reserved for future issuance under our 2004 Equity Incentive Plan effective as of the completion of this offering; and

- 2,800,000 shares of our common stock reserved for future issuance under our 2004 Non-Employee Directors Stock Option Plan and 2004 Employee Stock Purchase Plan, which we have adopted effective upon the completion of this offering.

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Selected financial data

We were incorporated in February 1991 under the laws of the State of Delaware as Pharmaceutical Discovery Corporation, or PDC. On December 12, 2001, AlleCure and CTL merged with wholly-owned subsidiaries of PDC. Pursuant to the merger, all of the outstanding shares of capital stock of AlleCure and CTL were exchanged for shares of capital stock of PDC, and AlleCure and CTL became wholly-owned subsidiaries of PDC. In connection with the merger, PDC changed its name to MannKind Corporation. On December 31, 2002, AlleCure and CTL merged with and into MannKind and ceased to be separate entities. For periods prior to January 1, 2002, the results of operations have been presented on a combined basis. For periods subsequent to December 31, 2001, the financial statements of MannKind and its wholly-owned subsidiaries have been presented on a consolidated basis.

The following statement of operations data for the years ended December 31, 1999 and 2000 and the balance sheet data as of December 31, 1999 and 2000 are unaudited. The following statement of operations data for the years ended December 31, 2001, 2002 and 2003 and the balance sheet data as of December 31, 2001, 2002 and 2003, are derived from our audited financial statements. The statement of operations data for each of the three years in the period ended December 31, 2003 and the balance sheet data at December 31, 2002 and 2003 were derived from our financial statements, which have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, and are included elsewhere in this prospectus. The balance sheet data at December 31, 2001 were derived from our financial statements, which have been audited by Deloitte & Touche LLP and are not included in this prospectus. The balance sheet data as of March 31, 2004 and the statement of operation data for each of the three months ended March 31, 2003 and 2004 and for the period from inception (February 14, 1991) through March 31, 2004 have been derived from our unaudited financial statements, which include, in the opinion of management, all adjustments necessary to present fairly the data for such periods. The historical results are not necessarily indicative of results to be expected in any future period. See the notes to the audited financial statements included elsewhere in this prospectus for an explanation of the method used to determine the number of shares used in computing historical and pro forma basic and diluted net loss per share.

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Selected financial data

The following financial data is only a summary and should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus, and Management s discussion and analysis of financial condition and results of operations. The following selected financial data is not intended to replace our financial statements included elsewhere in this prospectus.

	Year ended December 31,					Three months ended March 31,		Cumulative period from February 14, 1991 (date of inception) to
Statement of operations data:	**1999**	**2000**	**2001**	**2002**	**2003**	**2003**	**2004**	**March 31, 2004**
	(in thousands, except per share data)							
Revenue	$ 74	$ 154	$ 326	$	$	$	$	$ 2,858
Operating expenses:								
Research and development	3,994	20,542	19,763	42,724	45,613	11,564	12,799	156,446
General and administrative	1,654	4,854	10,629	13,215	20,699	8,807	3,769	61,226
In-process research and development costs			19,726					19,726
Goodwill impairment				151,428				151,428
Total operating expenses	5,648	25,396	50,118	207,367	66,312	20,371	16,568	388,826
Loss from operations	(5,574)	(25,242)	(49,792)	(207,367)	(66,312)	(20,371)	(16,568)	(385,968)
Other income (expense)	50	204	288	487	(25)	(51)	54	(2,142)
Interest income (expense)	(155)	379	1,261	617	459	86	105	4,744
Loss before provision for income taxes	(5,679)	(24,659)	(48,243)	(206,263)	(65,878)	(20,336)	(16,409)	(383,366)
Income taxes		(2)	(2)	(2)	(1)			(14)
Net loss	(5,679)	(24,661)	(48,245)	(206,265)	(65,879)	(20,336)	(16,409)	(383,380)
Deemed dividend related to beneficial conversion of convertible preferred stock				(1,421)	(1,017)		(612)	(3,050)
Accretion on redeemable preferred stock		(149)	(239)	(251)	(253)	(60)	(64)	(956)
Net loss applicable to common stockholders	$(5,679)	$(24,810)	$(48,484)	$(207,937)	$(67,149)	$(20,396)	$(17,085)	$(387,386)
Basic and diluted net loss per share:								
Historical	$ (1.38)	$ (3.95)	$ (4.60)	$ (15.43)	$ (3.63)	$ (1.24)	$ (0.86)	
Pro forma(1)					$ (3.34)		$ (0.71)	
Shares used to compute basic and diluted net loss per share:								
Historical	4,125	6,278	10,534	13,472	18,488	16,466	19,975	
Pro forma(1)					20,107		24,218	

(1) The pro forma basic and diluted net loss per share reflects the weighted effect of the assumed conversion of convertible preferred stock at the conversion prices in effect during the periods presented. See Note 2 to our financial statements for information regarding computation of basic and diluted net loss per share and pro forma basic and diluted net loss per share.

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Selected financial data

Balance sheet data:	As of December 31, 1999	2000	2001	2002	2003	As of March 31, 2004
			(in thousands)			
Cash, cash equivalents and marketable securities	$2,226	$35,053	$53,730	$31,052	$55,945	$59,305
Working capital	5,450	29,081	47,477	24,171	49,097	52,586
Total assets	9,296	42,645	251,487	104,773	125,876	128,766
Deferred compensation and other liabilities	7,500	132	231	207	404	447
Redeemable convertible preferred stock		4,445	4,684	4,935	5,188	5,252
Deficit accumulated during the development stage	(21,921)	(46,582)	(94,827)	(301,092)	(366,971)	(383,380)
Total stockholders equity (deficit)	(745)	31,890	235,017	90,773	111,577	114,431

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Management s discussion and analysis of financial condition and results of operations

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and the notes to those statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth under Risk factors and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

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. On December 12, 2001, AlleCure and CTL merged with wholly-owned subsidiaries of PDC. Pursuant to the merger, all of the outstanding shares of capital stock of AlleCure and CTL were exchanged for shares of capital stock of PDC, and AlleCure and CTL became wholly-owned subsidiaries of PDC. In connection with the merger, PDC changed its name to MannKind Corporation. On December 31, 2002, AlleCure and CTL merged with and into MannKind and ceased to be separate entities.

Since our inception in 1991 through March 31, 2004, we have incurred a cumulative net loss of $383.4 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 type 2 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, to date, we have not generated any revenues from sales of any product. We currently do not have the required approvals to

market any of our product candidates, and we may not receive them. We may not be profitable even if we succeed in commercializing any of our product candidates.

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 share. Of the $50.0 million of Series C convertible preferred stock subscribed for in 2003, $31.8 million, representing the purchase price for 624,449 shares of Series C convertible preferred stock, was received in 2003 and $18.2 million, representing the purchase price of the remaining 355,943 shares of Series C convertible preferred stock, was received in the first quarter of 2004. All of the shares of our Series C convertible preferred stock were issued in the first quarter of 2004.

Our business is subject to significant risks, including but not limited to the risks inherent in our ongoing clinical trials and the regulatory approval process, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates, the salaries, benefits and stock-based compensation of research and development personnel, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of laboratory equipment. We track research and development costs by the type of cost incurred.

Our research and development staff conducts our internal research and development activities, which include research, product development, clinical development and manufacturing and related activities. This staff is divided between our facilities in Valencia, California 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 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 type 2 diabetes. Based on the results of preclinical studies, we plan to develop additional applications of our Technosphere technology. Additionally, we anticipate that we will continue to determine which research and development projects to pursue, and how much funding to direct to each project, on an ongoing basis, in response to the scientific and clinical success of each product candidate. We cannot be certain when any revenues from the commercialization of our products will commence.

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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. On an ongoing basis we evaluate our estimates and judgments. 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 our assets to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. 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. For example, as described in Results of Operations for the years ended December 31, 2003 and 2002, near the end of the third quarter of 2002, we initiated an internal study to assess whether the product development programs acquired in the merger with AlleCure and CTL were meeting their objectives. As a result of this study, our management concluded in December 2002 that the major AlleCure product development program should be terminated and that the clinical trials of the CTL product should be halted and returned to the research stage. As a result of this determination, during the first quarter of 2003, we closed the CTL facility and reduced headcount for AlleCure and CTL by approximately 50%. In connection with

our annual test for impairment of goodwill as of December 31, 2002, we determined that on the basis of the internal study, the goodwill recorded for the AlleCure and CTL units was potentially impaired. We performed the second step of our annual impairment test as of December 31, 2002 for both the potentially impaired reporting units and estimated the fair value of the AlleCure and CTL programs, as acquired in the merger, using the expected present value of future cash flows which are now expected to be negligible. Accordingly, the goodwill balance of $151,428,000 was determined to be fully impaired and an impairment loss was recorded in the fourth quarter of 2002.

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.

Stock-based compensation

We have recorded compensation expense related to options to purchase our common stock issued to employees and consultants. We have elected to follow Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for our stock-options issued to employees, and we have adopted the disclosure-only alternative of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*. Accordingly, we have recorded stock-based compensation expense in connection with the grant of common stock options to employees based on the intrinsic-value method provided for under APB No. 25 rather than the alternative fair-value method provided for under SFAS No. 123. The intrinsic value of an employee stock option under APB No. 25 is equal to the difference between the exercise price of the option and the estimated fair value, 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 re-measurement of stock-option compensation on the modification date and thereafter under certain circumstances. On October 7, 2003, our board of directors approved a re-pricing program for certain outstanding options to purchase shares of our common stock granted under each of our stock plans. Under the re-pricing program, each holder of outstanding options granted under the stock plans who was our employee on November 5, 2003 could elect to exchange up to all of their outstanding options that had an exercise price greater than $7.95 for re-priced stock options with an exercise price of $7.95 per share and a term of four years. The option re-pricing 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 re-priced options. Employees who are involuntarily terminated in the 12-month period beginning November 5, 2003 will vest 50% upon termination. Compensation cost for all options re-priced under the re-pricing program will be re-measured on a quarterly basis until the options are exercised, canceled or expire.

Stock options issued to consultants are accounted for in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force 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, which have no vesting restrictions and are fully transferable. The Black-Scholes option valuation model requires the input of highly subjective assumptions, including the estimated fair value of our common stock and

expected stock price volatility. Stock-based compensation related to options granted to consultants is generally re-measured periodically as the underlying options vest.

We recognized stock-based compensation expense of $1.6 million in 2001, $352,000 in 2002 and $4.5 million in 2003. 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 financial statements. Stock-based compensation expense for 2002 includes the reversal of approximately $815,000 of stock-based compensation attributable to an in-substance stock option because the intrinsic value of the in-substance stock option was zero at December 31, 2003. 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.

Because there has been no public market for our common stock, we have estimated the fair value of our equity instruments. If future market conditions dictate significant changes in the estimates of fair value, or if a public market establishes a value for our common stock that is significantly higher than our estimated value, our results of operations could be materially impacted. In future periods, we are required to re-measure stock-based compensation cost for all employee options re-priced under the re-pricing program that remain outstanding and to periodically re-measure the stock-based compensation cost of options we have granted to consultants. Since the amount of compensation cost attributable to the re-priced options and consultant options is dependent on the fair value of our common stock underlying the options on the future re-measurement 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. At December 31, 2003, we recorded a full valuation allowance of $80.0 million against our gross deferred tax asset balance, due to uncertainties related to our deferred tax assets as a result of our history of operating losses. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods we may need to change the valuation allowance, which could materially impact our financial position and results of operations.

RESULTS OF OPERATIONS

Three months ended March 31, 2004 and 2003

Revenues

No revenues were recorded for the quarters ended March 31, 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 expenses

Research and development expenses increased by $1.2 million to $12.8 million for the quarter ended March 31, 2004 compared to $11.6 million for the quarter ended March 31, 2003, an increase of 10.3%. 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 $1.0 million. Continuation of clinical studies resulted in increased expenditures of $1.8 million, which also resulted in increased manufacturing costs of $1.7 million to supply clinical trial materials and our continued

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validation of our manufacturing system. These increased costs were offset by a decrease of $3.3 million in research and development costs resulting from the termination of AlleCure product development programs and the redesign of CTL product development programs. 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 expenses

General and administrative expenses decreased by $5.0 million to $3.8 million for the quarter ended March 31, 2004 compared to $8.8 million for the quarter ended March 31, 2003, a decrease of 56.8%. The decrease was primarily due to stock-based compensation expense of $2.5 million resulting primarily from the modification of certain employee stock options, which was recognized in 2003 as compared to $809,000 in 2004. Additionally, the consolidation of our California facilities into our Valencia, California facility and the reduction of the California workforce resulted in transition and severance expenses of $2.7 million in the quarter ended March 31, 2003.

Other income (expense)

Other income of $54,000 for the quarter ended March 31, 2004 relates primarily to investment income and receipt of $10,000 in rental income related to leasing a portion of our facility to a third party. For the quarter ended March 31, 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 $51,000.

Interest income

Interest income increased by $19,000 to $105,000 for the quarter ended March 31, 2004 compared to $86,000 for the quarter ended March 31, 2003, an increase of 22.1%. The increase was primarily due to higher levels of cash and marketable securities available for investment during 2004 compared to 2003.

Years ended December 31, 2003 and 2002

Revenues

No revenues were recorded for the years ended December 31, 2003 or 2002. 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 expenses

Research and development expenses increased by $2.9 million to $45.6 million for the year ended December 31, 2003 compared to $42.7 million for the year ended December 31, 2002, an increase of 6.8%. The increase was primarily due to increased clinical and manufacturing expenses for our Technosphere Insulin System. Our clinical expenses increased in 2003 due to an increase in the number of individuals participating in our Phase II clinical trials. The expansion of our manufacturing production capacity to support the anticipated Technosphere Insulin clinical trial material requirements increased manufacturing costs, which included depreciation, repair and maintenance of equipment, validation costs and development costs for new machinery. 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.

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General and administrative expenses

General and administrative expenses increased by $7.5 million to $20.7 million for the year ended December 31, 2003 compared to $13.2 million for the year ended December 31, 2002, an increase of 56.6%. The increase was primarily due to stock-based compensation expense of $3.8 million and transition and severance expenses of $3.3 million, which resulted from the consolidation of our California facilities into our Valencia, California facility and the reduction of the California workforce from 198 employees as of December 31, 2002 to 80 employees as of December 31, 2003.

Other income (expense)

Other expense of $25,000 for the year ended December 31, 2003 relates primarily to banking fees. For 2002, other income of $487,000 is comprised primarily of rental income related to leasing a portion of our facility to a third party. For 2003, we fully reserved the recorded rental income receivable related to the facility lease due to non-payment by the lessee.

Interest income

Interest income decreased by $158,000 to $459,000 for the year ended December 31, 2003 compared to $617,000 for the year ended December 31, 2002, a decrease of 25.6%. The decrease was primarily due to lower average fund balances available for investment.

Years ended December 31, 2002 and 2001

Revenues

No revenues were recorded for 2002 compared to $326,000 recorded for the year ended December 31, 2001. For the year ended December 31, 2001, the revenues we recorded were related to payments for contract research.

Research and development expenses

Research and development expenses increased by $22.9 million to $42.7 million for the year ended December 31, 2002 compared to $19.8 million in 2001, an increase of 116.2%. The increase resulted primarily from the expansion of our product development programs from 2001 to 2002. In addition, in 2002 we expanded our clinical, regulatory affairs and manufacturing efforts in Danbury, Connecticut to support our clinical trial program.

General and administrative expenses

General and administrative expenses increased by $2.6 million to $13.2 million for the year ended December 31, 2002 compared to $10.6 million for the year ended December 31, 2001, an increase of 24.3%. The increase was primarily due to the expansion of administrative staff at our three separate facilities.

In-process research and development costs

Purchased in-process research and development, or IPR&D, represents the portion of the purchase price of an acquisition related to research and development activities which have not demonstrated their technological feasibility, and have no alternative future uses. For the year ended December 31, 2001, we recorded $19.7 million of IPR&D related to the merger of AlleCure and CTL with wholly-owned subsidiaries of PDC. Since the IPR&D was determined to have no alternative future use, the $19.7 million was charged to expense in 2001. There was no IPR&D charge for the year ended December 31, 2002.

Goodwill and impairment

In 2001, we recorded goodwill of approximately $151.4 million as part of our acquisition of AlleCure and CTL on December 12, 2001. We reevaluate goodwill each year in connection with SFAS 142, and

any related impairment losses are recognized in earnings when identified. Toward the end of the third quarter of 2002, we initiated an internal study to assess whether the product development programs acquired in the merger with AlleCure and CTL were meeting their objectives. As a result of this study, our management concluded in December 2002 that the major AlleCure product development program should be terminated and that the clinical trials of the CTL product should be halted and returned to the research stage. As a result of this determination, during the first quarter of 2003, we closed the CTL facility and reduced headcount for AlleCure and CTL by approximately 50%. In connection with our annual test for impairment of goodwill as of December 31, 2002, we determined that on the basis of the internal study, the goodwill recorded for the AlleCure and CTL units was potentially impaired. We performed the second step of our annual impairment test as of December 31, 2002 for each of the potentially impaired reporting units and estimated the fair value of the AlleCure and CTL programs, as acquired in the merger, using the expected present value of future cash flows which are now expected to be negligible. Accordingly, the goodwill balance of $151,428,000 was determined to be fully impaired and an impairment loss was recorded in fourth quarter of 2002.

Other income (expense)

Other income increased by $199,000 to $487,000 for the year ended December 31, 2002 compared to $288,000 for the year ended December 31, 2001, an increase of 69.1%. The increase was primarily a result of rental income related to the leasing of facility space.

Interest income

Interest income decreased by $644,000 to $617,000 for the year ended December 31, 2002 compared to $1.3 million for the year ended December 31, 2001, a decrease of 51.1%. This decrease was primarily attributable to lower average fund balances available for investment and lower prevailing interest rates associated with cash investments.

LIQUIDITY AND CAPITAL RESOURCES

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 March 31, 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 March 31, 2004, we had $59.3 million in cash, cash equivalents and marketable securities. We estimate that the net proceeds from this offering will be approximately $69.8 million, assuming no exercise by the underwriters of their over-allotment option and an assumed initial public offering price of $14.00 per share and after deducting underwriting discounts and estimated offering expenses. Following this offering, we will have approximately $129.1 million in cash, cash equivalents and marketable securities. We believe that our available cash, cash equivalents, and marketable securities, together with the net proceeds of this offering, will be sufficient to fund anticipated levels of operations into the second quarter of 2005.

We intend to use our capital resources to continue the development of our Technosphere Insulin System and to develop additional applications for our proprietary Technosphere formulation

technology. In addition, portions of our capital resources will be devoted to expanding our other product development programs for the treatment of solid-tumor cancers 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 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. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, licensing arrangements, sales of securities and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including our Technosphere Insulin System development activities, or further reduction of costs for facilities and administration.

For the quarter ended March 31, 2004, we used net cash of $12.0 million in operating activities. This consisted primarily of a net loss for the period of $16.4 million, which included non-cash stock-based compensation of $1.2 million and depreciation of $1.8 million. Additionally, accounts payable and accrued expenses increased by an aggregate of $1.3 million. We used $2.8 million for investing activities for the quarter ended March 31, 2004, which consisted of $1.4 million in net purchases of marketable securities and $1.4 million in manufacturing equipment acquisitions. We received cash of $16.8 million from financing activities during the quarter ended March 31, 2004 consisting of $18.2 million of the remaining proceeds due from the sale of Series C convertible preferred stock offset by $1.4 million returned to a stockholder due to the oversubscribed sale of Series C convertible preferred stock.

Our operating activities used net cash of $52.8 million in 2003, $48.7 million in 2002 and $21.2 million in 2001. During these periods, we recorded increasing expenses caused principally by increases in research and development, expanded clinical trials, business planning and recruitment of management and technical staff, which resulted in increasing operating cash outflows. We expect our negative operating cash flow to continue for several years.

Our investing activities generated $4.1 million in 2003, principally from the proceeds from the net sales and purchases of marketable securities of $9.2 million, offset by the purchase of property and equipment of $5.2 million. Our investing activities used $45.3 million in 2002 and $39.7 million in 2001. In 2002, purchases of property and equipment used $34.1 million and net purchases and sales of marketable securities used $11.2 million. In 2001, investing activities consisted entirely of the purchase of property and equipment.

Our financing activities provided cash of $82.8 million in 2003, generated primarily from the collection of $31.8 million of stock subscriptions for 624,449 shares of Series C convertible preferred stock and $50.0 million from the sale of 3,493,194 shares of common stock. In 2002, financing

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activities generated $60.2 million primarily from the sale of 4,155,757 shares of common stock, which provided $58.9 million in proceeds. In 2001, financing activities generated $79.5 million primarily from the sale of 3,052,078 shares of common stock, which provided $78.0 million in proceeds.

As of March 31, 2004, we did not have any off balance sheet financing arrangements.

COMMITMENTS AND CONTINGENCIES

Our contractual obligations consist of operating leases, purchase obligations, capital lease commitments and deferred compensation. Certain stockholders and officers elected to defer part or all of their compensation from 1991 through 1998, resulting in total deferred compensation of $1.6 million at March 31, 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 March 31, 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 March 31, 2004 (in thousands):

	Payments due in				
Contractual obligations	Total	2004	2005	2006	After 2006
Open purchase order commitments(1)	$6,399	$4,749	$1,100	$550	
Operating lease obligations	419	322	61	36	
Total contractual obligations	$6,818	$5,071	$1,161	$586	

(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.

RELATED PARTY TRANSACTIONS

For a description of our related party transactions see Certain relationships and related party transactions.

RECENT ACCOUNTING PRONOUNCEMENTS

In January 2003, the Financial Accounting Standards Board (FASB) issued Financial Interpretation Number 46, *Consolidation of Variable Interest Entities* (FIN 46) with the objective of improving financial reporting by companies involved with variable interest entities. FIN 46 clarifies the application of Accounting Research Bulletin No. 51 to certain entities, defined as variable interest entities, in which equity investors do not have characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated support from other parties. In December 2003, the FASB issued a revision to FIN 46, or FIN 46R, to clarify some of the provisions of FIN 46. We currently have no entities that have the characteristics of a variable interest entity. Furthermore, our adoption of the remaining provisions of FIN 46R in the quarter ended March 31, 2004 did not have an impact on our financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the interim period

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commencing July 1, 2003, except for mandatory redeemable financial instruments of nonpublic companies, which is effective for fiscal periods beginning after December 31, 2004. The adoption did not have a material impact on our financial statements.

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 investment policy is designed to preserve capital and provide liquidity to meet projected cash requirements. Our investment portfolio currently consists of US government securities, bank obligations and corporate debt instruments for which the maturity dates average less than twelve months. We currently do not hedge against interest rate exposure. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest-sensitive financial instruments at March 31, 2004. The modeling technique that we used measures the change in fair values arising from an immediate, hypothetical shift in market interest rates and assumes that ending fair values include principal and accrued interest. Declines in interest rates over time will, however, reduce our interest income while increases in interest rates over time will increase our interest expense. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

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Business

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. On the basis of our clinical findings to date and our understanding of current diabetes therapy, 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.

In our clinical trials to date, we have observed that our Technosphere Insulin System produces a profile of insulin levels in the bloodstream that approximates the insulin profile normally seen in healthy individuals immediately following the beginning of a meal. As a result, we believe that our Technosphere Insulin System will be beneficial not only for insulin-using diabetes patients but also for patients with type 2 diabetes who are currently using conventional therapies other than insulin. The results of our earlier studies may not be confirmed by the results of later studies. However, if further clinical trials support our initial observations, we believe the Technosphere Insulin System has the potential to be indicated for the treatment of type 2 diabetes after a patient has failed to respond adequately to diet and exercise alone. The use of insulin earlier in the progression of diabetes would represent a paradigm shift in the treatment of this disease.

To date, we have conducted multiple Phase I and Phase II clinical trials of our Technosphere Insulin System involving more than 200 individuals in Europe and the United States. Our Technosphere Insulin System has had a favorable safety profile in our clinical trials to date. We are currently conducting late Phase II clinical trials to determine dosage tolerance and optimal dosing, which, when fully-enrolled, will involve approximately 325 individuals with diabetes in Europe and the United States. At this time, we expect results from some of these clinical trials to be available in the fourth quarter of 2004 with additional data to follow in early 2005. We intend to initiate Phase III clinical trials in the United States in the first half of 2005, subject to acceptance of our Phase III protocols by the FDA.

Our Technosphere Insulin System utilizes our proprietary Technosphere formulation technology, which is based on a class of organic molecules that are designed to self-assemble into small particles onto which drug molecules can be loaded. We are in the process of developing additional Technosphere-based products for the delivery of other drugs. We also have research programs focused on the development of therapies for cancer, inflammation and autoimmune disorders.

OVERVIEW OF DIABETES

Diabetes is a major disease characterized by the body s inability to properly regulate levels of blood glucose, or blood sugar. The cells of the body utilize glucose as fuel, which is consumed 24 hours a day. Between meals, when glucose is not being supplied from food, the liver releases glucose into the blood to sustain adequate levels. Insulin is a hormone produced by the pancreas that regulates the body s blood glucose levels. Patients with diabetes develop abnormally high levels of glucose, a state known as hyperglycemia, either because they produce insufficient levels of insulin or because they fail to respond adequately to insulin produced by the body. Over time, poorly controlled levels of blood glucose can lead to major complications, including significant weight gain, blindness, loss of circulation, kidney failure, impotence, heart attack, stroke and death.

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Business

According to the American Diabetes Association, or ADA, in the United States diabetes is estimated to cost society over $132 billion each year and is currently the fifth leading cause of death by disease. Data from the United States Centers for Disease Control, or CDC, and the National Institutes of Health indicate that the risk of death due to heart disease and the risk of stroke are up to four times higher in adults with diabetes than in those without the disease. Diabetes is the leading cause of new cases of blindness among adults, kidney disease and non-traumatic lower-limb amputations. The CDC estimated that, as of 2002, approximately 18.2 million people in the United States, or 6.3% of the population, suffered from diabetes. The CDC further estimated that 13 million cases were diagnosed and under treatment as of 2002 and that 1.3 million new cases would be diagnosed per year beyond that date. The ADA estimated that, in 2002, the direct costs for required drug treatment of diabetes in the United States were approximately $12 billion, of which approximately $7 billion were for insulin and delivery supplies and approximately $5 billion were for non-insulin oral medications.

There are two major forms of diabetes, type 1 and type 2. Type 1 diabetes is characterized by a complete lack of insulin secretion by the pancreas, so insulin must be supplied from outside the body in order to sustain life. In type 2 diabetes, the pancreas continues to produce insulin; however, over time it becomes increasingly unable to secrete adequate amounts of insulin to support metabolism. According to the CDC, type 2 diabetes is the more prevalent form of the disease, affecting approximately 90% to 95% of people diagnosed with diabetes.

The illustration below summarizes reports published in the *New England Journal of Medicine* and the *American Journal of Medicine* of the insulin-secretion profiles at meal time of healthy individuals and of patients with type 2 diabetes. When a healthy person begins to eat a meal, the pancreas responds with the two phases of insulin release into the bloodstream that are depicted by the solid line in the illustration below. The first phase of insulin release takes the form of a sharp spike in insulin that acts as a signal to the liver to shut off its release of glucose into the bloodstream. In the second phase of insulin release, the pancreas secretes an extended wave of insulin that acts on cells throughout the body, enabling them to absorb the glucose ingested from the meal.

Insulin-secretion profiles at meal time

As depicted by the dashed line in the illustration, individuals with early type 2 diabetes cannot produce the first-phase insulin release spike and, as a result, their liver continues to release glucose while they absorb additional glucose from the meal. This can worsen high blood sugar levels. This state forces the pancreas to compensate by secreting excessive amounts of insulin during the second phase. Over time, this repeated cycle of inadequate early release followed by over-insulinization is correlated with

subsequent exhaustion of the overall ability of the pancreas to secrete additional amounts of insulin at any point following a meal, which is depicted by the dotted line in the illustration. This situation is further complicated by a decline in the ability of insulin-sensitive cells throughout the body to respond to insulin a state known as insulin resistance. The inability to maintain control over blood glucose levels predisposes the patient with diabetes to serious, adverse health consequences.

Challenges of treating type 2 diabetes

Typically, the treatment of type 2 diabetes starts with management by diet and exercise and progresses to treatment with various non-insulin oral medications and then to treatment with insulin. Treatment through diet and exercise alone has not been an effective long-term solution for the vast majority of patients with type 2 diabetes. Non-insulin oral medications, which act by increasing the amount of insulin produced by the pancreas or by increasing the sensitivity of insulin-sensitive cells, generally have significant adverse effects and are limited in their ability to manage the disease effectively.

Insulin therapy usually involves administering several subcutaneous injections of insulin each day. However, this treatment regimen is inadequate for many reasons, including:

- Patients dislike injecting themselves with insulin due to inconvenience and pain, and so tend not to comply adequately with prescribed treatment regimens. As a result, they do not properly medicate themselves.

- Even when properly administered, subcutaneous injections of insulin do not replicate the natural first-phase insulin spike. Instead, injected insulin enters the bloodstream over a period of several hours. The consequence is for patients with diabetes to have inadequate levels of insulin present at the initiation of a meal and to be over-insulinized between meals. This results in high blood glucose levels early after meal onset followed by a tendency for glucose to fall to abnormally low levels, a state known as hypoglycemia, during the period between meals. Hypoglycemia can result in loss of mental acuity, confusion, increased heart rate, hunger, sweating and faintness and, at very low glucose levels, loss of consciousness, coma and death.

Because of the problems associated with the conventional administration of insulin by injection, patients and their physicians have sought alternative methods for the delivery of insulin, including insulin pumps and oral delivery of insulin. Insulin pumps are generally considered appropriate only for a small segment of the diabetes population. The development of an effective oral insulin formulation has been hampered by problems of delivering a sufficient supply of insulin to the body at the time when it is needed. Because insulin is largely broken down in the digestive system, much of the insulin delivered orally does not enter the bloodstream and there is an undesirable variability in the rate of insulin absorption.

One alternative to conventional insulin therapy being pursued by a number of pharmaceutical and biotechnology companies is the inhalation of an insulin formulation into the deep lung, where it can be absorbed directly into the bloodstream. Delivering insulin through the pulmonary route is less invasive than administering it by injection and, according to a 2001 study reported in *Diabetes Care*, is associated with greater patient satisfaction, which should increase patient compliance and lead to better glucose control.

We anticipate that the first pulmonary insulin product developed by another pharmaceutical company may be approved for commercial sale as early as 2005. Although this product should be an important development for diabetes care, we believe that it will only partially address the shortcomings of conventional insulin therapy. A long sought-after goal in the treatment of diabetes has been to produce a profile of insulin levels in the bloodstream that approximates the first-phase insulin release spike normally seen in healthy individuals following the beginning of a meal. Based on several published reports including a 2004 review article published in *Diabetes Care*, it would appear that the first

pulmonary insulin products, if and when approved, may not deliver insulin to the bloodstream rapidly enough to approximate the natural first-phase insulin release spike.

THE MANNKIND SOLUTION

Based upon our clinical data, we believe our Technosphere Insulin System will be the first commercially available therapy to produce a profile of insulin levels in the bloodstream that approximates the natural first-phase insulin release spike normally seen in healthy individuals following the beginning of a meal. To date, we have conducted Phase I and Phase II clinical trials involving more than 200 individuals in Europe and the United States; however, until we have completed larger studies of efficacy and long-term safety, we cannot be certain that we will be able to repeat and validate our findings from studies that involved fairly small numbers of participants.

The clinical data below show the approximation of first-phase insulin release in more detail. The chart on the left shows the mean changes in blood insulin levels of 12 patients with type 1 diabetes who inhaled a dose of our Technosphere Insulin prior to eating a standardized meal. For illustration purposes, we have shown data from a study of patients with type 1 diabetes, whom we studied in order to observe the response to administration of Technosphere Insulin without interference from the natural production of insulin. These results are typical of our observations recorded in the other clinical trials that we have completed, including trials involving patients with type 2 diabetes. Because different protocols are used for each clinical trial, it is not possible, nor would it be scientifically valid, for us to present blood insulin data aggregated across multiple trials. Moreover, not all of the clinical trials provided the kind of data presented in the chart below. However, the data presented below is consistent with the data obtained from each of our other clinical trials where comparable data was collected.

The key feature of the response shown on the left is the time taken for blood insulin levels to peak, which was approximately ten minutes in this study. The magnitude of the response is related to the dose of Technosphere Insulin administered; we have observed in our clinical trials that the timing of the response is consistent across a range of doses. For comparison purposes, these data are presented next to a chart that shows data published in 1981 in the *American Journal of Medicine* from nine healthy individuals who were rapidly administered a glucose solution intravenously an experimental protocol that allowed investigators to evaluate the characteristics of the normal first-phase insulin release. These charts show that the rapid time-to-peak blood insulin levels produced by the Technosphere Insulin System in this study approximates the timing that has been demonstrated for first-phase insulin release in healthy individuals, which generally occurs within six minutes after food reaches the digestive system.

Technosphere Insulin approximation of first-phase insulin release

First-phase insulin release in healthy individuals

By approximating the first-phase insulin release spike, our Technosphere Insulin System may allow patients with some pancreatic function to achieve greater control over their glucose levels, which we expect may reduce exhaustion of insulin-secreting cells in the pancreas and possibly also reduce the degree of insulin resistance. This effect would be beneficial in patients with type 2 diabetes that have advanced to the point of requiring conventional insulin therapy, patients that are being treated with non-insulin oral medications as well as patients currently using diet and exercise therapy but who are having difficulty achieving proper glucose control. If further clinical trials confirm our observations to date, we believe our Technosphere Insulin System has the potential to be indicated for the treatment of type 2 diabetes after a patient has failed to respond adequately to diet and exercise alone. The use of insulin earlier in the progression of diabetes would represent a paradigm shift in the treatment of the disease.

Our proprietary pulmonary delivery platform consists of our dry powder Technosphere formulation and our MedTone inhaler through which the powder is delivered into the deep lung. Our Technosphere formulation technology is centered on a class of organic molecules that are designed to self-assemble into small particles. Certain drugs, such as insulin, can be loaded onto these particles. The structural characteristics of loaded Technosphere particles (particle size and surface topography) impart aerodynamic properties that we believe make them particularly well suited for inhalation delivery.

In order to formulate Technosphere Insulin, we combine solutions of insulin and the Technosphere material to form a mixture, which is then dried to form the insulin-loaded powder. In our preclinical studies, we have observed that the Technosphere Insulin formulation is able to pass through the surface cells of the lung more rapidly than insulin alone. We believe this attribute is largely why our Technosphere Insulin System can approximate the natural first-phase insulin release spike.

We have developed a proprietary, palm-sized and easy-to-use dry powder inhaler for use with proprietary, single-use, disposable, plastic cartridges containing Technosphere-formulated drugs. The inhaler has been used in multiple Phase I and Phase II clinical trials with Technosphere Insulin. We believe that the compact size and design of our MedTone inhaler, shown below, make it simple to use and unobtrusive, which we believe should facilitate patient compliance. It also incorporates several features designed to ensure that the drug is delivered appropriately to the deep lung, including:

- breath actuation, which means that the patient does not need to coordinate a breath with any manipulation of the device, such as priming or pumping; and

- an airflow regulator that is intended to deliver a consistent airflow from patient to patient and from use to use, even in patients with restricted airflow capacity.

The MedTone inhaler in the closed position

We believe that our Technosphere Insulin System has advantages over other competitive pulmonary insulin delivery systems, principally due to our proprietary technology. These advantages include:

Approximates natural first-phase insulin release spike. A major advantage of our Technosphere Insulin System is the speed with which the insulin is delivered to the patient s bloodstream. Typically, regular insulin delivered by subcutaneous injection is delivered to the bloodstream slowly, resulting in peak insulin levels in about 120 to 180 minutes. Insulin suppliers have developed rapid-acting insulin analogs, which are variations of insulin that reach peak blood levels in 30 to 90 minutes. Based on our analysis of published reports, including a 2004 review article published in *Diabetes Care*, we believe that other pulmonary insulin products in development deliver peak insulin levels in 35 to 90 minutes. This timing does not approximate the natural first-phase insulin release spike, which generally occurs within six minutes after food reaches the digestive system. In contrast, our clinical trials have shown that our Technosphere Insulin System produces peak insulin levels in 10 to 14 minutes, which approximates the timing of the body s natural first-phase insulin release spike. Because our product produces an early insulin profile that resembles that seen in healthy individuals, we anticipate that our insulin therapy may be able to achieve better control over the patient s glucose levels throughout the day, especially following a meal.

Ease of use. Our MedTone inhaler is light, is easy to use and fits in the palm of the patient s hand. To administer a dose, the patient opens the device, inserts a single-dose cartridge of Technosphere Insulin powder into the inhaler, inserts the mouthpiece into the mouth and takes a deep breath, thereby drawing the powder deep into the lungs. Moreover, we believe the timing for administering Technosphere Insulin is more convenient than subcutaneous injection. In our clinical trials, the optimal time for taking a dose of Technosphere Insulin has been found to be at the start of a meal or shortly thereafter. With subcutaneous injection, it is recommended that the user try to time a dose 15 to 45 minutes before the expected mealtime.

More efficient delivery of pulmonary insulin. Based on our clinical trials of Technosphere Insulin and on our analysis of publicly available information regarding the performance of other pulmonary insulin systems in development, we believe that the inhalation of a specified amount of insulin formulated as Technosphere Insulin produces blood insulin levels over a measured period of time that are approximately three times greater than that produced by the same amount of insulin administered via the pulmonary delivery systems being developed by other pharmaceutical companies.

Safety. Based on our clinical trials to date, Technosphere Insulin appears to cross lung tissue rapidly, with no observed accumulation of either insulin or the carrier particles in the lung. In addition, our preclinical studies have shown that the Technosphere material does not need to be metabolized to be eliminated and is rapidly excreted in the urine. Technosphere Insulin has not generated any serious, drug-related adverse events in our clinical trials to date, but these results are necessarily preliminary until we have completed long-term safety studies.

OUR CLINICAL TRIAL RESULTS

We have conducted multiple Phase I and Phase II clinical trials of the Technosphere Insulin System in more than 200 individuals in Europe and the United States. We are currently conducting two late Phase II multi-center clinical trials: one in the United States involving approximately 125 individuals with diabetes and one in Europe, which, when fully-enrolled, will involve approximately 200 individuals with diabetes. This section describes the results of our completed studies; later stage clinical trials might not confirm the findings from these earlier stage trials.

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The first of our completed clinical trials were performed in Europe as Phase I trials in healthy volunteers. These clinical trials produced the first evidence in humans that inhalation of Technosphere Insulin was accompanied by a rapid rise in blood insulin levels. The chart below shows the mean profiles of insulin delivery into the bloodstream in five healthy volunteers following administration of Technosphere Insulin and following administration of insulin by subcutaneous injection. These data indicated that the administration of Technosphere Insulin could produce peak insulin levels in a much shorter period of time than could subcutaneous injection, fast enough to suggest that our product might be used to approximate the first-phase insulin release spike.

Rapid changes in blood insulin levels after Technosphere Insulin

We performed additional clinical trials in Europe and the United States as Phase II investigations in patients with type 1 and type 2 diabetes. These clinical trials evaluated various measures of the performance and safety of the Technosphere Insulin System, including the variability of insulin delivered to the bloodstream following inhalation as well as the variability of the effect of our Technosphere Insulin System on blood glucose levels. The results indicated that our Technosphere Insulin System produced no greater variability than that obtained with traditional subcutaneous insulin administration. In fact, a specified dose of Technosphere Insulin appeared to be able to maintain consistent blood glucose levels despite differences in the caloric content of a meal. This is unlike the situation with conventional subcutaneous injection of insulin, which has to be closely tied to the amount of food eaten in order to avoid the risk of hyper- or hypoglycemia. Another finding that emerged from our completed Phase II clinical trials was that the optimal time for individuals with diabetes to inhale Technosphere Insulin is immediately before the first mouthful of food or within 15 minutes thereafter. We believe this highly convenient treatment regimen should lend itself to compliant and reliable self-administration by patients, given that other forms of insulin delivery that are currently marketed recommend dosing up to 15 to 45 minutes before a meal begins, raising issues such as miscalculation of time or unanticipated change in meal availability.

Our Phase I and II clinical trials have indicated that use of the Technosphere Insulin System is associated with high insulin bioavailability, which is a measure of the amount of insulin that is transferred to the bloodstream from the dosage form of the product. Bioavailability is typically expressed as a relative measure, compared to the amount of insulin that enters the bloodstream over the same period of time following the subcutaneous administration of the same quantity of regular human insulin. Based on the results of our clinical trials and on our analysis of published reports of the performance of other pulmonary insulin systems in development, we believe that the relative

bioavailability associated with our Technosphere Insulin System is up to three times greater than that reported for the other inhaled insulin platforms.

We are currently conducting two late Phase II clinical trials, one in the United States and the other in Europe. These clinical trials will provide further information on safety of the Technosphere Insulin System and its efficacy in maintaining blood glucose control. These clinical trials will also assist with the selection of appropriate doses of Technosphere Insulin for use in subsequent Phase III clinical trials. Twenty-seven clinical research centers are participating in the US study and thirty centers are participating in the European trial. These sites include major university research centers as well as well-known diabetes specialty clinics. Our clinical trials in Europe are monitored by a clinical research organization.

We plan to conduct multiple Phase III safety and efficacy clinical trials in different regions of the world, including the United States and Europe. We anticipate that the first US-based Phase III clinical trials will start in the first half of 2005, although our current plans allow for the initiation of the Phase III program in other countries as early as the last quarter of 2004, subject to the regulatory approval process of the relevant jurisdictions. We anticipate that the total clinical trial program will involve more than three thousand patients using the Technosphere Insulin System alone or in combination with other therapies. In the United States, we have initiated the first of several long-term safety clinical trials, which will follow the safety experience of the individuals who participate in our Phase II and Phase III clinical trials.

To date, we have not observed any serious side effects in our clinical trials that can be directly attributed to the use of Technosphere Insulin. In some patients, we have observed mild coughing and some hypoglycemic events, all classified as mild to moderate. Other adverse events reported in our clinical trials including backache, common cold, pneumonia, anemia and diarrhea were either found to be unrelated to the administration of Technosphere Insulin or could not be conclusively linked to its usage. We have an ongoing program of safety surveillance and adverse event reporting for the purpose of evaluating the ongoing safety data concerning the use of our Technosphere Insulin System. Our safety data are necessarily preliminary until we have completed longer-term safety studies.

OUR RESEARCH PROGRAMS

Additional applications of our proprietary technosphere formulation technology

We believe that our proprietary Technosphere formulation technology is a platform that provides a wide range of alternatives for non-invasive pulmonary delivery of drugs that currently require injection. We believe our proprietary Technosphere formulation technology can also be extended to other forms of local administration, such as gastrointestinal delivery, because of its apparent ability to stabilize drugs and facilitate transport across cellular membranes, thereby enhancing the selectivity, ease of use and general effectiveness of existing drugs.

We are developing additional applications for our proprietary Technosphere formulation technology by formulating other drugs for pulmonary delivery, primarily for metabolic and immunological diseases.

Immunology research programs

Our Technosphere research activities are complemented by additional research efforts aimed at the discovery and development of novel drugs. The emphasis of our drug discovery program is to develop drugs that affect the activity of the immune system in order to treat cancer and a variety of inflammatory and autoimmune diseases.

The immune system is a network of cells and organs that defends the body against infection and abnormal cells, such as cancer and transplanted cells. A key element of the immune system is its ability to distinguish between healthy cells and foreign or diseased cells that do not belong in the body. The

immune system accomplishes this task by recognizing distinctive molecules found on the surface of each cell as either normal or abnormal, and responding to them appropriately.

Any substance capable of triggering an immune response is known as an antigen. An antigen can be all or part of a pathogenic organism or it can be a by-product of diseased cells. Certain specialized cells of the immune system sample antigens present in the body and present small fragments, known as epitopes, of foreign antigens to other cells of the immune system whose function is to destroy any cell that expresses the same epitope; this is known as cell-mediated immunity. In this way, the immune system can launch a very specific response to infection or disease.

We are developing therapies for the treatment of solid-tumor cancers using our proprietary technologies for discovering critical tumor-related antigens, for designing DNA- and peptide-based compounds that evoke a cell-mediated immune response to those antigens and for delivering the compounds in vivo to the immune system in a manner that stimulates a potent response.

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

Specificity. We target cancer epitopes to which the immune system has not developed a tolerance, instead of targeting the dominant epitopes expressed by cancerous cells, many of which are tolerated by the immune system. We have developed technology to identify the non-tolerated epitopes on the cancer cell surface and we have developed a method of modifying these epitopes that is designed to activate an immune response. Through this process, we believe that the body s tolerance of the cancer cells can be broken, leading to the destruction of the cancer by the immune system.

Administration. Our compounds are delivered directly into the patient s lymph nodes, where studies have shown they will have the greatest impact. In contrast to the conventional subcutaneous or intramuscular route of administration, we believe that the direct delivery of our compounds will bring local high concentrations of the active components of our compounds into contact with high concentrations of the cells needed to generate a potent cell-mediated immune response.

Selectivity, potency and duration of response. We deliver our therapeutic compounds in a manner that we believe primes the immune system to respond to cancer cells expressing specific epitopes, in much the same way that a chronic infection evokes a progressively increased immune response to an invading bacteria. Our administrative regimen is designed to boost the immune response over the course of a treatment cycle so that it becomes increasingly potent and long acting.

We have conducted initial studies of our cancer therapy in Europe and the United States, including Phase I and II clinical trials in the United States that involved 42 patients who had progressed to late stages of skin cancer. We observed that the delivery of a prototype formulation, targeting a single cancer epitope, was well tolerated by melanoma patients and produced a response by their immune system against that specific epitope. In late stages of such diseases, there are usually multiple generations of such cells, expressing multiple epitopes. Although we believe that our clinical data to date have been encouraging, we did not observe a strong correlation between the evoked immune response and clinical responses. As a result, we have continued to refine our cancer therapy program. We have developed several product candidates and expect to begin preclinical safety tests for one of these product candidates later this year, with the goal of commencing clinical trials in 2005. The results of these subsequent clinical trials may differ from the findings of our earlier trials.

To complement our cancer products and to broaden our addressable market, we are also developing drugs targeted toward inflammatory and autoimmune diseases. Several common diseases, including multiple myeloma, rheumatoid arthritis, lupus and multiple sclerosis, are characterized by the

dysfunction of key cells in the immune system, called B-cells and T-cells, which are agents of the immune system that the body uses to destroy infectious and aberrant materials. We have focused our attention on certain proteins that govern the development and function of B-cells and T-cells. By changing the activity of these proteins, we believe we can modify the immune response associated with a variety of immune system diseases. We have identified a number of molecules that are effective at changing the activity of these proteins in vitro and are in the process of optimizing these molecules.

OUR STRATEGY

Our objective is to develop products in the major therapeutic areas of diabetes, cancer, inflammatory and autoimmune diseases. Our strategy is to achieve this objective by doing the following:

Commercialize our Technosphere Insulin System for the insulin-using diabetes market. We intend to advance our Technosphere Insulin System into and through Phase III clinical trials and then into commercialization, with the goal of establishing a significant presence for Technosphere Insulin in the insulin-using diabetes market. We believe that the market for insulin products will expand significantly among patients with type 2 diabetes as a result of the entry of other pulmonary insulin products, primarily due to the non-invasive nature of pulmonary insulin delivery. We believe the advantages of the Technosphere Insulin System, as compared to other pulmonary insulin products, will enable us to capture a significant portion of the existing and expanded insulin-using diabetes market.

Establish our Technosphere Insulin System as the preferred drug therapy within the broader population of people with type 2 diabetes. Our target markets also include patients with type 2 diabetes who are currently using conventional therapies other than insulin, including:

Patients currently using diet and exercise therapy but who are having difficulty achieving proper blood glucose control;

Patients for whom diet and exercise therapy has failed but who otherwise would have started non-insulin oral medications; and

Patients currently using non-insulin oral medications.

We believe our Technosphere Insulin System will be the first commercially available therapy to produce a profile of insulin levels in the bloodstream that approximates the first-phase insulin release spike normally seen in healthy individuals following the beginning of a meal. We believe that no other conventional therapy has demonstrated that it can approximate the first-phase insulin release spike, and we are not aware of any other therapy in development that makes this claim. As a result, we believe that our Technosphere Insulin System has the potential to become the preferred drug therapy for the broader population of people with type 2 diabetes.

Seek a strategic collaboration for the development, marketing and commercialization of our Technosphere Insulin System. We are actively exploring collaborations with large pharmaceutical companies in the United States, Europe and Japan that would provide marketing, sales and financial resources to commercialize and sell our Technosphere Insulin System. We have not licensed or transferred any of our rights to this product and we believe this will enable us to obtain advantageous terms in potential collaborations. We intend to retain worldwide manufacturing rights for our Technosphere Insulin System.

Expand our proprietary Technosphere formulation technology for the delivery of other drugs. We are developing additional applications for our proprietary Technosphere formulation technology by formulating other drugs for pulmonary delivery, primarily for metabolic and immunological diseases. We believe our proprietary Technosphere formulation technology can also be extended to

other forms of local administration, such as gastrointestinal delivery, because of its apparent ability to stabilize drugs and facilitate transport across cellular membranes.

Build upon our expertise in immune system diseases to develop new drugs. We intend to build upon our expertise and intellectual property portfolio to develop new treatments for diseases other than diabetes. We are conducting research programs focused on the development of therapeutic compounds for the active immunological treatment of cancer as well as inflammatory and autoimmune diseases.

SALES AND MARKETING

We currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing or selling pharmaceutical products. Our efforts have primarily been directed at developing products for a number of different markets. Assuming that we receive regulatory approval for our product candidates, we anticipate that we will have to pursue different sales and marketing strategies tailored to each particular product and market segment. In order to commercially market any of our products, we will also need either to develop a sales and marketing infrastructure ourselves or collaborate with third parties who have greater sales and marketing capabilities and have access to potentially large markets.

Although we believe that establishing our own sales and marketing organizations in North America would have substantial advantages, we recognize that this will not be practical for some of our products and that collaborating with companies with established sales and marketing capabilities in a particular market or markets may be a more effective alternative for some products. To date, we have retained worldwide commercialization rights for all of our products, including our lead product, the Technosphere Insulin System. We believe that this will give us the flexibility to enter into favorable collaborations to provide the necessary sales and marketing support.

Our goal is to have our partners fund the clinical development and commercial launch of the Technosphere Insulin System in their respective countries. We are currently seeking to enter into collaborations to assist us in the development and commercialization of our Technosphere Insulin System in the United States, Europe and Japan, and we may also create in-house sales and marketing operations in certain key markets, particularly in the United States.

MANUFACTURING AND SUPPLY

We are in the process of negotiating a long-term supply agreement with the independent third party that is currently manufacturing and supplying our MedTone inhaler and the cartridges that are inserted into it. We rely on this manufacturer to comply with relevant regulatory requirements, including compliance with QSRs. We believe our manufacturer has the capacity to meet our Phase III clinical and initial commercial requirements and that it complies with relevant regulatory requirements. We purchase human recombinant insulin under a long-term contract with Diosynth B.V., a global producer of insulin. This agreement has no specified termination date, but generally may be terminated upon two-years advance notice by either party. In addition, Diosynth has agreed to support our regulatory filings relating to the Technosphere Insulin System in the United States and abroad. We believe Diosynth has sufficient capacity to provide us with sufficient quantities of insulin to support our needs through the initial stages of commercialization.

We must rely on our insulin supplier to maintain compliance with relevant regulatory requirements including cGMP. Currently, we manufacture the raw Technosphere material, but we are in the process of developing a relationship with a secondary manufacturer to supply us with commercial quantities of this raw material. Like us, our third-party manufacturers are subject to extensive governmental regulation.

We formulate and fill the Technosphere Insulin powder into plastic cartridges and blister package the cartridges in a manufacturing suite in our Danbury facility. We believe that our Danbury facility has adequate capacity to meet our currently anticipated clinical trial needs. We are continuing to increase our filling and packaging capacity through the acquisition of new equipment and the construction of new clean rooms and other manufacturing facilities. We believe that these building improvements have been adequately validated to date and that the facility continues to conform with cGMP. We recently initiated the design and construction of a modular filling and packaging system that will increase our filling and packaging capacity. The new system is designed to operate in a very small space and can be expanded using multiple units to meet our currently anticipated commercial production needs.

INTELLECTUAL PROPERTY AND PROPRIETARY TECHNOLOGY

Our success will depend in large measure on our ability to obtain and enforce our intellectual property rights, effectively maintain our trade secrets and avoid infringing the proprietary rights of third parties. Our policy is to file patent applications on what we deem to be important technological developments that might relate to our product candidates or methods of using our product candidates and to seek intellectual property protection in the United States, Europe, Japan and selected other jurisdictions for all significant inventions. We have obtained, are seeking and will continue to seek patent protection on the compositions of matter, methods and devices flowing from our research and development efforts. We have also in-licensed certain technology.

With respect to our Technosphere Insulin System, our core patents claim the composition of matter of the Technosphere material as well as methods for manufacturing unloaded Technosphere particles and Technosphere particles that incorporate drugs. The first of these patents expires in 2012, but subsequent patents provide additional coverage of the composition of matter of the current product until 2020. We also hold patents that claim methods of using Technosphere particles for the pulmonary delivery of drugs. These patents relating to Technosphere Insulin do not expire until 2015. In addition, we are prosecuting patent applications related to the MedTone inhaler device and the capsules that contain the dry powder. We have filed and intend to continue to file additional patent applications on improvements to the Technosphere technology and its manufacture, as well as on specific compositions of matter formed using this technology in combination with drugs. To date, we have been issued nine US and foreign Technosphere-related patents and have filed 25 applications in different jurisdictions claiming inventions related to the Technosphere technology and the dry powder inhaler.

Our cancer immunotherapy program is built on proprietary methods for the selection, design and administration of epitopes. We have filed 54 patent applications relating to this technology, both as methods of use and compositions of matter. We are pursuing patents on the use of our administration method to induce and maintain a cell-mediated immune response. The prosecution is ongoing in many jurisdictions; however, we have been granted patents for this method in Australia and New Zealand, which do not expire until 2018. We also have patent applications related to differential antigen processing and product designs. One patent from this group has issued in the United States, which provides us with protection until at least 2020. In addition to applications of these broad technologies, we have filed and will continue to file patent applications on specific compounds and the protocols for administering them.

In the area of immune modulation, we have obtained an exclusive license from Harvard University for two patent applications and licenses from the Dana Farber Cancer Institute and from the National Institutes of Health to five patents, all of which cover compositions of matter or methods for modulating the activity of B-cells and T-cells. These licenses are worldwide and include the right to sublicense. The issued patents have terms that expire beginning in 2010 and ending in 2020. We have

also filed and expect to continue to file additional patent applications on improvements to these technologies.

The fields of pulmonary drug delivery and cancer therapies are crowded and a substantial number of patents have been issued in these fields. In addition, because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of issued patents cannot be predicted. Further, there can be substantial delays in commercializing pharmaceutical products, which can partially consume the statutory period of exclusivity through patents.

In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we will be able to secure internationally. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In addition, patent applications in the United States filed before November 29, 2000 are currently maintained in secrecy until the patent issues, although in certain countries, including the United States for applications filed after November 29, 2000, applications are generally published 18 months after the application s priority date. In any event, because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by our pending patent applications or that we were the first to file patent applications on such inventions.

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 and compositions of matter related to DNA-based vaccines that also may trigger an allegation of infringement upon the commercial manufacture and sale of cancer therapy. We believe, based in part on advice of counsel, that we are not infringing any valid claims of any patent owned by a third party. However, if a court were to determine that our inhaled 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 in order to avoid legal liability for infringement of these patents. Proving patent invalidity 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 either have to 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. In either event, our business would be harmed and our profitability could be materially adversely impacted. If third parties file patent applications, or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in

interference proceedings in the USPTO to determine priority of invention. We may be required to participate in interference proceedings involving our issued patents and pending applications.

We also rely on trade secrets and know-how, which are not protected by patents, to maintain our competitive position. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of our relationship must be kept confidential, except in specified circumstances. These agreements also provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. 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.

We also execute confidentiality agreements with outside collaborators. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators apply technological information developed independently by them or others to our projects, or apply our technology to outside projects, and there can be no assurance that any such disputes would be resolved in our favor. In addition, any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. 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.

COMPETITION

The pharmaceutical and biotechnology industries are intensely competitive and characterized by rapidly evolving technology and intense research and development efforts. We expect to compete with companies, including the major international pharmaceutical companies, and other institutions that have substantially greater financial, research and development, marketing and sales capabilities and have substantially greater experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals and marketing and selling biopharmaceutical products. We will face competition based on, among other things, product efficacy and safety, the timing and scope of regulatory approvals, ease of use and cost.

We believe our Technosphere Insulin System provides us with important competitive advantages in the delivery of insulin when compared with currently known alternatives. However, new drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits, or comparable benefits at lower cost, than our Technosphere Insulin System. There can be no assurance that existing or new competitors will not introduce products or processes competitive with or superior to our product candidates.

We have set forth below more detailed information about certain of our competitors. The following is based on information currently available to us.

Pulmonary and oral insulin delivery systems

Several pharmaceutical and biotechnology companies are developing systems for the pulmonary delivery of insulin. 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. On the

basis of published reports, we believe that the performance characteristics of our Technosphere Insulin System will have an advantage over these other pulmonary insulin products, particularly with respect to time-to-peak blood insulin levels and relative bioavailability.

There are also several companies, including Nobex Corporation, Generex Biotechnology Corporation and Emisphere Technologies, Inc., that are pursuing development of products for the oral delivery of insulin. We believe these products are currently in relatively early clinical trials.

Non-insulin oral medications

We expect that our Technosphere Insulin System will compete with currently available non-insulin oral medications for type 2 diabetes. These products include sulfonylureas, metformin and insulin sensitizers. The sulfonylureas, which are mostly generic, act by directly stimulating insulin secretion and have been the principal non-insulin oral medication used to treat type 2 diabetes for several decades. Metformin, which is now available as a generic drug and is also marketed by Bristol-Meyers Squibb Company as Glucophage, has also been widely used for the treatment of type 2 diabetes. Insulin sensitizers, including Avandia, which is being marketed by GlaxoSmithKline PLC, and Actos, which is being marketed by Takeda Pharmaceuticals North America, Inc./Eli Lilly & Company, are increasingly being used to treat type 2 diabetes.

Injected insulin

In the subcutaneous insulin market, our competitors have made considerable efforts to develop faster acting injectable insulin formulations. Humalog, which was developed by Eli Lilly and Company, and Insulin Aspart, or NovoLog, which was developed by Novo Nordisk A/S, are the two principal injectable insulin formulations with which we expect to compete.

Immunotherapy

Over the last decade or so, a variety of companies have sought to develop therapeutic compounds that provide a selective immune response against cancer. Some of these companies, including Dendreon Corporation, Antigenics Inc., CancerVax Corporation and Corixa Corporation, have focused on products derived from the patients own cancer, which can take the form of whole cells or cell fragments, or on tumor antigens extracted from cancerous cells. Other companies, including Progenics Pharmaceuticals, Inc., Therion Biologics Corporation and Vical Incorporated, are pursuing therapies designed to work across a broad spectrum of patients and tumor types.

GOVERNMENT REGULATION AND PRODUCT APPROVAL

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of medical devices and drug products. These agencies, through regulations that implement the Food, Drug and Cosmetic Act, as amended, or FDCA, and other regulation, regulate research and development activities and the development, testing, manufacture, labeling, storage, shipping, approval, advertising, promotion, sale and distribution of such products. In addition, if our products are marketed abroad, they also are subject to export requirements and to regulation by foreign governments. The regulatory clearance process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including hold letters, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

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The steps typically required before a new pharmaceutical product for use in humans may be marketed in the United States include:

Preclinical studies that include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may commence. The results of the preclinical studies are submitted to the FDA as part of the IND. Unless the FDA objects, the IND becomes effective 30 days following receipt by the FDA.

Approval of clinical protocols by independent investigational review boards, or IRBs, at each of the participating clinical centers conducting a study. The IRBs consider, among other things, ethical factors, the potential risks to individuals participating in the trials and the potential liability of the institution. The IRB also approves the consent form signed by the trial participants.

Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product. Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified medical investigator according to an approved protocol. The clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor participant safety and efficacy or other criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Companies also must generally determine the details of properly treating pediatric patients with a drug and this can sometimes mean that specific pediatric studies must be performed. Human clinical trials are typically conducted in the following four sequential phases that may overlap or be combined:

In Phase I, the drug is initially introduced into a small number of individuals and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase I clinical trials are often conducted in healthy human volunteers and such cases do not provide evidence of efficacy. In case of severe or life-threatening diseases, the initial human testing is often conducted in patients rather than healthy volunteers. Because these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase II clinical trials. Consequently, these types of trials are frequently referred to as Phase I/ II clinical trials. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension or termination of clinical trials if it concludes that an unwarranted risk is presented to patients or healthy volunteers.

Phase II involves clinical trials in a limited patient population to further identify any possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase III clinical trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites. Phase III clinical trials usually include a broader patient population so that safety and efficacy can be substantially established. Phase III clinical trials begin once Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile.

Phase IV clinical trials are performed if the FDA requires, or a company pursues, additional clinical trials after a product is approved. These clinical trials may be made a condition to be

satisfied after a drug receives approval. The results of Phase IV clinical trials can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA s voluntary adverse drug reaction reporting system.

Concurrent with clinical trials and preclinical studies, companies also must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity, and potency of the final products. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Submission to the FDA of a new drug application, or NDA, for non-biological drugs such as insulin, based on the clinical trials. The results of pharmaceutical development, preclinical studies, and clinical trials are submitted to the FDA in the form of an NDA for approval of the marketing and commercial shipment of the product.

The FDA reviews all NDAs submitted before it accepts them for filing. It may request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA has substantial discretion in the approval process and may disagree with an applicant s interpretation of the data submitted in its NDA and information. Also, as part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee. Manufacturing establishments often also are subject to inspections prior to NDA approval to assure compliance with cGMP and with manufacturing commitments made in the relevant marketing application. Under the Prescription Drug User Fee Act, or PDUFA, submission of an NDA with clinical data requires payment of a fee. In fiscal year 2004 the required fee is $573,500. In return, the FDA assigns a goal for standard applications of 10 months from acceptance of the application to return of a first complete response, in which the FDA may approve the product or request additional information. There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA.

FDA approval of the NDA must be granted prior to any commercial sale or shipment of the product. The FDA may deny an NDA approval if safety, efficacy or other regulatory requirements are not satisfied. The FDA may also require additional testing or information before approving the NDA. If regulatory approval of the product is granted, such approval may require post-marketing testing and surveillance to monitor the safety of the product or may entail limitations on the indicated uses for which the product may be marketed or advertised. The FDA may require additional testing or information before approving the NDA. In addition, product approval may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following the commencement of marketing.

Clinical trials are designed and conducted in a variety of ways. A placebo-controlled trial is one in which the trial tests the results of a group of patients, referred to as an arm of the trial, receiving the drug being tested against those of an arm that receives a placebo, which is a substance of identical appearance that is not therapeutic in a medical or chemical sense. In a double-blind study, neither the researcher nor the patient knows into which arm of the trial the patient has been placed, or whether the patient is receiving the drug or the placebo. Randomized means that upon enrollment,

patients are placed into one arm or the other at random by computer. Parallel control trials generally involve a study arm with a patient population that is not exposed to the study medication (i.e., is either on placebo or standard treatment protocols) for comparison to the drug being tested and groups are assigned upon patient admission to the study and remain in those groups for the duration of the study. An open label study is one where the researcher and the patient know that the patient is receiving the drug. A trial is said to be pivotal if it is designed to meet statistical criteria with respect to pre-determined endpoints, or clinical objectives, that the sponsor believes, based usually on its interactions with the relevant regulatory authority, will be sufficient for regulatory approval. In most cases, at least two pivotal Phase III clinical trials are necessary for approval. Under the Pediatric Research Equity Act of 2003, an NDA also must include an assessment, generally based on clinical study data, on the safety and efficacy of a drug for all relevant pediatric populations. The statute provides for waivers or deferrals in certain situations but we can make no assurances that such situations will apply to us or our products.

Medical products containing a combination of new drugs, biological products, or medical devices may be regulated as combination products in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (*e.g.,* drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic, or device. In order to facilitate premarket review of combination products, the FDA designates one of its centers to have primary jurisdiction for the premarket review and regulation of both components. The determination whether a product is a combination product or two separate products is made by the FDA on a case-be-case basis. We have had discussions with the FDA about the status of our Technosphere Insulin System as a combination product and we have been told that the FDA considers our product a combination drug/device. 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 Metabolism 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. Although the FDA has not made an official final decision in this regard, we currently understand that the Metabolic and Endocrine Drug Products Division will be the lead group and obtain consulting reviews from the other two FDA groups.

The testing and approval process requires substantial time, effort and financial resources. We cannot be certain that any approval of our products will be granted on a timely basis, if at all. If any of our products are approved for marketing by the FDA, we will be subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with certain electronic records and signature requirements. Prior to and following approval, if granted, all manufacturing sites are subject to inspection by the FDA and other national regulatory bodies and must comply with cGMP, QSR and other requirements enforced by the FDA and other national regulatory bodies through their facilities inspection program. Foreign manufacturing establishments must comply with similar regulations. In addition, our drug-manufacturing facilities located in Connecticut and the facilities of our insulin supplier and the supplier of our MedTone inhaler and cartridges are subject to federal registration and listing requirements and, if applicable, to state licensing requirements. Facilities are subject to inspection by the FDA and similar national agencies, as well as state and local authorities at any time. Failure, including those of our insulin and MedTone inhaler suppliers, to obtain and maintain applicable federal registration or state license, or to meet the inspection criteria of the FDA or the other national regulatory bodies, would disrupt our manufacturing processes and would harm our business. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production

and quality control to ensure full compliance. Currently, we believe we are operating under all of the necessary guidelines and permits.

It is not yet clear to what extent we will be subject to regulations governing medical devices separate from those governing drugs. After the FDA permits a device to enter commercial distribution, however, numerous regulatory requirements apply. These include:

- product labeling regulations;
- general prohibition against promoting products for unapproved or off-label uses;
- corrections and removals (e.g., recalls);
- establishment registration and device listing;
- general prohibitions against the manufacture and distribution of adulterated and misbranded devices; and
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions, and/or criminal prosecution of responsible individuals and us. Further, the company we have contracted to manufacture our MedTone inhaler and cartridges will be subject to the QSRs, which require manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process of medical devices, among other requirements.

Failure to adhere to regulatory requirements at any stage of development, including the preclinical and clinical testing process, the review process, or at any time afterward, including after approval, may result in various adverse consequences. These consequences include action by the FDA or other national regulatory body that has the affect of delaying approval or refusing to approve a product; suspending or withdrawing an approved product from the market; seizing or recalling a product; or imposing criminal penalties against the manufacturer. In addition, later discovery of previously unknown problems may result in restrictions on a product, its manufacturer, or the NDA holder, or market restrictions through labeling changes or product withdrawal. Also, new government requirements may be established or they may change at any time that could delay or prevent regulatory approval of our products under development. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

In addition, the FDA imposes a number of complex regulations on entities that advertise and promote drugs, which include, among others, standards for and regulations of direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FDCA, and failure to comply with these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Products manufactured in the United States and marketed outside the United States are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold. We also would be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are marketed abroad. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries usually must be obtained prior

to the marketing of the product in those countries. The approval process varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Product development and approval within this regulatory framework take a number of years, involve the expenditure of substantial resources and are uncertain. Many drug products ultimately do not reach the market because they are not found to be safe or effective or cannot meet the FDA s other regulatory requirements. In addition, there can be no assurance that the current regulatory framework will not change or that additional regulation will not arise at any stage of our product development that may affect approval, delay the submission or review of an application or require additional expenditures by us. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our product candidates under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business and results of operations.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this latter procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the application and assessment report, each member state must decide whether to recognize approval. We plan to choose the appropriate route of European regulatory filing in an attempt to accomplish the most rapid regulatory approvals. However, the chosen regulatory strategy may not secure regulatory approvals or approvals of the chosen product indications. In addition, these approvals, if obtained, may take longer than anticipated.

We cannot assure you that any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

In addition to the foregoing, we are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, controlled drug substances, safe working conditions, manufacturing practices, environmental protection and fire hazard control. We may incur significant costs to comply with those laws and regulations now or in the future.

Patent restoration and marketing exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, permits the FDA to approve abbreviated NDAs, or ANDAs, for generic versions of innovator drugs and also provides certain patent restoration and exclusivity protections to innovator drug manufacturers. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses as an innovator drug but does not require the conduct and submission of clinical studies demonstrating safety and efficacy for that product. Instead of safety and efficacy data, therefore, a competitor could make a copy of any of our drugs and only need to submit data demonstrating that the copy is bioequivalent to our product and gain marketing approval from the FDA.

Hatch-Waxman requires a competitor that submits an ANDA for a copy of one of our drugs or otherwise relies in part on data from one of our drugs regarding its safety and efficacy, to notify us of their application and potential infringement of our patent rights. Hatch-Waxman Act places certain timing requirements on us with respect to filing an infringement action against such an ANDA applicant, if we choose to do so.

While Hatch-Waxman Act provides competitors the ability to market copies of innovator products with the submission of significantly less clinical data, the Act also provides for the restoration of a portion of a product s patent term that is lost during a drug s clinical development and NDA review by the FDA. Hatch-Waxman also provides for a statutory protection, known as market exclusivity, which prohibits the FDA s approval or acceptance of certain competitor drug applications. Patent term restoration can return up to five years of patent term for a patent that covers a new product or its use to compensate for time lost during product development and the regulatory review process. This period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, subject to a maximum extension of five years and no extension can extend the total patent life beyond 14 years after the drug approval date. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension, and there can be no guarantee that the application will be granted.

Hatch-Waxman also provides for differing periods of statutory protection for new drugs approved under an NDA. Among the types of exclusivity are those for a new molecular entity and those for a new formulation or a new indication for a previously approved drug. Our lead product, the Technosphere Insulin System, is an innovative change to a previously approved product with the same active ingredient, insulin. Marketing exclusivity for the Technosphere Insulin System, if granted by the FDA, likely would prohibit the agency from approving another drug that relies, at least in part, on data regarding the safety and efficacy of our new formulation for that same active ingredient for three years. This three-year exclusivity, however, only covers the innovation associated with the NDA to which it attaches. Thus, the three-year exclusivity would not prohibit the FDA from approving applications for drugs containing the same active ingredient but without our new innovative change.

The FDA Modernization Act of 1997 included a pediatric exclusivity provision that was extended by the Best Pharmaceuticals for Children Act of 2002. Pediatric exclusivity is designed to provide an incentive to manufacturers for conducting research about the safety and efficacy of their products in children. Pediatric exclusivity, if granted, provides an additional six months of market exclusivity in the United States for new or currently marketed drugs, if certain pediatric studies requested by the FDA are completed by the applicant. To obtain this additional six months of exclusivity, it would be necessary for us to first receive a written request from the FDA to conduct pediatric studies and then to conduct the requested studies according to a previously agreed timeframe and submit the report of the study. There can be no assurances that we would receive a written request from the FDA and if so that we would complete the studies in accordance with the requirements for this six-month exclusivity. The current pediatric exclusivity provision is scheduled to end on October 1, 2007, and there can be no assurances that it will be reauthorized.

EMPLOYEES

As of March 31, 2004, we had 223 full-time employees, all of whom are employed at-will. Seventy-three of these employees were engaged in research and development, 81 in manufacturing, 31 in clinical, regulatory affairs and quality assurance and 38 in administration, finance, management, information systems, corporate development and human resources. Thirty of our employees have a Ph.D. degree and/or M.D. degree and are engaged in activities relating to research and development, manufacturing, quality assurance and business development. None of our employees is subject to a collective bargaining agreement. We believe our relations with our employees are good.

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SCIENTIFIC ADVISORS

We seek advice from a number of leading scientists and physicians on scientific, technical and medical matters. These advisors are leading scientists in the areas of pharmacology, chemistry, immunology and biology. Our scientific advisors are consulted regularly to assess, among other things:

- our research and development programs;
- the design and implementation of our clinical programs;
- our patent and publication strategies;
- market opportunities from a clinical perspective;
- new technologies relevant to our research and development programs; and
- specific scientific and technical issues relevant to our business.

The following are some of our scientific advisors and their primary affiliations:

Name	Primary affiliation
Harvey Cantor, M.D.	Professor of Pathology at Harvard Medical School
James J. Collins, D.Phil	Professor at Boston University
Alexander Fleming, M.D.	Chief Executive Officer of the Kinexum Corporation
Laurie Glimcher, M.D.	Member of the National Academy of Sciences and Professor of Immunology at Harvard Medical School
Edward S. Horton, M.D.	Chief of Clinical Research at the Joslin Diabetes Center
Thomas Kundig, M.D.	Professor at the University of Zurich
Harold E. Lebovitz, M.D.	Professor of Medicine and the Chief of Endocrinology Emeritus at the State University of New York Brooklyn
Frederick Levy, Ph.D.	Associate Member of the Ludwig Institute for Cancer Research
Greg Petsko, Ph.D.	Professor at Brandeis University
Barrett Rollins, M.D., Ph.D.	Associate Professor of Medicine at Harvard Medical School
Jesse Roth, M.D.	Chief Geriatrician of the Long Island Jewish Medical Center
Jay S. Skyler, M.D.	Chief of Diabetes & Endocrinology at the University of Miami School of Medicine
Rolf Zinkernagel, M.D., Ph.D.	Nobel Laureate in Medicine and Institute Director at the University of Zurich

FACILITIES

In early 2001, we acquired a facility in Danbury, Connecticut to house our Technosphere-related activities, including development and manufacturing of Technosphere Insulin. This facility includes two buildings comprising approximately 187,000 square feet and currently house our research and development, administrative and manufacturing functions, including the Technosphere Insulin formulation, filling and packaging plant. We also lease approximately 20,000 square feet of laboratory space in Elmsford, New York for approximately $36,000 per month, pursuant to an 11-year, renewable lease that expires in October 2004. We believe that our facility in Danbury has sufficient space to contain additional Technosphere Insulin manufacturing capacity necessary to satisfy potential commercial demand for our products for several years after we launch our Technosphere Insulin System and other Technosphere-related products.

We own and occupy approximately 120,000 square feet of laboratory, office and manufacturing space in Valencia, California. The facility contains our principal executive offices and houses our research

and development laboratories for our cancer and other immunology programs. We also use this facility to provide support for the development of our Technosphere programs.

LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may from time to time become a party to legal proceedings arising in the ordinary course of business.

WEBSITE

We maintain an Internet website at http://www.mannkindcorp.com. The information in, or that can be accessed through, our website is not incorporated into and does not form a part of this prospectus.

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Management

EXECUTIVE OFFICERS AND DIRECTORS

The following table sets forth our current executive officers and directors and their ages as of March 31, 2004:

Name	Age	Position(s)
Alfred E. Mann	78	Chairman of the Board of Directors and Chief Executive Officer
Hakan S. Edstrom	54	President, Chief Operating Officer and Director
Richard L. Anderson	64	Corporate Vice President and Chief Financial Officer
Dan R. Burns	52	Corporate Vice President and President, MannKind BioPharmaceuticals
Wayman Wendell Cheatham, M.D., FACE	55	Corporate Vice President and Senior Vice President, Medical & Regulatory Affairs, MannKind BioPharmaceuticals
David Thomson, Ph.D., J.D.	37	Corporate Vice President, Associate General Counsel and Corporate Secretary
Kathleen Connell, Ph.D.(1)(2)(3)	56	Director
Ronald Consiglio(2)(3)	60	Director
Michael Friedman, M.D.(1)(2)	60	Director
Llew Keltner, M.D., Ph.D.	54	Director
Kent Kresa	66	Director
David H. MacCallum(3)	66	Director

(1) Member of the Compensation Committee.

(2) Member of the Nominating and Corporate Governance Committee.

(3) Member of the Audit Committee.

Alfred E. Mann has been one of our directors since April 1999, our Chairman of the Board since December 2001 and our Chief Executive Officer since October 2003. He founded and formerly served as Chairman and Chief Executive Officer of MiniMed, Inc., a publicly traded company focused on diabetes therapy and microinfusion drug delivery that was acquired by Medtronic, Inc. in August 2001. Mr. Mann also founded and, from 1972 through 1992, served as Chief Executive Officer of Pacesetter Systems and its successor, Siemens Pacesetter, a manufacturer of cardiac pacemakers. Since 1993, Mr. Mann has served as Chairman and Co-Chief Executive Officer of Advanced Bionics Corporation, a medical device manufacturer that has entered into an agreement to be acquired by Boston Scientific Corporation. Mr. Mann holds a bachelor s and master s degree in Physics from the University of California at Los Angeles, honorary doctorates from Johns Hopkins University, the University of Southern California and Western University and is a member of the National Academy of Engineering.

Hakan S. Edstrom has been our President and Chief Operating Officer since April 2001 and has served as one of our directors since December 2001. Mr. Edstrom was with Bausch & Lomb, Inc., a health care product company, from January 1998 to April 2001, advancing to the position of Senior Corporate Vice President and President of Bausch & Lomb, Inc. Americas Region. From 1981 to 1997, Mr. Edstrom was with Pharmacia Corporation, where he held various executive positions, including President and Chief Executive Officer of Pharmacia Opthalmics Inc. Mr. Edstrom is currently a director of Q-Med AB, a biotechnology and medical device company, and Ixion Biotechnology, Inc.,

a biotechnology company. Mr. Edstrom was educated in Sweden and holds a master s degree in Business Administration from the Stockholm School of Economics.

Richard L. Anderson has been our Corporate Vice President and Chief Financial Officer since October 2002. He was previously Senior Vice President, Chief Financial Officer and Secretary at NeoRx Corporation, a Seattle-based publicly traded biotechnology company. From January 1997 to September 2002, Mr. Anderson held various executive positions at NeoRx, including President, Chief Operating Officer and Senior Vice President, Finance and Operations. Mr. Anderson holds a master s degree in Management from Johns Hopkins University, a master s degree in Solid State Physics from the University of Maryland and a bachelor s degree in Physics from Bucknell University.

Dan R. Burns has been our Corporate Vice President and President of MannKind BioPharmaceuticals, which is our Danbury, Connecticut operation, since September 2002. Prior to joining us, he served as Chief Executive Officer of Trophix Pharmaceuticals, Inc., a pharmaceutical company in 1997, and from 1998 to 1999 he served as Chief Executive Officer of ProScript, Inc., a biopharmaceutical company. From 2000 to 2002, he served as Chief Executive Officer of HealthTalk Interactive, a pharmaceutical services firm. Mr. Burns has held senior executive positions internationally and domestically with Bristol Myers Squibb. Mr. Burns holds degrees in Psychology and Business Administration from McMaster University and Mohawk College.

Wayman Wendell Cheatham, M.D., FACE has been our Corporate Vice President and Senior Vice President, Medical & Regulatory Affairs of MannKind BioPharmaceuticals since August 2002. From April 1999 to August 2002, he was Vice President of Medical & Regulatory Affairs for Takeda Pharmaceuticals North America, Inc., a manufacturer of ethical pharmaceuticals. From August 1996 to April 1999, Dr. Cheatham served as Director of Medical Affairs for Novo Nordisk Pharmaceuticals, Inc., a manufacturer of pharmaceutical preparations. Dr. Cheatham received his M.D. degree from the Pennsylvania State University College of Medicine in 1975. Dr. Cheatham has also been nominated to serve as a member of the board of directors of the American Diabetes Association beginning June 2004.

David Thomson, Ph.D., J.D. has been our Corporate Vice President, Associate General Counsel and Corporate Secretary since January 2002. Prior to joining us, he practiced corporate/commercial and securities law at the Toronto law firm of Davies Ward Phillips & Vineberg LLP from May 1999 through December 2001, except for a period from May to December 2000, when he served as Vice President, Business Development for CTL ImmunoTherapies Corp. From March 1994 to August 1996, Dr. Thomson held a post-doctoral position at the Rockefeller University, where he conducted medical research in the Laboratory of Neurophysiology. Dr. Thomson obtained his bachelor s degree, master s degree and Ph.D. degree from Queens University and obtained his J.D. degree from the University of Toronto.

Kathleen Connell, Ph.D. has been one of our directors since November 2003. Currently, Dr. Connell is president of Connell Group, an investment advisory firm and teaches international finance at the UC Berkeley Haas School of Business. From 1995 to 2002, she served as State Controller of California. Her prior experience includes serving as a president of a NASD-registered investment banking firm, as vice-president of a New York-based bank and as the founder and Chair of the UCLA Center for Finance and Real Estate at the John E. Anderson School of Management, where she taught for five years. Dr. Connell holds a Ph.D. degree from the University of California, Los Angeles.

Ronald Consiglio has been one of our directors since October 2003. Since 1999, Mr. Consiglio has been the managing director of Synergy Trading, a securities-trading partnership. From 1999 to 2001, Mr. Consiglio was Executive Vice President and Chief Financial Officer of Trading Edge, Inc., a national automated bond-trading firm. His prior experience includes serving as Senior Vice President and Chief Financial Officer of Cantor Fitzgerald & Co. and as a member of its board of directors.

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Mr. Consiglio is currently a member of the board of directors of Natrol, Inc, a manufacturer of dietary supplements and a trustee on the board of directors of Metropolitan West Trust, a management investment company. Mr. Consiglio holds a bachelor s degree in Accounting from California State University at Northridge.

Michael Friedman, M.D. has been one of our directors since December 2003. Currently, Dr. Friedman is the President and Chief Executive Officer of the City of Hope National Medical Center. Previously, from September 2001 until April 2003, Dr. Friedman held the position of Senior Vice President of Research and Development, Medical and Public Policy, for Pharmacia Corporation and, from July 1999 until September 2001, was a Senior Vice President of Searle, a subsidiary of Monsanto Company. From 1995 until June 1999, Dr. Friedman served as Deputy Commissioner for Operations for the FDA, and was Acting Commissioner and Lead Deputy Commissioner from 1997 to 1998. Dr. Friedman holds a bachelor s degree, magna cum laude, from Tulane University, New Orleans, Louisiana, and a doctorate in medicine from the University of Texas, Southwestern Medical School.

Llew Keltner, M.D., Ph.D. has been one of our directors since October 2003. He founded EPISTAT, an international pharmaceutical and health care strategy company and has served as its Chief Executive Officer since 1985. He has also served as Chief Executive Officer of MetaStat, an oncology drug development firm, since 1994. In addition, Dr. Keltner is Chairman of Light Sciences Corporation, a company developing light-activated drugs. Dr. Keltner is currently on the board of directors of Infostat, Inc., a contract research organization, Oregon Life Sciences, a venture investment company focused on the bio-med and biotech sectors, LKHealthnet Inc., a company that acquires healthcare network assets, and Goodwell Technologies, Inc., a provider of real-time communications and collaboration services in the health care, financial, travel and lodging and other industries. Dr. Keltner holds a master s degree in Epidemiology and Biostatistics, a Ph.D. degree in Biomedical Informatics and a medical degree from Case Western Reserve University.

Kent Kresa has been one of our directors since June 2004. Currently, Mr. Kresa is Chairman Emeritus of Northrop Grumman Corporation and from September 1990 until October 2003, he was its Chairman. He also served as Chief Executive Officer of Northrop Grumman Corporation from January 1990 until March 2003 and as its president from 1987 until September 2001. Mr. Kresa serves on the boards of Avery Dennison Corporation, Eclipse Aviation Corporation, Fluor Corporation, General Motors Corporation, and several non-profit organizations and universities. He is also a senior advisor for The Carlyle Group and on the Advisory Board of Trust Company of the West. As a graduate of M.I.T., he received a B.S. in 1959, an M.S. in 1961, and an E.A.A. in 1966, all in Aeronautics and Astronautics.

David H. MacCallum has been one of our directors since June 2004. Currently, Mr. MacCallum is the Managing Partner of Outer Islands Capital, a hedge fund specializing in health care investments. From June 1999 until November 2001, he was Global Head of Health Care investment banking for Salomon Smith Barney, part of Citigroup. Prior to joining Salomon Smith Barney, he was Executive Vice President and Head of the Health Care group at ING Barings Furman Selz LLC, an investment banking firm and subsidiary of ING Group, a Dutch financial institution, from April 1998 to June 1999. Prior to that Mr. MacCallum formed the Life Sciences group at UBS Securities LLC, an investment banking firm, where he was Managing Director and Global Head of Life Sciences from May 1994 to April 1998. Before joining UBS Securities LLC, he founded the health care practice at Hambrecht & Quist, an investment banking firm, where he was Head of Health Care and Co-Head of Investment Banking. Mr. MacCallum received an A.B. degree from Brown University and an M.B.A. degree from New York University. He is a Chartered Financial Analyst.

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BOARD COMPOSITION

Our business and affairs are managed under the direction of our board of directors. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets regularly on a quarterly basis and additionally as required. Written board materials are distributed in advance of meetings as a general rule, and our board of directors schedules meetings with and presentations from members of our senior management on a regular basis.

Our board of directors consists of eight members, two of which are employees of ours. Five of these directors, Dr. Connell, Mr. Consiglio, Dr. Friedman, Mr. Kresa and Mr. MacCallum are independent directors, as defined by Rule 4200(a)(15) of the National Association of Securities Dealers.

In accordance with the terms of our amended and restated certificate of incorporation and bylaws, upon the completion of this offering, the term of each director then serving shall expire at the next annual meeting of stockholders, at which time the newly elected directors shall serve from the time of election and qualification until the following annual meeting of stockholders and until their successors are duly elected and qualified.

Our amended and restated certificate of incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors. Our directors may be removed for cause by the affirmative vote of the holders of a majority of our voting stock and may be removed without cause by the affirmative vote of the holders of at least two-thirds of our voting stock.

Over the past year, our board of directors has devoted considerable time to further improving our governance by addressing the rules promulgated under the Sarbanes-Oxley Act of 2002 and the proposals and requirements of Nasdaq. In connection with such activities, our board of directors has evaluated its role and function, and examined the following, among other things:

- board and board committee meeting schedules;
- board committee governance and composition; and
- the size and composition of our board of directors and director independence.

As a result of its evaluation and recent corporate governance rules enacted under the Sarbanes-Oxley Act of 2002 and Nasdaq, our board of directors has:

- revised the charter of our audit committee of the board;
- created a separate compensation committee and a nominating and corporate governance committee of the board;
- approved the audit committee s formation of a disclosure committee;
- adopted a code of business conduct and ethics governing our employees, officers and directors to promote high standards of integrity by conducting our affairs in an honest and ethical manner; and
- adopted a policy of non-retaliation and a procedure for reporting complaints to protect our employees against unlawful retaliation as a result of their lawful, good-faith reporting of violations of federal or state law or our code of business conduct and ethics by us or any of our agents.

BOARD COMMITTEES

Our board of directors has an audit committee, compensation committee and nominating and corporate governance committee, each of which has the composition and responsibilities described

below. Our board of directors is responsible for determining the composition of the members of these key committees.

Audit committee

Our audit committee consists of Mr. Consiglio (chair), Dr. Connell and Mr. MacCallum, each of whom is an independent member of our board of directors. The functions of this committee include, among others:

- evaluating the independent registered public accounting firm s qualifications, independence and performance;
- determining the engagement of the independent registered public accounting firm;
- approving the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- monitoring the rotation of partners of the independent registered public accounting firm on our engagement team as required by law;
- reviewing our financial statements;
- reviewing our critical accounting policies and estimates;
- discussing with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members, including compliance of the audit committee with its charter.

We have appointed Mr. Consiglio as our audit committee financial expert. Both our independent registered public accounting firm and internal financial personnel regularly meet privately with our audit committee and have unrestricted access to this committee.

Compensation committee

Our compensation committee consists of Dr. Friedman (chair) and Dr. Connell, each of whom is an independent member of our board of directors. The functions of this committee include, among others:

- reviewing and recommending policy relating to compensation and benefits of our officers and employees, including reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and other senior officers, evaluating the performance of these officers in light of those goals and objectives, and setting compensation of these officers based on such evaluations;
- administering our benefit plans and the issuance of stock options and other awards under our stock plans;
- reviewing and establishing appropriate insurance coverage for our directors and executive officers;
- recommending the type and amount of compensation to be paid or awarded to members of our board of directors, including consulting, retainer, meeting, committee and committee chair fees and stock option grants or awards;
- reviewing and approving the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for our executive officers; and

reviewing and evaluating, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter.

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Dr. Connell (chair), Dr. Friedman and Mr. Consiglio, each of whom is an independent member of our board of directors. The functions of this committee include, among others:

planning for succession with respect to the position of CEO and other senior executives;

reviewing and recommending nominees for election as directors;

assessing the performance of the board of directors and monitoring committee evaluations;

suggesting, as appropriate, ad-hoc committees of the board of directors;

developing guidelines for board composition; and

reviewing and evaluating, at least annually, the performance of the nominating and corporate governance committee and its members, including compliance of the nominating and corporate governance committee with its charter.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Prior to establishing our compensation committee, our board of directors as a whole made decisions relating to compensation of our executive officers. Drs. Glen Nelson, Donald Drakeman and Edward L. Korwek, former directors, served on our compensation committee in 2002 and 2003. During 2002 and 2003, none of our executive officers served as a member of the board of directors or compensation committee of any other entity that had one or more executive officers who served on our board of directors or compensation committee.

DIRECTOR COMPENSATION AND REIMBURSEMENT

Each of Messrs. Consiglio and Keltner and Drs. Connell and Friedman was granted an option to purchase 10,000 shares of our common stock under our 2004 equity plan effective upon joining our board. These options vest over three years. Effective upon the closing of this offering, all of our non-employee directors will receive an option to purchase 30,000 shares of our common stock as well as annual grants to purchase 10,000 shares of our common stock under the 2004 Non-Employee Directors Stock Option Plan, which is described elsewhere in this prospectus. Each of our non-employee directors receive an annual retainer of $15,000. Each non-employee director who serves as a committee chair receives an additional retainer of $2,000 per year. In addition, we reimburse our non-employee directors for their expenses incurred in connection with attending board and committee meetings, and these directors receive $1,500 for each meeting of the board attended in person, $750 for each telephonic board meeting attended and $750 for each meeting of a committee attended in person or by phone. See also Certain relationships and related transactions Other transactions.

EXECUTIVE COMPENSATION

Summary compensation table

The following table provides information for the fiscal year ended December 31, 2003, regarding compensation awarded to, earned by or paid to our chief executive officers, each of our four other most highly compensated executive officers whose combined salary and bonus for 2003 exceeded $100,000 and an additional individual for whom disclosures would have been provided but for the

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fact that the individual was not serving as an executive officer at the end of 2003. We refer to the individuals listed in the table below as our named executive officers elsewhere in this prospectus.

Name and principal position(s)	Annual compensation(1)		Long-term compensation	All other compensation
	Salary	Bonus	securities underlying options	
Alfred E. Mann Chief Executive Officer and Chairman of the Board of Directors	$100,000	$	240,972	$
Michael G. Page Former Chief Executive Officer and Director	350,015(2)		88,004	166,385(3)
Solomon S. Steiner Former Senior Vice President, Technology and Director	36,676(4)		171,138	452,148(4)
Hakan S. Edstrom President, Chief Operating Officer and Director	322,115	87,000	333,206	
Dan R. Burns Corporate Vice President and President, MannKind BioPharmaceuticals	273,963		133,333	44,731(5)
Richard L. Anderson Corporate Vice President and Chief Financial Officer	280,288		116,666	59,950(6)
David Thomson Corporate Vice President, Associate General Counsel and Corporate Secretary	223,269	63,000	109,095	37,842(7)

(1) In accordance with the rules of the SEC, the compensation described in this table does not include medical, group life insurance or other benefits which are available generally to all of our salaried employees and certain perquisites and other personal benefits received which do not exceed the lesser of $50,000 or 10% of any named executive officer s salary and bonus disclosed in this table.

(2) In October 2003, Dr. Michael Page s employment with us terminated. In accordance with the terms of his severance agreement, we are obligated to pay Dr. Page his base salary at the rate of $330,000 per year for up to 18 months.

(3) In connection with Dr. Page s resignation, he received a severance payment of $165,000. Also includes $1,385 in auto allowance.

(4) In February 2003, Dr. Solomon Steiner s employment with us terminated. In accordance with the terms of his settlement agreement, we were obligated to pay Dr. Steiner approximately $1,049,288 over three years, comprised of $775,365 in deferred compensation from prior years and the remainder comprised of other severance-related items. In 2003, we paid his base salary through February. Additionally, we paid $258,455 in deferred compensation, $192,655 in severance-related items and $1,038 in auto allowance.

(5) Includes $35,731 in temporary housing reimbursements and $9,000 in auto allowance.

(6) Includes $50,546 in relocation reimbursements and $9,404 in auto allowance. Does not include compensation related to an amount loaned to Mr. Anderson, which has been subsequently repaid, or an amount paid to Mr. Anderson for the purchase of his residence, by a limited liability company that is not owned or controlled by us but is controlled by Mr. Mann. See Note 7 to the financial statements for further

information.

(7) Includes $28,842 in relocation reimbursements and $9,000 in auto allowance. Does not include compensation related to an amount loaned to Mr. Thomson, which has been subsequently repaid, by a limited liability company that is not owned or controlled by us but is controlled by Mr. Mann. See Note 7 to the financial statements for further information.

Stock option grants in 2003

On October 7, 2001, our board of directors adopted, and our stockholders approved, our 2001 Stock Awards Plan. On March 23, 2004, our board of directors adopted, and our stockholders approved, an amendment and restatement to this plan to become effective upon the closing of this offering. We refer to this plan as the 2004 equity plan, both before and after the effective date of the amendment and restatement. All options granted prior to the closing of this offering are governed by the terms of the

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2004 equity plan prior to its amendment and restatement. In 2003, we granted options to purchase a total of 1,664,886 shares of our common stock, with a weighted average exercise price of $9.36 per share, to our employees, including grants to our named executive officers. This total includes 781,572 options issued under the repricing program in exchange for 781,572 outstanding options that were tendered into the program for cancellation. All options granted to our named executive officers are nonstatutory stock options that do not qualify as incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or the Code. Under the terms of our 2004 plan, any options to purchase shares of our common stock that expire or are otherwise terminated are returned to the option pool and become available for future grant under the plan. Options expire ten years from the date of grant. See Employee benefit plans 2004 Equity Incentive Plan.

The exercise price per share of each option granted to our named executive officers was equal to the fair market value or 85% of the fair market value of our common stock as determined by our board of directors on the date of the grant. The exercise price is payable in cash, by promissory note, shares of our common stock previously owned by the optionee or pursuant to the net exercise of the option. In determining the fair market value of the stock granted on the grant date, our board of directors considered many factors, including:

- our absolute and relative levels of revenues and other operating results;
- the fact that our options involved illiquid securities in a nonpublic company;
- prices of preferred stock issued by us to outside investors in arm s-length transactions;
- the rights, preferences and privileges of our preferred stock over our common stock; and
- the likelihood that our common stock would become liquid through an initial public offering, a sale of us or another event.

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Options granted in 2003

The following table provides information concerning grants of options to purchase shares of our common stock under our 2004 equity plan to our named executive officers in 2003. No stock appreciation rights covering our common stock were granted to our named executive officers in 2003.

Name	Number of securities underlying options granted	Percentage of total options granted to employees in fiscal year(1)	Exercise or base price per share	Expiration date	Potential realizable value at assumed annual rates of stock price appreciation for option term(2)	
					5%	10%
					(in thousands)	
Alfred E. Mann		%	$		$	$
Michael G. Page	83,333	5.0	12.75	4/7/05	241	385
Solomon S. Steiner						
Hakan S. Edstrom	233,206(3)	14.0	7.95	11/5/07	2,114	2,926
	100,000	6.0	7.95	11/20/13	1,485	2,836
Dan R. Burns	83,333(3)	5.0	7.95	11/5/07	756	1,046
	50,000	3.0	7.95	11/20/13	743	1,418
Richard L. Anderson	83,333(3)	5.0	7.95	11/5/07	756	1,046
	33,333	2.0	7.95	11/20/13	495	945
David Thomson	50,000(3)	3.0	7.95	11/5/07	453	627
	50,000	3.0	7.95	11/20/13	743	1,418

(1) Based on 1,664,886 options granted during the fiscal year ended December 31, 2003 under our 2004 plan, including grants to executive officers.

(2) Potential realizable values are computed by (a) multiplying the number of shares of common stock subject to a given option by an assumed public offering price of $14.00 per share, (b) assuming that the aggregate stock value derived from that calculation compounds at the annual 5% or 10% rate shown in the table for the entire term of the option and (c) subtracting from that result the aggregate option exercise price. The 5% and 10% assumed annual rates of stock price appreciation are mandated by the rules of the SEC and do not represent our estimate or projection of future common stock prices.

(3) Represents the replacement, pursuant to our option re-pricing program, of options granted in an earlier year.

Aggregated option exercises during 2003 and fiscal year-end option values

The following table provides information concerning options granted under our equity plans that were exercised during 2003, and unexercised options held as of December 31, 2003 by each of our named executive officers.

The value realized and the value of unexercised in-the-money options at December 31, 2003 are based on an assumed initial public offering price of $14.00 per share, less the per share exercise price, multiplied by the number of shares subject to the option, without taking into account any taxes that

may be payable in connection with the transaction. Options outstanding as of December 31, 2003 may not be exercised prior to vesting.

Name	Shares acquired on exercise	Value realized	Number of securities underlying unexercised options at fiscal year-end		Value of unexercised in-the-money options at fiscal year-end	
			Exercisable	Unexercisable	Exercisable	Unexercisable
					(in thousands)	
Alfred E. Mann(1)			60,243	180,729	$	$
Michael G. Page(2)			88,004		104	
Solomon S. Steiner(3)			171,138		1,328	
Hakan S. Edstrom(2)				333,206		2,016
Dan R. Burns(2)				133,333		807
Richard L. Anderson(2)				116,666		706
David Thomson(4)			6,821	102,274	28	614

(1) All options were granted outside of our plans. These options have the same terms as those granted under our 2004 plan.

(2) All options were granted under our 2004 equity plan.

(3) 46,585 options were granted under the 1991 plan and 124,553 options were granted under the 1999 plan.

(4) 9,095 options were granted under the CTL plan and 100,000 options were granted under the 2004 plan.

EMPLOYEE BENEFIT PLANS

1991 Stock Option Plan

On March 15, 1991, our board of directors adopted, and our stockholders approved, our 1991 Stock Option Plan, or the 1991 plan. The 1991 plan was terminated pursuant to its own terms on March 15, 2001. As of May 31, 2004, options to purchase 126,099 shares of our common stock were outstanding under the 1991 plan. We will not grant additional equity awards under the 1991 plan.

Share reserve. Except with respect to the outstanding options referenced above, no shares of our common stock remain reserved or available for issuance under the 1991 plan.

Administration. Our board of directors administers the 1991 plan, but the board may delegate authority to administer the 1991 plan to a committee of three or more members of the board who qualify under the terms of the 1991 plan. Subject to the terms of the 1991 plan, the plan administrator has authority to construe and interpret the 1991 plan and to determine the option recipients, grant dates, numbers and types of options granted and the terms and conditions of the options, including the period of their exercisability and vesting. The plan administrator also has authority to make adjustments upon changes in capitalization.

Eligibility of awards. The 1991 plan provided for the grant of incentive stock options, or ISOs and nonstatutory stock options, or NSOs, only to our employees. ISOs are subject to section 422 of the Internal Revenue Code of 1986, as amended, or the Code.

Stock options. Stock options were granted under the 1991 plan pursuant to a stock option agreement. All outstanding options granted under the 1991 plan are now fully vested. In general, the term of stock options granted under the 1991 plan may not exceed ten years. Unless an optionee s stock option agreement provides otherwise, if an optionee s service with us terminates for any reason other than death, the optionee may exercise any vested option for up to three months following the termination of service. However, in the event the optionee is an employee of ours and is terminated for

cause, all options held by the optionee under the 1991 plan immediately expire and cease to be exercisable.

Shares of common stock subject to options granted under the 1991 plan may be paid for only in cash consideration.

Transferability. Generally, options granted under the 1991 plan are not assignable or transferable, other than by will or the laws of descent and distribution. During the life of the optionee, all rights granted to the optionee under the 1991 plan or under any agreement shall be exercisable only by the optionee.

Additional provisions. Our board of directors has the authority to amend outstanding options granted under the 1991 plan, except that no amendment may adversely affect an optionee without the optionee s written consent.

The 1991 plan provides that we will use our best efforts to cause a registration statement with respect to the common stock issuable under the 1991 plan to be filed within 18 months after we become a publicly reporting company.

1999 Stock Plan

On October 15, 1999, our board of directors adopted, and our stockholders approved, our 1999 Stock Plan, or the 1999 plan. As of May 31, 2004, awards to purchase 305,430 shares of our common stock were outstanding under the 1999 plan. The 1999 plan has been terminated and we will not grant additional equity awards under the 1999 plan.

Share reserve. Except with respect to the outstanding options referenced above, no shares of our common stock remain reserved or available for issuance under the 1999 plan.

Administration. Our board of directors administers the 1999 plan, but the board may delegate authority to administer the 1999 plan to a committee consisting of two or more non-employee directors. The board may adopt, amend and rescind rules and regulations relating to the 1999 plan and may interpret and construe the 1999 plan. Subject to the terms of the 1999 plan, the plan administrator will determine which persons meet the requirements for eligibility, grant dates, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards. Also subject to the limitations set forth in the 1999 plan, the administrator may make appropriate adjustments upon changes to our common stock to the number and type of shares or other securities that may be acquired pursuant to awards granted under the 1999 plan.

Eligibility of awards. The 1999 plan provided for the grant of ISOs, NSOs, stock sales, stock bonuses, restricted stock, reload stock options, stock purchase warrants, other rights to acquire stock, securities convertible into or redeemable for stock, stock appreciation rights, limited stock appreciation rights, phantom stock, dividend equivalents, performance units, performance shares and other awards. All of our directors, employees, consultants or advisers were eligible to be considered for the above awards.

Stock Options. Stock options were granted under the 1999 plan pursuant to a stock option agreement. Common stock may be issued under the 1999 plan for any lawful consideration as determined by the committee, including services rendered by the recipient. The term of options granted under the 1999 plan is for no more than ten years from the date the option was granted. Unless an optionee s stock option agreement provides for earlier termination, if an optionee s service relationship with us terminates due to disability or death, the optionee, or his or her beneficiary, generally may exercise any vested options for up to six months after the date of termination. If an optionee s relationship with us ceases for any reason other than disability or death, the optionee may exercise any vested options for up to thirty days after the date of termination.

Additional provisions. The board of directors has the authority to amend or terminate the 1999 plan provided that no such amendment or termination deprives the recipient of any award granted under the 1999 plan, without consent of such recipient, of any of his or her rights.

Upon certain changes in our control, all awards under the 1999 plan will vest in full and be exercisable prior to the effectiveness of such transaction. The committee may also accelerate the vesting or exercisablity of any award under the 1999 plan. In no event could any grantee receive, in any fiscal year, awards which exceeded an aggregate of 500,000 shares of our common stock.

Non-employee director options. The 1999 plan included provisions for the automatic grant of options to non-employee directors. Such provisions have never been put into effect and will not be used in the future.

AlleCure Corp. 2000 Stock Option and Stock Plan and CTL ImmunoTherapies Corp. 2000 Stock Option and Stock Plan

In connection with the acquisition by us of AlleCure Corp. and CTL ImmunoTherapies Corp. on December 12, 2001, we assumed all of the outstanding options granted under the AlleCure Corp. 2000 Stock Option and Stock Plan, or the AlleCure plan, and the CTL ImmunoTherapies Corp. 2000 Stock Option and Stock Plan, or the CTL plan. Subsequent to the acquisition, these options were adjusted to cover shares of our common stock at the exchange ratios set forth in the applicable merger agreements. As of May 31, 2004, options to purchase an aggregate of 120,347 shares of our common stock under the AlleCure plan and the CTL plan were outstanding. The AlleCure plan and CTL plan were terminated and we will not grant additional equity awards under the AlleCure plan or the CTL plan, collectively known as the 2000 plans.

Share Reserve. Except with respect to the outstanding options referenced above, no shares of our common stock remain reserved or available for issuance under the 2000 plans.

Administration. Pursuant to the merger, our board of directors administers the 2000 plans, but the board may delegate authority to administer the 2000 plans to a committee that complies with applicable law. Our board of directors has broad authority to administer the 2000 plans.

Eligibility of awards. The 2000 plans provided for the grant of ISOs, NSOs and stock purchase rights to employees, directors and consultants.

Stock Options. Stock options were granted under the 2000 plans pursuant to a stock option agreement. Options granted under the 2000 plans have a maximum term of ten years and vest at the rate specified in the option agreements. Except in the case of options granted to officers, directors, and consultants, options become exercisable at a rate of no less than 20% per year over five years from the date the options were granted.

Acceptable consideration for the purchase of common stock issued pursuant to options granted under the 2000 plans includes cash, common stock previously owned by the optionee, a promissory note or consideration received through a cashless exercise program.

Generally, options under the 2000 plans may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by laws of descent and distribution and may be exercised, during the lifetime of the optionee, only by the optionee.

Unless an optionee s stock option agreement provides for earlier termination, if an optionee s service relationship with us terminates due to disability or death, the optionee, or his or her beneficiary, generally may exercise any vested options for up to twelve months after the date the service relationship ends. If an optionee s relationship with us ceases for any reason other than disability or death, the optionee may exercise his or her option within the time specified in the option agreement,

or if not specified, for three months. In no event may an option be exercised after the expiration of the term of the option set forth in the option agreement.

The administrator may at any time offer to buy out for a payment in cash or shares, an option previously granted, based on such terms and conditions as the administrator may establish and communicate to the optionee at the time such offer is made.

Stock Purchase Rights. Unless the administrator determines otherwise, a restricted stock purchase agreement grants us a repurchase option exercisable upon the voluntary or involuntary termination of the purchaser s service with us for any reason (including death or disability). The purchase price for shares repurchased pursuant to the restricted stock purchase agreement is the original price paid by the purchaser and may be paid by cancellation of any indebtedness of the purchaser. The repurchase option lapses at such rate as the administrator may determine. Except with respect to shares purchased by officers and directors, the repurchase option lapses at a rate of no less than 20% per year over five years from the date of purchase.

Corporate transactions or changes in control. Our board of directors will make appropriate adjustments for a stock split, reverse stock split, stock dividend, combination or reclassification of the stock, or any other increase or decrease in the number of issued shares of common stock effected without receipt of consideration by the company.

In the event of the proposed dissolution or liquidation of the company, the administrator shall notify each optionee as soon as practicable prior to the effective date of such proposed transaction. The administrator in its discretion may provide for an optionee to have the right to exercise his or her option or stock purchase right until fifteen days prior to such transaction as to all of the optioned stock covered thereby, including shares as to which the option or stock purchase right would not otherwise be exercisable. In addition, the administrator may provide that any company repurchase option applicable to any shares purchased upon exercise of an option or stock purchase right shall lapse as to all such shares, provided the proposed dissolution or liquidation takes place at the time and in the manner contemplated. To the extent it has not been previously exercised, an option or stock purchase right will terminate immediately prior to the consummation of such proposed action.

In addition, in the event we merge or sell all or substantially all of our assets, all outstanding stock awards under the 2000 plans will be assumed, continued or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or substitute for these awards, each participant will be given notice of the transaction and permitted to exercise all outstanding awards held under the 2000 plans for a period of fifteen days after notice is provided. To the extent it has not been previously exercised, an option or stock purchase right will terminate at the end of such period.

Additional provisions. Our board of directors has the authority to amend outstanding awards granted under the 2000 plans, except that no amendment may adversely affect an award without the recipient s written consent. Our board of directors has the power to amend the 2000 plans. We are required to provide annual financial statements to participants in the 2000 plans.

2004 Equity Incentive Plan

On October 7, 2001, our board of directors adopted, and our stockholders approved, our 2001 Stock Awards Plan. On March 23, 2004, our board of directors adopted, and our stockholders approved, an amendment and restatement of the 2001 Stock Awards Plan to become effective upon the closing of this offering. We refer to this plan as the 2004 plan, both before and after the effective date of the amendment and restatement. All awards granted under the 2004 plan prior to the closing of this offering will continue to be governed by the terms of the 2004 plan prior to its amendment and restatement. All awards granted under the 2004 plan after the closing of this offering will be governed

by the terms of the 2004 plan as amended and restated. The material differences between the terms of options granted under the 2004 plan prior to and following this offering are identified below.

Share reserve. An aggregate of 3,659,926 shares of our common stock are reserved for future issuance under the 2004 plan. Shares subject to options and stock awards that expire, terminate, are repurchased or are forfeited under the 2004 plan will again become available for the grant of awards under the 2004 plan. Shares issued under the 2004 plan may be previously unissued shares or reacquired shares bought on the market or otherwise. 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 net exercise, the number of shares that are not delivered to the participant shall remain available for the grant of awards under the 2004 plan. If the exercise of any stock award is satisfied by tendering shares of common stock held by the participant, the number of shares tendered shall become available for the grant of awards under the 2004 plan. The maximum number of shares that may be issued under the 2004 plan subject to incentive stock options is 7,000,000.

As of May 31, 2004, options to purchase 1,340,074 shares of our common stock subject to the terms of the 2004 plan prior to its amendment and restatement were outstanding. As of the date hereof, no shares of our common stock have been issued under the terms of the 2004 plan as amended and restated. The 2004 plan prior to its amendment and restatement provided for multiple forms of equity awards, but only options were granted by our board of directors.

Administration. Our board of directors will administer the 2004 plan, but the board may delegate authority to administer the 2004 plan to a committee of one or more members of the board. Subject to the terms of the 2004 plan, the plan administrator will determine the stock award recipients and grant dates, the numbers and types of stock awards to be granted under the 2004 plan and the terms and conditions of the stock awards, including the period of their exercisability and vesting. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, purchase price or strike price, as applicable, for stock awards granted under the 2004 plan.

Eligibility of awards. The 2004 plan provides for the grant of ISOs, NSOs, restricted stock awards, stock appreciation rights, phantom stock awards and other stock awards based in whole or in part by reference to our common stock. ISOs may be granted solely to our employees, including officers. All other stock awards under the 2004 plan may generally be granted to our employees, directors, officers and consultants.

Stock options. Stock options are granted under the 2004 plan pursuant to a stock option agreement. Generally, the exercise price for an ISO cannot be less than 100% of the fair market value of the common stock subject to the option on the date of grant. The exercise price for an NSO is determined by our board of directors. Options granted under the 2004 plan vest at the rate specified in the stock option agreement. In addition, following this offering, our 2004 plan will allow for the early exercise of options, as set forth in an applicable stock option agreement. All shares of our common stock acquired through options exercised early may be subject to repurchase by us. Options granted under the 2004 plan prior to its amendment and restatement must vest at the rate of at least 20% per year and may not be exercised early.

In general, the term of stock options granted under the 2004 plan may not exceed ten years. With respect to options granted under the 2004 plan following this offering, unless the terms of an optionee s stock option agreement provide for earlier termination, if an optionee s service relationship with us, or any affiliate of ours, terminates due to disability, death or retirement, the optionee, or his or her beneficiary, generally may exercise any vested options after the date the service relationship ends for up to twelve months in the event of disability, up to eighteen months in the event of death and up to twenty-four months in the event of selected retirements. If an optionee s relationship with us, or any

affiliate of ours, ceases for any reason other than disability, death or retirement, the optionee may exercise any vested options for up to three months after the termination of service, unless the terms of the stock option agreement provide for earlier termination. However, in the event the optionee s service with us, or an affiliate of ours, is terminated for cause (as defined in the 2004 plan), all options held by the optionee under the 2004 plan will terminate in their entirety on the date of termination.

With respect to options granted under the 2004 plan prior to this offering, if an optionee s service with us is terminated due to disability or death, the optionee, or his or her beneficiary, may exercise any vested options for up to six months after the date of termination. If an optionee s service with us is terminated for any reason other than disability or death, the optionee may exercise any vested options for up to thirty days after the date of termination. However, in the event an optionee s service with us is terminated for cause under the terms of the 2004 plan, all options held by the optionee under the 2004 plan will terminate on the date of termination.

Acceptable consideration for the purchase of our common stock issued under the 2004 plan will be determined by our board of directors and may include cash or common stock previously owned by the optionee, or may be paid through a deferred payment arrangement, a broker assisted exercise, the net exercise of the option or other legal consideration or arrangements approved by our board of directors.

Generally, options granted under the 2004 plan may not be transferred other than by will or the laws of descent and distribution unless the optionee holds an NSO and the related option agreement provides otherwise. However, an optionee may designate a beneficiary who may exercise the options granted under the 2004 plan following the optionee s death.

Tax limitations on stock option grants. ISOs may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock subject to ISOs that are exercisable for the first time by an optionee during any calendar year under all of our stock plans may not exceed $100,000. The options or portions of options that exceed this limit are treated as NSOs. No ISO may be granted to a 10% stockholder unless the following conditions are satisfied:

- the option exercise price is at least 110% of the fair market value of the stock subject to the option on the grant date; and
- the term of any ISO award must not exceed five years from the grant date.

Section 162(m). When we become subject to the requirements of Section 162(m) of the Code, which denies a deduction to publicly held corporations for certain compensation paid to specified employees in a taxable year to the extent that the compensation exceeds $1,000,000, no person may be granted options under the 2004 plan covering more than 2,000,000 shares of our common stock in any calendar year.

Restricted stock awards. Restricted stock awards are purchased through a restricted stock award agreement. To the extent required by law, the purchase price for restricted stock awards must be at least the par value of the stock. The purchase price for a restricted stock award may be payable in cash or through a deferred payment or related arrangement, the recipient s past services performed for us, or any other form of legal consideration or arrangement acceptable to our board of directors. Rights to acquire shares under a restricted stock award may be transferred only as set forth in the restricted stock award agreement.

Stock appreciation rights. Stock appreciation rights are granted under the 2004 plan pursuant to stock appreciation rights agreements. The plan administrator determines the strike price for a stock appreciation right. Stock appreciation rights granted under the 2004 plan vest at the rate specified in the stock appreciation rights agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2004 plan. Unless the terms of an awardee s stock appreciation rights agreement provides otherwise, if an awardee s service relationship with us, or any affiliate of ours, terminates for any reason, the awardee, or his or her beneficiary, may exercise any vested stock appreciation rights for up to three months after the date the service relationship ends unless the terms of the agreement provide for earlier or later termination.

Phantom stock. Phantom stock awards are granted under the 2004 plan pursuant to phantom stock award agreements. A phantom stock award may require the payment of at least the par value of the option subject to the award. Payment of any purchase price may be made in cash or common stock previously owned by the recipient or a combination of the two. Dividend equivalents may be credited in respect of shares covered by a phantom stock award, as determined by our board of directors. All phantom stock awards will be forfeited upon termination of the holder s service relationship with us, or any affiliate of ours, to the extent not vested on that date.

Other stock awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award, the purchase price, if any, the timing of exercise and vesting and any repurchase rights associated with these awards.

Corporate transactions and changes in control. In the event of certain corporate transactions, all outstanding stock awards granted under the 2004 plan following this offering either will be assumed, continued or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or substitute for these awards, the vesting provisions of these awards will generally be accelerated and the awards will be terminated if not exercised prior to the effective date of the corporate transaction. We may assign any repurchase or reacquisition rights held by us with respect to outstanding stock awards to the surviving or acquiring entity. Following certain change in control transactions, the vesting and exercisability of certain stock awards granted under the 2004 plan following this offering generally will be accelerated only if and to the extent provided in the awardee s award agreement.

Our board of directors will make appropriate adjustments for a stock split, reverse stock split, stock dividend, combination or reclassification of the stock, or any other increase or decrease in the number of issued shares of common stock effected without receipt of consideration by the company.

Additional provisions. Our board of directors has the authority to amend outstanding awards granted under the 2004 plan, except that no amendment may adversely affect an award without the recipient s written consent. Our board of directors has the power to amend, suspend or terminate the 2004 plan. However, some amendments also require stockholder approval.

We are required to provide annual financial statements to individuals who participated in the 2004 plan prior to its amendment and restatement.

2004 Employee Stock Purchase Plan

We adopted, and our stockholders approved, our 2004 Employee Stock Purchase Plan, or the purchase plan, on March 23, 2004. The purchase plan will become effective upon the closing of this offering. The purchase plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. Under the purchase plan, eligible employees will be able to purchase shares of our common stock at a discount price in periodic offerings.

Share reserve. An aggregate of 2,000,000 shares of our common stock are reserved for issuance pursuant to purchase rights granted to our employees or to employees of any of our affiliates under

the purchase plan. On the first day of each calendar year, for a period of ten years beginning on January 1, 2005, the share reserve will automatically increase by the lesser of:

700,000 shares;

1% of the total number of shares of our common stock outstanding on that date; or

an amount as may be determined by our board of directors.

However, under the terms of the purchase plan, in no event shall the annual increase cause the total number of shares reserved under the purchase plan to exceed 10% of the total number of shares of our capital stock outstanding on December 31 of the prior year. As of the date hereof, no shares of common stock have been purchased under the purchase plan.

Administration. Our board of directors will administer the purchase plan, but the board may delegate authority to administer the purchase plan to a committee of one or more members of the board. Subject to the terms of the purchase plan, the plan administrator will determine grant dates for purchase rights, interpret the purchase plan and purchase rights and establish rules for the administration of the purchase plan.

Eligibility. The purchase plan is implemented by offerings of rights to eligible employees. Our board of directors will establish the criteria for determining which employees are eligible to participate in an offering. Generally, all regular employees, including executive officers, who work more than twenty hours per week and are customarily employed by us or by any of our affiliates for more than five months per calendar year may participate in the purchase plan. Eligible employees may be granted rights only if the rights, together with any other rights granted under employee stock purchase plans, do not permit such employees rights to purchase our stock to accrue at a rate which exceeds $25,000 of the fair market value of such stock for each calendar year in which such rights are outstanding. In addition, no employee shall be eligible for the grant of any rights under the purchase plan if immediately after such rights are granted, the employee has voting power over 5% or more of our outstanding capital stock, measured by vote or value. For purposes of the purchase plan, stock which may be purchased under an outstanding purchase right is treated as owned by an employee. All outstanding purchase rights granted to an employee will terminate if the employee ceases to be employed by us or by any of our affiliates.

Offerings. Under the purchase plan, employees may purchase shares of our common stock during offerings through payroll deductions. Offerings may last up to 27 months. The first offering will begin on the effective date of this offering and last approximately six months, with one purchase occurring at the end of the six-month period. Eligible employees who participate in an offering may have up to 20% of their earnings for the period of that offering withheld for the purchase of common stock under the purchase plan. The price paid for common stock on the purchase dates will be determined by the plan administrator and will not be less than the lower of 85% of the fair market value of a share of our common stock on the first day of the offering period or 85% of the fair market value of a share of our common stock on the purchase date. Employees may end their participation in the offering at any time during the offering period, and participation ends automatically on termination of employment.

Transferability. Generally, a purchase right granted under the purchase plan may not be transferred other than by will or the laws of descent and distribution. However, an employee may designate a beneficiary who may exercise the purchase right following the optionee s death.

Corporate transactions. In the event of certain corporate transactions, any outstanding rights to purchase our stock under the purchase plan will be assumed, continued or substituted for by the surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or

substitute for these rights, then the participants accumulated contributions will be used to purchase shares of our common stock within ten days prior to the corporate transaction and the purchase rights will terminate immediately thereafter.

Our board of directors will make appropriate adjustments for a stock split, reverse stock split, stock dividend, combination or reclassification of the stock, or any other increase or decrease in the number of issued shares of common stock effected without receipt of consideration by the company.

Other provisions. Our board of directors has the authority to amend or terminate the purchase plan. However, no amendment or termination of the purchase plan or outstanding offering may adversely affect any outstanding rights to purchase shares of our common stock other than an amendment or termination as a result of an accounting treatment for the purchase plan that is detrimental to our best interests. Amendments generally will be submitted for stockholder approval only to the extent required by law or applicable exchange rules.

2004 Non-Employee Directors Stock Option Plan

We adopted, and our stockholders approved, our 2004 Non-Employee Directors Stock Option Plan, or the directors plan, on March 23, 2004. The directors plan will become effective upon the closing of this offering. The directors plan provides for the automatic non-discretionary grant of NSOs to our non-employee directors.

Share reserve. An aggregate of 800,000 shares of our common stock are reserved for issuance under the directors plan. Shares subject to options granted under the directors plan that expire or otherwise terminate without being exercised will be returned to the director s plan and become available for issuance under the plan. Shares subject to options granted under the directors plan that are withheld upon the exercise of an option or shares that are provided by a non-employee director to exercise an option, will remain available for issuance under the directors plan. As of the date hereof, no shares of common stock have been issued under the directors plan.

Administration. Our board of directors will administer the directors plan, but the board may delegate authority to administer the directors plan to a committee of one or more members of the board. Our board of directors has broad discretion to interpret and administer the directors plan.

Automatic grants. Pursuant to the terms of the directors plan, upon the completion of this offering, each of our non-employee directors will automatically receive an initial option grant to purchase 30,000 shares of our common stock. Each person who is not an employee of ours who is first elected or appointed to our board of directors after the closing of this offering will receive an initial option grant on the date of his or her election or appointment to purchase 30,000 shares of our common stock. Any person who is a non-employee director on the day of an annual meeting of our stockholders, beginning in 2005, will automatically be granted an option to purchase 10,000 shares of our common stock under the directors plan on that date, the annual grant. However, in the event a non-employee director has not been a non-employee director since the date of the preceding annual meeting of our stockholders, that director will receive an annual grant that has been reduced *pro rata* for each full quarter prior to the date of grant during which such person did not serve as a non-employee director.

Terms. In general, the term of the stock options granted under the directors plan may not exceed 10 years and the exercise price for the options cannot be less than 100% of the fair market value of the common stock on the date of grant. Acceptable consideration for the purchase of our common stock issued under the directors plan will be determined by our board of directors and may include cash or common stock previously owned by the optionee or may be paid through a broker assisted exercise or net exercise feature. All initial option grants under the directors plan vest in three equal annual installments and all annual option grants under the directors plan vest in full on the grant

date. An optionee whose service relationship with us or any of our affiliates, whether as a non-employee director or subsequently as an employee, director or consultant of either us or one of our affiliates, ceases for any reason may exercise options for the term provided in the option agreement to the extent the options were exercisable on the date of termination.

Transferability. Generally, an option granted under the directors plan may not be transferred other than by will or by the laws of descent and distribution or pursuant to the terms of the option agreement. However, an optionee may designate a beneficiary who may exercise the option following the optionee s death.

Corporate transactions. In the event of certain corporate transactions, all outstanding options granted under the directors plan will be assumed, continued or substituted for by any surviving entity. If the surviving or acquiring entity elects not to assume, continue or substitute for these options, the options will be terminated if not exercised prior to the effective date of the corporate transaction.

Our board of directors will make appropriate adjustments for a stock split, reverse stock split, stock dividend, combination or reclassification of the stock, or any other increase or decrease in the number of issued shares of common stock effected without receipt of consideration by the company.

Additional provisions. Our board of directors may amend or terminate the directors plan at any time. However, some amendments will require stockholder approval and no amendment or termination may adversely affect a non-employee director s outstanding options without the non-employee director s written consent.

401(k) Plan

We sponsor a 401(k) plan that is a defined contribution plan. Employees who complete one month of service with us prior to an open enrollment date are eligible to participate in our 401(k) plan. Participants may make pre-tax contributions to the 401(k) plan each year of up to the statutorily prescribed annual limit, which is $13,000 for 2004. Under the plan, each employee is fully vested in his or her deferred salary contributions after two years of service. Employee contributions are held in trust as required by law and invested by the plan s trustee according to the employee s instructions. Under our 401(k) plan, we may also make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. During the year ended December 31, 2003, we contributed an aggregate of $235,000 to our 401(k) plan. The 401(k) plan is intended to qualify under Section 401(a) of the Code so that contributions to the 401(k) plan, and income earned on these contributions, are not taxable to participants until withdrawn or distributed from the plan.

EXECUTIVE SEVERANCE AGREEMENTS

On August 1, 2003, we entered into executive severance agreements with Drs. Cheatham and Thomson and Messrs. Edstrom, Anderson and Burns. Each agreement is for a period of two years and will be automatically renewed for additional one-year periods unless either party gives notice to terminate the agreement at least 90 days prior to the end of its initial term or any subsequent term.

The agreements provide that each executive is an at will employee and that his employment with us may be terminated at any time by the employee or us. Under the agreements, in the event we terminate an executive s employment without cause (as defined below) or the employee terminates his employment with us for good reason (as defined below), the employee is generally entitled to receive the following:

- the portion of the employee s annual base salary earned through the termination date that was not paid prior to his termination, if any;

on the condition the employee executes a general release and settlement agreement, or Release, in favor of us, the employee s annual base salary on the date of termination for a period of 18 months following his termination, subject to certain limitations;

on the condition the employee executes a Release, an amount equal to the average annual bonus received by the employee for the three years prior to his termination (or the prior period up to three years during which the employee was one of our executive officers and received a bonus);

in the event the employee met the performance criteria for earning an annual bonus prior to his termination, a portion of the annual bonus earned for the year based on the number of days worked during the year;

any compensation previously deferred by the employee and any accrued paid time-off that the employee is entitled to under our policy; and

on the condition the employee executes a Release, health insurance and, under certain circumstances, life, disability and other insurance benefits for a period expiring on the earlier of 18 months following his termination or until he qualifies for related benefits from another employer.

In addition, the executive severance agreements provide that, on the condition the employee executes a Release, each vested stock option held by the employee on the date of termination will be exercisable for a period ending on the earlier of 18 months following that date or the end of the original term of the option.

Under the agreements, an employee may be terminated for cause if he, among other things:

refuses to carry out or satisfactorily perform any of his lawful duties or any lawful instruction of our board of directors or senior management;

violates any local, state or federal law involving the commission of a crime other than a minor traffic offense;

is grossly negligent, engages in willful misconduct or breaches a fiduciary obligation to us;

engages in any act that materially compromises his reputation or ability to represent us with investors, customers or the public; or

reaches a mandatory retirement age established by us.

Under the agreements, good reason includes, among other things:

a reduction of the executive s annual base salary to a level below his salary as of August 1, 2003;

a material diminution in the executive s position, authority, duties or responsibilities with us, subject to certain limitations;

an order by us to relocate the executive to an office located more than 50 miles from the executive s current residence and worksite;

any non-renewal of the executive severance agreement by us, on the condition that the executive may terminate the agreement for good reason only during the 30-day period after he receives notice from us that we intend to terminate the agreement; and

any material violation of the executive severance agreement by us.

Under the agreements, an employee must inform us if he intends to terminate his agreement for good reason. We have 30 days from the date we receive notice of the employee s intent to terminate the agreement for good reason to cure the default.

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CHANGE OF CONTROL AGREEMENTS

On August 1, 2003, we entered into change of control agreements with Drs. Cheatham and Thomson and Messrs. Edstrom, Anderson and Burns. Each agreement is for a period of two years and will be automatically renewed for additional one-year periods unless either party gives notice to terminate the agreement at least 90 days prior to the end of its initial term or any subsequent term.

Under the agreements, a change of control will be deemed to occur upon:

- any transaction that results in a person or group acquiring beneficial ownership of 50% or more of our voting stock, other than us, one of our employee benefit plans, Mr. Mann or any other entity in which Mr. Mann holds a majority of the beneficial interests;
- any merger, consolidation or reorganization of us in which our stockholders immediately prior to the transaction hold less than 50% of the voting power of the surviving entity following the transaction, subject to certain limitations;
- any transaction in which we sell all or substantially all of our assets, subject to certain limitations;
- our liquidation; or
- any reorganization of our board of directors in which our incumbent directors (as defined in the agreements) cease for any reason to constitute a majority of the members of our board.

The agreements provide that in the event of a change of control, the employee is generally entitled to maintain the same position, authority and responsibilities held before the change of control, as well as the following compensation and benefits during the period ending on the earlier of 24 months following the change of control or the termination of his employment with us:

- his annual base salary in an amount equal or greater to his annual salary as of the date the change of control occurs;
- an annual bonus in an amount equal to the average annual bonus received by him for the three years prior to his termination (or the prior period up to three years during which he was one of our executive officers and received a bonus);
- medical, dental and other insurance, and any other benefits we may offer to our executives; and
- prompt reimbursement for all reasonable employment expenses incurred by him in accordance with our policies and procedures.

Under the change of control agreements, we may terminate an executive with or without cause (as defined below) and the executive may terminate his employment with us for good reason (as defined below) or any reason at any time during the 2-year period following a change of control. In the event we terminate an executive without cause or an executive terminates his employment with us for good reason, he is generally entitled to receive the following:

- the portion of his annual base salary earned through the termination date that was not paid prior to his termination, if any;
- on the condition the employee executes a Release in favor of us, the employee s annual base salary on the date of termination for a period of 18 months following his termination, subject to certain limitations;
- on the condition the employee executes a Release, an amount equal to 150% of his average annual bonus received by the employee for the three years prior to his termination (or the prior period up to three years during which the employee was one of our executive officers and received a bonus);

in the event the employee met the performance criteria for earning an annual bonus prior to his termination, a portion of the annual bonus earned for the year based on the number of days worked during the year;

any compensation previously deferred by the employee and any accrued paid time-off that the employee is entitled to under our policy; and

on the condition the employee executes a Release, health insurance and, under certain circumstances, life, disability and other insurance benefits for a period expiring on the earlier of 18 months following his termination or until he qualifies for related benefits from another employer.

In addition, the agreements provide that, on the condition the employee executes a Release, each option to purchase shares of our common stock held by him as of the termination date will become fully vested and exercisable at any point during the term of the option, subject to certain limitations.

Under the agreements, in the event we terminate an employee with cause or an employee terminates his employment with us without good reason, his agreement will terminate without any further obligation to either party.

The change of control agreements provide that an employee may be terminated for cause if he, among other things:

refuses to carry out or satisfactorily perform any of his lawful duties or any lawful instruction of our board of directors or senior management;

violates any local, state or federal law involving the commission of a crime other than a minor traffic offense;

is grossly negligent, engages in willful misconduct or breaches a fiduciary obligation to us;

engages in any act that materially compromises his reputation or ability to represent us with investors, customers or the public; or

reaches a mandatory retirement age established by us before a change of control occurs.

Under the agreements, good reason includes, among other things:

a failure by us to make all compensation payments and provide all insurance and related benefits to the employee required under the agreement during his employment following a change of control, subject to certain limitations;

a material diminution in the employee s position, authority, duties or responsibilities with us;

an order by us to relocate the employee to an office located more than 50 miles from the employee s current residence and worksite;

any non-renewal of the change of control agreement by us, on the condition that the employee may terminate the agreement for good reason only during the 30-day period after he receives notice from us that we intend to terminate the agreement; and

any material violation of the change of control agreement by us.

Under the change of control agreements, an employee must inform us if he intends to terminate his agreement for good reason. We have 30 days from the date we receive notice of the employee s intent to terminate the agreement for good reason to cure the default.

The executive and change of control agreements provide that in the event an executive becomes entitled to benefits under both agreements, compensation payments and other benefits will be coordinated to ensure the executive is entitled to receive the benefits described above without duplicating coverage.

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LIMITATIONS OF LIABILITY AND INDEMNIFICATION OF OFFICERS AND DIRECTORS

We were incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law, or DGCL, generally provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), by reason of the fact that the person is or was an officer, director, employee or agent of the corporation, or is or was serving at the request of the corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, provided that the person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may also indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided the person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation s best interests, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which the officer or director has actually and reasonably incurred.

Our amended and restated certificate of incorporation and amended and restated bylaws provide for the indemnification of our directors and executive officers to the fullest extent permitted under the DGCL and other applicable laws.

As permitted by Delaware law, we have entered into indemnity agreements with each of our directors and executive officers. These agreements generally require us to indemnify our directors and executive officers against any and all expenses (including attorneys fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any of these individuals may be made a party by reason of the fact that he or she is or was a director, officer, employee, or other agent of ours or serving at our request as a director, officer, employee, or other agent of another corporation or enterprise, provided that he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. Under the indemnification agreements, all expenses incurred by one of our directors or executive officers in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of the director or executive officer, to repay all advanced amounts if it is ultimately determined that the director or executive officer is not entitled to be indemnified by us under his or her indemnification agreement, our amended and restated bylaws or the DGCL. The indemnification agreements also set forth certain procedures that will apply in the event any of our directors or executive officers brings a claim for indemnification under his or her indemnification agreement.

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In addition, Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for:

- any transaction from which the director derives an improper personal benefit;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock purchase or redemptions of shares; or
- any breach of a director s duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation includes such a provision.

There is currently no pending litigation or proceeding involving any of our directors or executive officers for which indemnification is being sought. We are not currently aware of any threatened litigation that may result in claims for indemnification against us by any of our directors or executive officers.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or Securities Act, or otherwise. The policy expires on March 14, 2005.

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Certain relationships and related party transactions

The following is a description of transactions or series of transactions since January 1, 2000 to which we have been a party, in which the amount involved in the transaction or series of transactions exceeds $60,000, and in which any of our directors, executive officers or persons who we know held more than five percent of any class of our capital stock, including their immediate family members, had or will have a direct or indirect material interest, other than compensation arrangements, which are described under Management. Except as specifically described below regarding loans to former directors and former executive officers, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm s-length transactions.

MERGER OF PDC, CTL AND ALLECURE

On December 12, 2001, we acquired AlleCure and CTL, and these entities became wholly-owned subsidiaries of ours. Pursuant to the terms of the acquisition, all outstanding shares of capital stock of CTL were exchanged for 2,504,928 shares of our common stock and 267,212 shares of our Series A preferred stock. In addition, all outstanding shares of capital stock of AlleCure were exchanged for 3,697,275 shares of our common stock and 192,618 shares of our Series B preferred stock. At the time of this transaction, we valued the stock issued to the former stockholders of CTL and AlleCure at approximately $195,153,000. Following the acquisition, we changed our name from Pharmaceutical Discovery Corporation to MannKind Corporation. On December 31, 2002, we merged AlleCure and CTL with and into us and became one entity. Our shares of preferred stock issued to the former stockholders of AlleCure and CTL in connection with the merger on December 12, 2001, or the Merger, constitute 100% of the shares of Series A preferred stock and Series B preferred stock issued by us to date.

Prior to the Merger, Alfred E. Mann, our Chief Executive Officer and Chairman of the Board of Directors, held approximately 63.1% of the outstanding shares of common stock and 83.4% of the outstanding shares of preferred stock of CTL, approximately 51.7% of the outstanding shares of common stock and 100% of the outstanding shares of preferred stock of AlleCure and approximately 76% of the outstanding shares of common stock of PDC. In the Merger, in exchange for all of the outstanding shares of capital stock of AlleCure and CTL held by Mr. Mann, he received 222,864 shares of our Series A preferred stock and 192,618 shares of our Series B preferred stock, and 3,493,850 shares of common stock, which, when combined with his holdings of PDC common stock, totalled 8,107,029 shares of our common stock.

In connection with the Merger, we assumed the obligation under a warrant issued by CTL for the purchase of 118,424 shares of our common stock at an exercise price of $21.12 per share initially issued to Mr. Mann by CTL on March 30, 2001. This warrant expired unexercised on March 31, 2003.

SEVERANCE AGREEMENTS

Dr. Solomon Steiner ceased to be an employee and a director of ours on February 6, 2003 pursuant to a settlement agreement with us. Under the settlement agreement, we became obligated to pay Dr. Steiner approximately $1,049,288 over three years, comprised of approximately $775,365 in deferred compensation from prior years and the remainder comprised of severance-related items. We have paid approximately $451,110 of this amount. An additional $271,378 is due in April 2004, $42,500 is due in September 2004 and the remaining $284,300 is due in April 2005. The settlement

agreement further provides that the options held by Dr. Steiner to purchase up to 46,585 shares of our common stock remain fully exercisable through April 2007, and options to purchase up to 124,553 shares of our common stock remain fully exercisable until at least April 2006.

Dr. Stephen McCormack resigned as an employee and a director of ours in February 2003 pursuant to a settlement agreement with us dated March 28, 2003. Under the settlement agreement, we became obligated to pay Dr. McCormack his base salary at the rate of approximately $22,468 per month through December 2003, and a lump sum payment of $67,404 in February 2005.

Mr. John Simard resigned as an employee and a director of ours in September 2002 pursuant to a post-employment agreement with us. The post-employment agreement provides that options held by Mr. Simard to purchase up to 30,316 shares of our common stock remain fully exercisable until January 2, 2006.

Dr. Michael Page, our Chief Executive Officer from January 1, 2003, resigned as an employee and a director of ours effective October 7, 2003. Under the terms of a severance agreement, we are obligated to pay Dr. Page his base salary at the rate of approximately $27,500 per month through April 2005 and a severance payment of $165,000. The agreement also provides for accelerated vesting of an option held by Dr. Page permitting him to purchase up to 83,333 shares of our common stock until April 7, 2005.

LOANS TO FORMER DIRECTORS AND FORMER EXECUTIVE OFFICERS

On May 18, 2000, CTL sold and issued 1,965,000 shares of its common stock to Mr. Simard in exchange for a promissory note in the aggregate principal amount of $1,179,000. The promissory note was due in May 2005, was full recourse as to both principal and interest, and was collateralized by the underlying shares of common stock issued in connection with the note. The note accrued interest at a fixed interest rate, which was less than the market interest rate available for a loan of similar size and terms from a third party. As a result, CTL recognized compensation expense of approximately $121,000 in 2002, which was equal to the amount of the discount on the promissory note based on the difference between a market interest rate and the fixed interest rate and the term of the note. In connection with the Merger, Mr. Simard s shares of common stock of CTL were exchanged for 119,145 shares of our common stock and we were assigned the benefit of the promissory note. All outstanding principal and interest accrued under the note were repaid in full in March 2002.

On September 15, 2000, December 15, 2000 and April 2, 2001, AlleCure sold and issued an aggregate of 1,715,000 shares of its common stock to Dr. McCormack in exchange for three promissory notes in the aggregate principal amount of $1,963,380. The promissory notes are due at various dates from 2005 to 2006, are full recourse as to both principal and interest and are collateralized by the underlying shares of common stock issued in connection with the notes. The notes are pre-payable by Dr. McCormack and he has no service obligation to us under the terms of the stock purchase. The note-for-stock transaction was accounted for as in-substance stock option grants to an employee. As a result, AlleCure recognized stock-based compensation expense of $815,000 during 2001 in connection with these notes, which represented the intrinsic value of the in-substance stock options. This amount was reversed in 2002 because the in-substance options had no intrinsic value as of December 31, 2002. In connection with the Merger, Dr. McCormack s shares of common stock of AlleCure were exchanged for 110,113 shares of our common stock and we were assigned the benefit of the promissory notes. As of December 31, 2003, an aggregate of $2,274,474 in principal and accrued interest was outstanding under the notes.

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Certain relationships and related party transactions

COMMON STOCK FINANCINGS

From January 2001 through December 31, 2003, we sold shares of our common stock in private financings as follows:

on June 30, 2001 and on August 31, 2001, we sold 159,048 and 1,192 861 shares of common stock, respectively, for a purchase price of $25.14 per share;

on May 2, 2002 we sold an aggregate of 233,849 shares of common stock for a purchase price of $25.23 per share;

during the period of June 2002 through December 2002 we sold 3,921,767 shares of common stock for a purchase price of $15.00 per share;

in January 2003, we entered into an agreement to sell an aggregate of 41,534 shares of common stock for a purchase price of $15.00 per share, which we sold on December 22, 2003;

during the period February 2003 through May 2003 we sold an aggregate of 2,838,315 shares of common stock for a purchase price of $13.80-$14.55 per share; and

on August 9, 2003 we sold an aggregate of 654,879 shares of common stock for a purchase price of $15.27 per share.

The investors in these financings included the following executive officers, directors, holders of more than five percent of our securities, and the immediate family members and affiliated entities of each:

Purchaser	Shares
Directors and executive officers	
Alfred E. Mann(1)	1,393,443
Kent Kresa(2)	20,000
David H. MacCallum	6,666
Immediate family members	
Claude Girault(3)	66,667
Howard Mann(4)	271,344
Richard Mann(5)	146,302
Carla Mann(6)	100,000
Kevin Mann(7)	26,667
Alfred Mann, Jr.(8)	40,000
Robert Mann(9)	19,818
Rosalind Koff(10)	25,667
5% or greater stockholders	
Biomed Partners, LLC(11)	2,420,496
Biomed Partners II, LLC(11)	2,406,027

(1) Alfred E. Mann holds the shares set forth opposite his name as trustee of the Alfred E. Mann Living Trust dated April 9, 1999.

(2) Kent Kresa holds the shares set forth opposite his name as trustee of the Kresa Family Trust.

(3) Claude Girault is the spouse of Alfred E. Mann.

(4) Howard Mann holds the shares set forth opposite his name as trustee of the Howard T. and Joni C. Mann Family Trust. Howard Mann is the son of Alfred E. Mann.

(5)

Richard Mann holds the shares set forth opposite his name as trustee of the Richard Mann Family Trust #1, the Richard Mann Family Trust #2 and the Richard and Cheryl Mann Revocable Living Trust. Richard Mann is the son of Alfred E. Mann.

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(6) *Carla Mann holds the shares set forth opposite her name as trustee of the Carla Mann Revocable Trust. Carla Mann is the daughter of Alfred E. Mann.*

(7) *Kevin Mann is the son of Alfred E. Mann.*

(8) *Alfred Mann, Jr. is the son of Alfred E. Mann.*

(9) *Robert Mann is the brother of Alfred E. Mann.*

(10) *Rosalind Koff is the sister of Alfred E. Mann.*

(11) *The Alfred E. Mann Living Trust and Minimed Infusion, Inc. are each 0.1% managing members of each of Biomed Partners, LLC and Biomed Partners II, LLC. Alfred Mann has voting and dispositive power over the shares set forth opposite the names of each of these entities.*

SERIES C CONVERTIBLE PREFERRED STOCK FINANCING

On December 31, 2003 we sold 980,392 shares of our Series C convertible preferred stock in a private financing at a price of $51.00 per share, including 364,589 shares to the Alfred E. Mann Living Trust.

We effected a one-for-three reverse split of our common stock on July 22, 2004. After giving effect to the reverse split of our common stock, upon the closing of this offering, the outstanding shares of our Series A preferred stock, Series B preferred stock and Series C convertible preferred stock will automatically convert into an aggregate of 6,166,372 shares of our common stock.

INDEMNIFICATION AGREEMENTS WITH DIRECTORS AND EXECUTIVE OFFICERS

We have entered into indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. See Management Limitations of liability and indemnification of officers and directors.

CONSULTING SERVICES

In 2002, while he was one of our directors, Dr. Page provided us with consulting services relating to our research and development programs. We paid Dr. Page approximately $124,000 for his services. We did not enter into a written agreement with Dr. Page regarding his consulting services.

In 2004, we engaged one of our directors, Llew Keltner, to provide consulting services to our management in connection with our efforts to seek potential partners in the development and commercialization of our Technosphere Insulin System. As of March 31, 2004, we have paid Dr. Keltner approximately $36,900 for consulting services rendered.

OTHER TRANSACTIONS

In connection with certain meetings of our board of directors and on other occasions when our business necessitated air travel for Mr. Mann and other MannKind employees, we utilized Mr. Mann s private aircraft and we paid the charter company that manages the aircraft on behalf of Mr. Mann approximately $441,000 in 2002 and approximately $321,278 in 2003.

From January 2002 to October 2003, we leased property located in Sylmar, California from Sylmar Biomedical Park LLC, a company owned by Mr. Mann. Under the lease, we paid Sylmar Biomedical Park approximately $39,081 and $19,709 during the years ended December 31, 2002 and 2003, respectively.

On December 11, 2001, Mr. Mann entered into a put agreement with Mr. Simard whereby Mr. Simard had the right to require Mr. Mann to purchase 119,145 shares of our common stock held by Mr. Simard for a fixed price of approximately $2,948,830, or $24.75 per share. In February 2002 Mr. Simard exercised a portion of the put for approximately $1,921,000, or 77,611 shares, which Mr. Mann paid to Mr. Simard in

cash. Mr. Simard resigned in September 2002 and, pursuant to a post-employment agreement that was formalized and executed in January 2003, we assumed

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Certain relationships and related party transactions

Mr. Mann s remaining obligation under the put agreement of approximately $1,028,000. In January 2003, Mr. Simard exercised the remaining 41,534 shares covered by the put agreement and we paid Mr. Simard approximately $1,028,000 in cash. In January 2003, in connection with our assumption of the remaining obligations under the put agreement, Mr. Mann agreed to purchase 41,534 shares of common stock for an aggregate price of approximately $623,000. This price corresponded to the estimated fair value per share of our common stock at the time we entered into the agreement with Mr. Mann, which had declined below the exercise price of the put. We recorded approximately $405,000 as a stock-based compensation expense representing the intrinsic value of the 41,534 shares of common stock subject to the put agreement at the time that we assumed the obligations thereunder.

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Principal stockholders

The following table sets forth information regarding beneficial ownership of our capital stock as of May 31, 2004, as adjusted to reflect the sale of shares of our common stock in this offering, by the following:

- each person, or group of affiliated persons, known by us to be the beneficial owner of more than five percent of any class of our voting securities;
- each of our directors;
- each of the named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and is generally based on voting or investment power with respect to securities. Under SEC rules, in computing the number of shares beneficially owned and the percentage ownership, options and warrants to purchase shares of our capital stock that are exercisable within 60 days of May 31, 2004 are deemed to be beneficially owned by the persons holding these options or warrants for the purpose of determining beneficial ownership and computing percentage ownership of that person but are not treated as outstanding for the purpose of computing any other person s ownership percentage.

All information in this table relating to the number and percent of shares for the period before the offering is based on a total of 19,975,089 shares of common stock outstanding on May 31, 2004, 4,930,341 shares of our common stock issuable upon conversion of all outstanding shares of our preferred stock, at the conversion prices then in effect, and shares beneficially owned pursuant to options and warrants. All information in this table relating to the number and percent of shares for the period after the offering is based on a total of 19,975,089 shares of common stock outstanding on May 31, 2004, 5,500,000 shares of common stock offered hereby, 6,166,372 shares of common stock issuable upon conversion of all outstanding shares of preferred stock, at the conversion prices in effect on the date of the offering resulting from an assumed initial public offering price of $14.00 per share, and shares beneficially owned pursuant to options and warrants. Except as indicated in the footnotes below, we believe, based on information furnished to us and subject to applicable community property laws, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. The information below also does not reflect any potential participation in our directed share program by such persons

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Principal stockholders

or their affiliates. Unless otherwise indicated, the address for each of the stockholders in the table below is MannKind Corporation, 28903 North Avenue Paine, Valencia, California 91355.

	Number of shares beneficially owned		Percent of shares beneficially owned	
Beneficial owner	**Before offering**	**After offering**	**Before offering**	**After offering**
Named executive officers and directors:				
Alfred E. Mann(1)	15,512,007(2)	15,996,612(3)	62.0%	50.4%
Hakan S. Edstrom			*	*
Richard L. Anderson			*	*
Dan R. Burns			*	*
David Thomson(4)	9,095	9,095	*	*
Kathleen Connell			*	*
Ronald Consiglio			*	*
Michael Friedman			*	*
Llew Keltner			*	*
Kent Kresa	20,000	20,000	*	*
David H. MacCallum	6,666	6,666	*	*
All directors and current executive officers as a group (12 persons)(5)	15,547,768	16,032,373	62.1%	50.5%
Solomon S. Steiner(6)	583,574	583,574	2.3%	1.8%
Michael G. Page(7)	88,004	88,004	*	*
Five percent stockholders:				
Biomed Partners, LLC(8)	2,420,496	2,420,496	9.7%	7.6%
Biomed Partners II, LLC(8)	2,406,027	2,406,027	9.7%	7.6%

* Represents beneficial ownership of less than one percent.

(1) Includes 7,824,173 shares held by the Alfred E. Mann Living Trust, 10,968 shares held by Mannco LLC, 120,486 shares issuable to Alfred E. Mann upon the exercise of options vested as of 60 days following May 31, 2004, 2,420,496 shares held by Biomed Partners, LLC and 2,406,027 shares held by Biomed Partners II, LLC. The Alfred E. Mann Living Trust and Minimed Infusion, Inc. are each 0.1% managing members of each of Biomed Partners, LLC and Biomed Partners II, LLC. Alfred Mann has voting and dispositive power over the shares set forth opposite the names of each of these entities.

(2) Includes 2,729,857 shares issuable upon conversion of preferred stock held by the Alfred E. Mann Living Trust.

(3) Includes 3,214,462 shares issuable upon conversion of preferred stock held by the Alfred E. Mann Living Trust.

(4) Includes 9,095 shares issuable to Dr. Thomson upon the exercise of options vested as of 60 days following May 31, 2004.

(5) Our current executive officers include each of the named executive officers and Wayman Wendell Cheatham.

(6) Includes 171,138 shares issuable to Dr. Steiner upon the exercise of options vested as of 60 days following May 31, 2004.

(7) Includes 88,004 shares issuable to Dr. Page upon the exercise of options vested as of 60 days following May 31, 2004.

(8) The Alfred E. Mann Living Trust and Minimed Infusion, Inc. are each 0.1% managing members of each of Biomed Partners, LLC and Biomed Partners II, LLC. Alfred Mann has voting and dispositive power over the shares set forth opposite the names of each of these

entities.

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Description of capital stock

The following description of our capital stock gives effect to a one-for-three reverse stock split of our common stock that we effected on July 22, 2004 and to the amendment and restatement of our certificate of incorporation and bylaws which will occur effective upon the closing of this offering, and the conversion, upon the closing of this offering, of all then outstanding shares of our preferred stock, at an assumed initial public offering price of $14.00 per share, into 6,166,372 shares of our common stock.

Upon completion of this offering, our authorized capital stock will consist 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. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, the DGCL and our restated certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part.

COMMON STOCK

Outstanding shares

As of May 31, 2004, 19,975,089 shares of our common stock were outstanding and held of record by 319 stockholders. In addition, as of May 31, 2004, 2,132,922 shares of our common stock were subject to outstanding options, 175,227 shares of our common stock were subject to outstanding warrants, and options to purchase 3,659,926 shares of our common stock were available for grant under our 2004 equity plan. Upon completion of this offering, there will be 31,641,461 shares of common stock outstanding, assuming no exercise of the underwriter s overallotment option, no exercise of outstanding options to purchase shares of our common stock and no exercise of warrants to purchase shares of common stock.

Voting rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of our stockholders, including the election of our directors. Under our amended and restated certificate of incorporation and bylaws, our stockholders will not have cumulative voting rights. Accordingly, the holders of a majority of our outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. Any action by our common stockholders requires the majority vote of our outstanding shares of common stock.

Dividends

Subject to preferences that may be applicable to any outstanding shares of our preferred stock, holders of our common stock are entitled to receive ratably any dividends our board of directors declares out of funds legally available for that purpose. Dividends on our common stock will be non-cumulative.

Liquidation, dissolution or winding up

If we liquidate, dissolve or wind up, the holders of our common stock are entitled to share ratably in all assets legally available for distribution to our stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of our preferred stock.

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Description of capital stock

Rights and preferences

Our common stock has no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any outstanding shares of our of preferred stock, which we may designate and issue in the future.

PREFERRED STOCK

Our current certificate of incorporation authorizes 5,000,000 shares of preferred stock, including:

267,213 shares designated Series A preferred stock;

192,618 shares designated Series B preferred stock; and

980,393 shares designated Series C preferred stock.

See Note 9 of the notes to our financial statements for a description of our currently outstanding preferred stock. Upon the closing of this offering, all outstanding shares of our Series A preferred stock, Series B preferred stock and Series C preferred stock will be converted into 6,166,372 shares of our common stock, at an assumed initial public offering price of $14.00 per share. Following the conversion, our certificate of incorporation will be amended and restated to delete all references to these shares of preferred stock.

Under our amended and restated certificate of incorporation to be filed upon completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of our undesignated preferred stock in one or more series and to fix or alter the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon any wholly unissued series of preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption and any liquidation preferences, and to establish from time to time the number of shares constituting any such series. The issuance of preferred stock could result in one or more of the following:

decreasing the market price of our common stock;

restricting dividends on our common stock;

diluting the voting power of our common stock;

impairing the liquidation rights of our common stock; or

delaying or preventing a change in control of us.

We currently have no plans to issue any shares of our undesignated preferred stock.

WARRANTS

As of May 31, 2004, warrants to purchase an aggregate of 175,227 shares of our common stock were outstanding, with a weighted average exercise price of $12.54 per share, all of which were exercisable as of that date. On July 22, 2004, certain warrantholders elected to convert their warrants into an aggregate of 22,309 shares of our common stock pursuant to conversion rights held only by these warrantholders. As a result, as of the date hereof, 135,328 shares of our common stock are issuable upon exercise of the remaining warrants, with a weighted average exercise price of $12.54 per share. Each warrant contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event we declare any stock dividends or effect any stock split, reclassification or consolidation of our common stock. The warrants also contain a

provision that provides for an adjustment to the exercise price and number of shares issuable in the event that we issue certain securities for a per share price less than a specified price. We may be in breach of certain notice provisions contained in the outstanding warrants. However, we believe that the impact of any such breach would not be material to our financial condition.

STOCK OPTIONS

As of May 31, 2004, options to purchase an aggregate of 2,132,922 shares of our common stock were outstanding, comprised of:

- options to purchase 126,099 shares of our common stock granted under the 1991 plan, all of which were exercisable as of that date;
- options to purchase 305,430 shares of our common stock granted under the 1999 plan, 304,728 of which were exercisable as of that date;
- options to purchase 14,366 shares of our common stock granted under the AlleCure plan, 10,053 of which were exercisable as of that date;
- options to purchase 105,981 shares of our common stock granted under the CTL plan, 103,583 of which were exercisable as of that date;
- options to purchase 1,340,074 shares of our common stock granted under our 2004 equity plan, 125,301 of which were exercisable as of that date; and
- options to purchase 240,972 shares of our common stock granted outside our equity incentive plans, 120,486 of which were exercisable as of that date.

The options outstanding as of May 31, 2004 had a weighted average exercise price of $10.18 per share of our common stock.

Based on options outstanding as of May 31, 2004, 3,659,926 shares of our common stock are reserved for future issuance under our 2004 equity plan effective as of the completion of this offering. In March 2004, our board of directors adopted, and our stockholders subsequently approved, effective upon completion of this offering, our director plan and purchase plan and an increase in the number of shares available for grant under our 2004 equity plan. See Management Employee benefit plans.

REGISTRATION RIGHTS

Following completion of this offering, under a registration rights agreement and pursuant to outstanding and previously exercised warrants to purchase shares of our common stock, holders of an aggregate of 1,048,343 shares of our common stock or their transferees may be entitled to rights with respect to the registration of these shares under the Securities Act, subject to limitations and restrictions described below.

Demand registration rights

On October 15, 1998, in connection with a loan to CTL, CTL granted registration rights pursuant to a registration rights agreement, or Rights Agreement, to debtholders that subsequently converted their debt into preferred stock. The rights covered shares of common stock of CTL issued or issuable upon conversion of its preferred stock. In connection with the Merger, we issued 267,212 shares of our Series A preferred stock to former holders of CTL preferred stock and we assumed CTL s registration obligations with respect to these shares under the Rights Agreement.

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Under the Rights Agreement, at any time after 180 days following the completion of this offering, the holders of a majority of the shares of our common stock (on an as converted basis) subject to the Rights Agreement may require us, on not more than two occasions, to file a registration statement under the Securities Act covering these shares as long as the aggregate sale price of these shares to the public is at least $5 million, subject to certain limitations. We will also be required to use our best efforts to have the registration statement declared effective. However, if we believe in our reasonable judgment that proceeding with the registration would have a material and adverse impact on any financing, acquisition, reorganization or other material transaction involving us, we may delay filing the registration statement for a period not to exceed 60 days. Also, if the stockholders requesting registration request that the shares be offered for distribution through an underwriting, we may reduce the number of shares of our common stock requested to be registered upon the advice of our underwriters. If shares of our stock requested to be included in a registration must be excluded pursuant to the underwriters advice, we will register a portion of the shares requested to be registered on a pro rata basis upon the holders of our stock requesting registration.

Piggyback registration rights

Subject to certain limitations, our stockholders who have registration rights under the Rights Agreement also have the right to request that their shares covered by the Rights Agreement be included in any registration of our common stock that is initiated either for our own account or for the account of our other securityholders. However, these stockholders have no registration rights with respect to registrations relating solely to our employee benefit plans or registrations on certain registration statement forms. In each case, we are required to give these holders notice of our intent to file a registration statement with the SEC at least 15 days prior to the filing date.

We have also granted registration rights to holders of 22,309 shares of our common stock issued upon conversion of warrants and holders of outstanding warrants to purchase up to 135,328 shares of our common stock. Under the terms of the warrants, in the event we propose to register any shares of our common stock on a registration statement, these warrantholders may have unlimited rights to request that their shares of common stock issued upon exercise of the warrants and any other shares of our common stock held by the warrantholders be included in the registration. However, if we are offering shares for distribution through an underwriting, we may reduce the number of shares of our common stock requested to be registered by the warrantholders upon the advice of our underwriters. If shares of our stock requested to be included in a registration must be excluded pursuant to the underwriters advice, we will register a portion of the shares requested to be registered on a pro rata basis upon the holders of our stock requesting registration.

Additional registration rights

In addition, we are required to use our best efforts to file a registration statement covering our common stock issuable under the 1991 plan within 18 months after we become a publicly reporting company. We intend to register these shares on a registration statement on Form S-8 under the Securities Act following this offering. See Shares eligible for future sale Stock Options and Form S-8 Registration Rights.

Transferability

The registration rights granted under the Rights Agreement are only transferable to a transferee or assignee who, after the transfer, holds at least 6,063 shares of our common stock (on an as converted basis) subject to the Rights Agreement. The registration rights granted under the warrants may be transferred to any transferee of shares of our common stock issued pursuant the warrants.

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Expenses

Generally, we are required to bear all registration, selling and related expenses incurred in connection with the demand and piggyback registrations described above.

ANTI-TAKEOVER EFFECTS OF PROVISIONS OF DELAWARE LAW AND OUR CERTIFICATE OF INCORPORATION AND BYLAWS

We are subject to Section 203 of the DGCL, which regulates acquisitions of some Delaware corporations. In general, Section 203 prohibits, with some exceptions, a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date of the transaction in which the person became an interested stockholder, unless:

- the board of directors of the corporation approved the business combination or the other transaction in which the person became an interested stockholder prior to the date of the business combination or other transaction;
- upon consummation of the transaction that resulted in the person becoming an interested stockholder, the person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers of the corporation and shares issued under employee stock plans under which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date the person became an interested stockholder, the board of directors of the corporation approved the business combination and the stockholders of the corporation authorized the business combination at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding stock of the corporation not owned by the interested stockholder.

Section 203 of the DGCL generally defines a business combination to include any of the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the corporation s assets or outstanding stock involving the interested stockholder;
- in general, any transaction that results in the issuance or transfer by the corporation of any of its stock to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any person who, together with the person s affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock.

Section 203 of the DGCL could depress our stock price and delay, discourage or prohibit transactions not approved in advance by our board of directors, such as takeover attempts that might otherwise involve the payment to our stockholders of a premium over the market price of our common stock.

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Amended and restated certificate of incorporation and bylaw provisions

Our amended and restated certificate of incorporation and amended and restated bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in our control or our management, including, but not limited to the following:

- Our board of directors can issue up to 10,000,000 shares of preferred stock with any rights or preferences, including the right to approve or not approve an acquisition or other change in our control.
- Our restated certificate of incorporation provides that all stockholder actions upon completion of this offering must be effected at a duly called meeting of holders and not by written consent.
- Our amended and restated bylaws provide that special meetings of the stockholders may be called only by the Chairman of our board of directors, by our Chief Executive Officer, by our board of directors upon a resolution adopted by a majority of the total number of authorized directors or, under certain limited circumstances, by the holders of at least 5% of our outstanding voting stock.
- Our amended and restated bylaws provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely notice in writing and also specify requirements as to the form and content of a stockholder s notice. These provisions may delay or preclude stockholders from bringing matters before a meeting of our stockholders or from making nominations for directors at a meeting of stockholders, which could delay or deter takeover attempts or changes in our management.
- Our amended and restated certificate of incorporation provides that, subject to the rights of the holders of any outstanding series of preferred stock, all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum. In addition, our amended and restated certificate of incorporation provides that our board of directors may fix the number of directors by resolution.
- Our amended and restated certificate of incorporation does not provide for cumulative voting for directors. The absence of cumulative voting may make it more difficult for stockholders who own an aggregate of less than a majority of our voting stock to elect any directors to our board of directors.

These and other provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. However, these provisions could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which our stockholders might otherwise receive a premium for their shares over market price of our stock and may limit the ability of stockholders to remove our current management or approve transactions that our stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

LIMITATIONS OF LIABILITY AND INDEMNIFICATION MATTERS

We have adopted provisions in our amended and restated certificate of incorporation that limit the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the DGCL. Delaware law permits corporations to eliminate the

personal liability of their directors for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we must indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under our bylaws covers at least negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our bylaws would permit indemnification.

We have also entered into separate indemnification agreements with our directors and executive officers. These agreements among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by them in any action or proceeding arising out of their services as a director or executive officer or at our request. We believe that these provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws and the indemnification agreements are necessary in order for us to attract and retain qualified persons as directors and executive officers.

TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for our common stock is expected to be Chase Mellon Investor Services. Chase Mellon Investor Services address is 400 South Hope Street, Suite 400, Los Angeles, California 90071.

NASDAQ NATIONAL MARKET LISTING

There is currently no established public trading market for our common stock. Our common stock has been approved for quotation on The Nasdaq National Market under the trading symbol MNKD.

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Shares eligible for future sale

Prior to this offering, no public market existed for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that these sales could occur, could adversely affect prevailing market prices of our common stock.

Based on 19,975,089 shares of our common stock outstanding on May 31, 2004, upon completion of this offering, we will have 31,641,461 shares of common stock outstanding, assuming no exercise of currently outstanding options or warrants or the underwriters over-allotment option and assuming the conversion, upon the closing of this offering, of all shares of preferred stock into common stock. All of the shares sold in this offering, plus any additional shares sold upon exercise of the underwriters over-allotment option, will be freely transferable without restriction under the Securities Act unless they are held by our affiliates, as that term is defined under the Securities Act and the rules and regulations promulgated thereunder. The remaining shares of our common stock held by existing stockholders are restricted securities. Restricted securities may be sold in the public market only if registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which are summarized below, or another exemption.

LOCK-UP AGREEMENTS

We, our executive officers and directors and our existing stockholders holding an aggregate of over 90% of the shares of our capital stock have entered into lock-up agreements with the underwriters. Under these agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of UBS Securities LLC, offer, sell, contract to sell or otherwise dispose of, directly or indirectly, or hedge, our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus. The 180-day lock-up period may be extended for up to 37 additional days under certain circumstances where we announce or pre-announce earnings or material news or a material event within approximately 18 days prior to, or approximately 16 days after, the termination of the 180-day period. Even under those circumstances, however, the lock-up period will not extend if we are actively traded, meaning that we have a public float of at least $150.0 million and average trading volume at least $1.0 million per day. At any time and without public notice, UBS Securities LLC may, in its sole discretion, release all or some of the securities from these lock-up agreements. See Underwriting.

RULE 144

In general, under Rule 144 of the Securities Act as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, a person who has beneficially owned shares of our common stock that are restricted securities for at least one year, including the holding period of any prior owner other than us or one of our affiliates, would be entitled to sell the number of restricted shares within any three-month period that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding, which will equal approximately 316,415 shares immediately after the offering; or
- the average weekly reported trading volume of our common stock on The Nasdaq National Market during the four preceding calendar weeks.

Sales of restricted shares under Rule 144 are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us.

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Shares eligible for future sale

RULE 144(k)

Under Rule 144(k) of the Securities Act as currently in effect, a stockholder who is not one of our affiliates at any time during the 3 months preceding a sale and who has beneficially owned the restricted securities proposed to be sold for at least two years, including the holding period of any prior owner other than us or an affiliate of us, may sell those restricted securities without complying with the manner of sale, notice, public information or volume limitation provisions of Rule 144. However, these manner of sale, notice, public information and volume restrictions always apply to affiliates who sell shares in reliance on Rule 144.

RULE 701

Our directors, officers, other employees and consultants who acquired or will acquire shares of our common stock upon exercise of options granted under our equity incentive plans prior to this offering or who were granted options by AlleCure or CTL and assumed by us in connection with the Merger are entitled to rely on the resale provisions of Rule 701 under the Securities Act. Rule 701, as currently in effect, permits our affiliates and non-affiliates to sell their shares of our common stock issued pursuant to Rule 701 in reliance on Rule 144 beginning 90 days after the effective date of the registration statement of which this prospectus forms a part. Non-affiliates may sell Rule 701 shares without having to comply with the one-year holding period restrictions, subject only to the manner of sale provisions of Rule 144. Affiliates may also sell Rule 701 shares without having to comply with the one-year holding period restrictions, but they must meet the manner of sale, notice, public information and volume limitation provisions of Rule 144. However, substantially all Rule 701 shares of our common stock are subject to lock-up agreements described below and will only become eligible for sale at the expiration of the 180-day lock-up period.

SALE OF RESTRICTED SHARES

Based on the anticipated date of this offering, 26,141,461 shares of our common stock outstanding on a pro forma basis, assuming conversion of our preferred stock prior to consummation of this offering, will become eligible for sale under Rule 144 and Rule 701 without registration approximately as follows:

- approximately 6,877,892 shares of our common stock will be eligible for sale in the public market without restriction;
- approximately 14,799,303 shares of our common stock will be eligible for sale in the public market under Rule 144 or Rule 701, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the volume, manner of sale and other limitations under those rules, approximately 10,722,753 of which are owned or controlled directly or indirectly by Mr. Mann and therefore are subject to the manner of sale, notice, public information and volume limitation provisions described above; and
- the remaining approximately 4,464,266 shares of our common stock will become eligible for sale in the public market from time to time under Rule 144.

The discussion above does not take into consideration the effect of lock-up agreements as described above. Additionally, of the 2,132,922 shares issuable upon exercise of options to purchase our common stock outstanding as of May 31, 2004, approximately 1,387,750 shares will be vested and eligible for sale 180 days after the effective date of this offering under Rule 701.

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REGISTRATION RIGHTS

The holders of 1,048,343 shares of our common stock (after giving effect to the conversion of our Series A preferred stock and the exercise of our outstanding warrants), or their transferees, have the right in specified circumstances to require us to register their shares under the Securities Act for resale beginning 180 days from the effective date of this offering. If those holders with demand registration rights, by exercising these rights, cause a large number of shares to be registered and sold in the public market, such sales could have an adverse effect on the market price for our common stock. In addition, if at any time we are required to include in a registration initiated either for our account or for the account of our other securityholders shares held by these holders upon the exercise of their piggyback registration rights, these sales may have an adverse effect on our ability to raise needed capital. See Description of capital stock Registration rights.

STOCK OPTIONS AND FORM S-8 REGISTRATION STATEMENTS

As of May 31, 2004, options to purchase 126,099 shares of our common stock were outstanding under the 1991 plan, options to purchase 305,430 shares of our common stock were outstanding under the 1999 plan, options to purchase 14,366 shares of our common stock were outstanding under the AlleCure plan, options to purchase 105,981 shares of our common stock were outstanding under the CTL plan, options to purchase 1,340,074 shares of our common stock were outstanding under the 2004 equity plan and options to purchase 240,972 shares of our common stock granted outside of our equity plans were outstanding. We have reserved for issuance, effective as of the closing of this offering, 3,659,926 shares of our common stock for issuance under our 2004 equity plan, and 2,800,000 shares of our common stock for issuance under our directors plan and purchase plan.

We intend to register the shares subject to these plans and the options on a registration statement on Form S-8 under the Securities Act following this offering. Subject to the lock-up agreements, the restrictions imposed under the 1991 plan, the 1999 plan, the AlleCure plan, the CTL plan, the 2004 equity plan and related option agreements, shares of common stock issued under these plans or agreements after the effective date of any registration statement on Form S-8 will be available for sale in the public market without restriction to the extent that they are held by persons who are not our affiliates.

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Underwriting

We are offering the shares of our common stock described in this prospectus through the underwriters named below. UBS Securities LLC, Piper Jaffray & Co., Wachovia Capital Markets, LLC, Jefferies & Company, Inc. and Harris Nesbitt Corp. are the representatives of the underwriters. UBS Securities LLC is the sole book-running manager for this offering. We have entered into an agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, each of the underwriters has severally agreed to purchase the number of shares of common stock listed next to its name in the following table:

Underwriters	Number of shares
UBS Securities LLC	
Piper Jaffray & Co.	
Wachovia Capital Markets, LLC	
Jefferies & Company, Inc.	
Harris Nesbitt Corp.	
Total	5,500,000

The underwriting agreement provides that the underwriters must buy all of the shares if they buy any of them. However, the underwriters are not required to take or pay for the shares covered by the underwriters over-allotment option described below.

Our common stock is offered subject to a number of conditions, including:

- receipt and acceptance of our common stock by the underwriters; and
- the underwriters right to reject orders in whole or in part.

We have been advised by the representatives that the underwriters intend to make a market in our common stock but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with this offering certain of the underwriters or securities dealers may distribute prospectus electronically.

Sales of shares made outside the United States may be made by affiliates of the underwriters.

OVER-ALLOTMENT OPTION

We have granted the underwriters an option to buy 825,000 additional shares of our common stock. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with this offering. The underwriters have 30 days from the date of this prospectus to exercise this option. If the underwriters exercise this option they will each purchase additional shares approximately in proportion to the amounts specified in the table above.

COMMISSIONS AND DISCOUNTS

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. Any of these securities dealers may resell any shares purchased from the underwriters to other brokers or dealers at a discount of up to $ per share from the initial public offering price. If all the shares are not sold

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at the initial public offering price, the representatives may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares at the prices and upon the terms stated therein and, as a result, will thereafter bear any risk associated with changing the offering price to the public or other selling terms. The underwriters have informed us that they do not expect discretionary sales to exceed 5% of the shares of common stock to be offered.

The following table shows the per share and total underwriting discounts and commissions we will pay to the underwriters assuming both no exercise and full exercise of the underwriters option to purchase up to 825,000 additional shares.

	No exercise	Full exercise
Per share	$	$
Total	$	$

We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately $1,800,000.

NO SALES OF SIMILAR SECURITIES

We, our executive officers and directors and our existing stockholders holding an aggregate of over 90% of the shares of our capital stock have entered into lock-up agreements with the underwriters. Under these agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of UBS Securities LLC, offer, sell, contract to sell or otherwise dispose of, directly or indirectly, or hedge, our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus. The 180-day lock-up period may be extended for up to 37 additional days under certain circumstances where we announce or pre-announce earnings or material news or a material event within approximately 18 days prior to, or approximately 16 days after, the termination of the 180-day period. Even under those circumstances, however, the lock-up period will not extend if we are actively traded, meaning that we have a public float of at least $150.0 million and average trading volume at least $1.0 million per day. At any time and without public notice, UBS Securities LLC may, in its sole discretion, release all or some of the securities from these lock-up agreements.

INDEMNIFICATION

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

NASDAQ NATIONAL MARKET QUOTATION

Our common stock has been approved for quotation on The Nasdaq National Market under the trading symbol MNKD.

PRICE STABILIZATION, SHORT POSITIONS, PASSIVE MARKET MAKING

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock, including:

stabilizing transactions;

short sales;

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purchases to cover positions created by short sales;

imposition of penalty bids;

syndicate covering transactions; and

passive market making.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress. These transactions may also include short sales of our common stock, which involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering and purchasing shares of common stock in the open market to cover positions created by short sales. Short sales may be covered short sales, which are short positions in an amount not greater than the underwriters over-allotment option referred to above, or may be naked short sales, which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

As a result of these activities, the price of the common stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. The underwriters may carry out these transactions on The Nasdaq National Market, in the over-the-counter market or otherwise.

DETERMINATION OF OFFERING PRICE

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiation by us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

the information set forth in this prospectus and otherwise available to the representatives;

the history of, and the prospects for, the industries in which we compete;

our past and present financial performance and an assessment of our management;

our prospects for future earnings and the present state of our development;

the general condition of the securities markets at the time of this offering;

the recent market prices of, and the demand for, publicly traded common stock of generally comparable companies; and

other factors deemed relevant by the underwriters and us.

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DIRECTED SHARE PROGRAM

At our request, certain of the underwriters have reserved up to 30% of the common stock being offered by this prospectus for sale at the initial public offering price to our directors, officers, employees and other individuals associated with us and members of their families. The sales will be made by UBS Financial Services Inc., a selected dealer affiliated with UBS Securities LLC, through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares available to the general public. Certain employees and other persons purchasing these reserved shares will be prohibited from disposing of or hedging the shares for a period of at least 180 days after the date of this prospectus.

AFFILIATIONS

Certain of the underwriters and their affiliates have provided in the past and may provide from time to time certain commercial banking, financial advisory, investment banking and other services for us for which they will be entitled to receive separate fees. The underwriters may, from time to time, engage in transactions with us and perform services for us in the ordinary course of their business.

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Legal matters

The validity of our shares of common stock being offered by this prospectus and certain other legal matters will be passed upon for us by Cooley Godward LLP, San Diego, California. Dewey Ballantine LLP, East Palo Alto, California, is counsel for the underwriters in connection with this offering.

Experts

The financial statements included in this prospectus, and the financial statements from which the Selected financial data included in this prospectus have been derived, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements and Selected financial data have been included herein in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Where you can find additional information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all of the information in the registration statement, including the exhibits and schedules filed with the registration statement. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. For further information about us and our common stock, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed as an exhibit to the registration statement of which this prospectus forms a part. You may obtain copies of any materials we file with the SEC at the SEC s Public Reference Room at 450 Fifth Street, N.W., Washington, DC 20549, at prescribed rates. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy and information statements and other information about issuers that file electronically with the SEC. The address of that website is http://www.sec.gov.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended. Under the Exchange Act, we will file annual, quarterly and current reports, as well as proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC s Public Reference Room and the website of the SEC referred to above.

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MannKind Corporation and Subsidiary (A Development Stage Company)

INDEX TO FINANCIAL STATEMENTS

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MannKind Corporation and Subsidiary (A Development Stage Company)

Report of Independent Registered Public Accounting Firm

Board of Directors

MannKind Corporation
Valencia, California

We have audited the accompanying consolidated balance sheets of MannKind Corporation and subsidiaries (a development stage company) (the Company) as of December 31, 2002 and 2003 and the related statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2003 and for the period from February 14, 1991 (date of inception) to December 31, 2003. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of MannKind Corporation and subsidiaries at December 31, 2002 and 2003 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 and for the period from February 14, 1991 (date of inception) to December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

Los Angeles, California

April 29, 2004

(July 22, 2004 as to the fifth paragraph of Note 1)

DELOITTE & TOUCHE LLP

Los Angeles, California

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MannKind Corporation and Subsidiary (A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,		March 31,	Pro forma Stockholders Equity at March 31,
	2002	2003	2004	2004
			(unaudited)	(unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 19,917	$ 54,120	$ 56,111	
Marketable securities	11,135	1,825	3,194	
Prepaid expenses and other current assets	949	1,859	1,917	
Total current assets	32,001	57,804	61,222	
Property and equipment net	72,675	67,323	66,881	
Restricted cash		559	559	
Other assets	97	190	104	
Total	$ 104,773	$ 125,876	$ 128,766	
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	$ 4,209	$ 1,926	$ 2,329	
Accrued expenses and other current liabilities	1,757	4,015	4,947	
Payable to stockholder		1,406		
Deferred compensation current	1,864	1,360	1,360	
Total current liabilities	7,830	8,707	8,636	
Deferred compensation		284	284	
Other liabilities	207	120	163	
Total liabilities	8,037	9,111	9,083	
Commitments and contingencies				
Series A redeemable convertible preferred stock, $0.01 par value 267,213 shares authorized; 267,212, issued and outstanding at December 31, 2002 and 2003 and March 31, 2004 (unaudited), respectively; aggregate liquidation value, $5,188 as of December 31, 2003 and $5,252 as of March 31, 2004 (unaudited)	4,935	5,188	5,252	
Common stock subject to repurchase	1,028			
Stockholders equity:				
Series B convertible preferred stock, $0.01 par value 192,618 shares authorized, issued and outstanding at December 31, 2002 and 2003 and March 31, 2004 (unaudited), respectively; aggregate liquidation value, $15,000 at December 31, 2003 and March 31, 2004 (unaudited)	15,000	15,000	15,000	
Series C convertible preferred stock issuable		50,000		

Series C convertible preferred stock subscriptions receivable		(18,153)		
Series C convertible preferred stock, $.01 par value 980,393 shares authorized; 980,392 shares issued and outstanding at March 31, 2004 (unaudited), aggregate liquidation value of $50,000 at March 31, 2004 (unaudited)			50,000	
Common stock, $0.01 par value 100,000,000 shares authorized; 16,463,904, 19,974,727, 19,975,089 and 26,141,461 shares issued and outstanding at December 31, 2002, 2003, March 31, 2004 (unaudited) and March 31, 2004 (pro forma unaudited), respectively	165	200	200	261
Additional paid-in capital	378,010	433,141	434,202	504,393
Notes receivable from stockholders	(1,310)	(1,412)	(1,438)	(1,438)
Notes receivable from officers		(228)	(153)	(153)
Deficit accumulated during the development stage	(301,092)	(366,971)	(383,380)	(383,380)
Total stockholders equity	90,773	111,577	114,431	119,683
Total	$ 104,773	$ 125,876	$ 128,766	$ 128,766

See notes to financial statements.

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year ended December 31,			Cumulative period from February 14, 1991 (date of inception) to December 31,	Three Months Ended March 31,		Cumulative period from February 14, 1991 (date of inception) to March 31,
	2001	2002	2003	2003	2003	2004	2004
					(unaudited)		(unaudited)
Revenue	$ 326	$	$	$ 2,858	$	$	$ 2,858
Operating expenses:							
Research and development	19,763	42,724	45,613	143,647	11,564	12,799	156,446
General and administrative	10,629	13,215	20,699	57,457	8,807	3,769	61,226
In-process research and development costs	19,726			19,726			19,726
Goodwill impairment		151,428		151,428			151,428
Total operating expenses	50,118	207,367	66,312	372,258	20,371	16,568	388,826
Loss from operations	(49,792)	(207,367)	(66,312)	(369,400)	(20,371)	(16,568)	(385,968)
Other income (expense)	288	487	(25)	(2,196)	(51)	54	(2,142)
Interest income	1,261	617	459	4,639	86	105	4,744
Loss before provision for income taxes	(48,243)	(206,263)	(65,878)	(366,957)	(20,336)	(16,409)	(383,366)
Income taxes	(2)	(2)	(1)	(14)			(14)
Net loss	(48,245)	(206,265)	(65,879)	(366,971)	(20,336)	(16,409)	(383,380)
Deemed dividend related to beneficial conversion feature of convertible preferred stock		(1,421)	(1,017)	(2,438)		(612)	(3,050)
Accretion on redeemable preferred stock	(239)	(251)	(253)	(892)	(60)	(64)	(956)
Net loss applicable to common stockholders	$(48,484)	$(207,937)	$(67,149)	$(370,301)	$(20,396)	$(17,085)	$(387,386)
Basic and diluted net loss per share:							
Historical	$ (4.60)	$ (15.43)	$ (3.63)		$ (1.24)	$ (0.86)	
Pro Forma (unaudited)			$ (3.34)			$ (0.71)	
Shares used to compute basic and diluted net loss per share:							
Historical	10,534	13,472	18,488		16,466	19,975	
Pro Forma (unaudited)			20,107			24,218	

See notes to financial statements.

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(in thousands)

	Series B convertible preferred stock		Series C convertible preferred stock		Series C convertible preferred stock issuable	Series C convertible preferred stock subscriptions receivable
	Shares	Amount	Shares	Amount		
BALANCE, FEBRUARY 14, 1991						
Issuance of common stock for cash		$		$	$	$
Net loss						
	—	—	—	—	—	—
BALANCE, FEBRUARY 29, 1992						
Issuance of common stock for cash and services						
Capital contribution						
Net loss						
	—	—	—	—	—	—
BALANCE, FEBRUARY 28, 1993						
Issuance of common stock for cash						
Issuance of stock for notes receivable						
Net loss						
	—	—	—	—	—	—
BALANCE, FEBRUARY 28, 1994						
Issuance of common stock for cash and services						
Collection of stock subscription						
Net loss						
	—	—	—	—	—	—
BALANCE, DECEMBER 31, 1994						
Issuance of common stock for services						
Exercise of stock options						
Stock compensation						
Net loss						
	—	—	—	—	—	—
BALANCE, DECEMBER 31, 1995						
Issuance of common stock for cash and services						
Exercise of stock options						

Stock compensation						
Net loss						
	—	—	—	—	—	—
BALANCE, DECEMBER 31, 1996						
Issuance of common stock for cash and services						
Stock compensation						
Exercise of stock options						
Conversion of notes payable						
Net loss						
	—	—	—	—	—	—
BALANCE, DECEMBER 31, 1997						
Issuance of common stock for cash and services						
Stock compensation						
Exercise of stock options						
Conversion of notes payable						
Net loss						
	—	—	—	—	—	—

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Common stock		Additional paid-in capital	Notes receivable from stockholders	Notes receivable from officers	Deficit accumulated during the development stage	Total
	Shares	Amount					
BALANCE, FEBRUARY 14, 1991							
Issuance of common stock for cash	998	$ 10	$ 890	$	$	$	$ 900
Net loss						(911)	(911)
	—	—	—	—	—	—	—
BALANCE, FEBRUARY 29, 1992	998	10	890			(911)	(11)
Issuance of common stock for cash and services	73	1	887				888
Capital contribution			20				20
Net loss						(1,175)	(1,175)
	—	—	—	—	—	—	—
BALANCE, FEBRUARY 28, 1993	1,071	11	1,797			(2,086)	(278)
Issuance of common stock for cash	11		526				526
Issuance of stock for notes receivable	8		400	(400)			
Net loss						(1,156)	(1,156)
	—	—	—	—	—	—	—
BALANCE, FEBRUARY 28, 1994	1,090	11	2,723	(400)		(3,242)	(908)
Issuance of common stock for cash and services	36		1,805				1,805

Collection of stock subscription				400			400
Net loss						(2,004)	(2,004)
BALANCE, DECEMBER 31, 1994	1,126	11	4,528			(5,246)	(707)
Issuance of common stock for services			8				8
Exercise of stock options	1		22				22
Stock compensation			384				384
Net loss						(2,815)	(2,815)
BALANCE, DECEMBER 31, 1995	1,127	11	4,942			(8,061)	(3,108)
Issuance of common stock for cash and services	1		59				59
Exercise of stock options	3		12				12
Stock compensation			126				126
Net loss						(2,570)	(2,570)
BALANCE, DECEMBER 31, 1996	1,131	11	5,139			(10,631)	(5,481)
Issuance of common stock for cash and services	548	6	190				196
Stock compensation			2				2
Exercise of stock options	27		135				135
Conversion of notes payable	12		60				60
Net loss						(2,280)	(2,280)
BALANCE, DECEMBER 31, 1997	1,718	17	5,526			(12,911)	(7,368)
Issuance of common stock for cash and services	2,253	23	12,703				12,726
Stock compensation			150				150
Exercise of stock options	68	1	24				25
Conversion of notes payable	215	2	1,200				1,202
Net loss						(3,331)	(3,331)

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (continued)
(in thousands)

	Series B convertible preferred stock		Series C convertible preferred stock		Series C convertible preferred stock issuable	Series C convertible preferred stock subscriptions receivable
	Shares	Amount	Shares	Amount		
BALANCE, DECEMBER 31, 1998		$		$	$	$
Issuance of common stock						
Conversion of notes payable						
Net loss						
BALANCE, DECEMBER 31, 1999						
Conversion of notes payable						
Issuance of Series B preferred stock for cash	193	15,000				
Issuance of common stock for cash, services and notes						
Discount on notes below market rate						
Accrued interest on notes						
Purchase of Series A redeemable convertible preferred stock						
Amount in excess of redemption obligation						
Accretion to redemption value on Series A redeemable convertible preferred stock						
Stock-based compensation						
Net loss						
BALANCE, DECEMBER 31, 2000	193	15,000				
Issuance of common stock for cash						
Cash received for common stock to be issued						
Issuance of common stock for services						
Exercise of stock options						
Accrued interest on notes						
Payments on notes receivable						
Accretion to redemption value on Series A redeemable convertible preferred stock						

Stock-based compensation						
Issuance of put option by stockholder						
Record merger of entities						
Net loss						
BALANCE, DECEMBER 31, 2001	193	15,000				
Issuance of common stock for cash						
Issuance of common stock for cash already received						
Issuance of stock award to employee						
Cash received for common stock issuable						
Accrued interest on notes						

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Common stock		Additional paid-in capital	Notes receivable from stockholders	Notes receivable from officers	Deficit accumulated during the development stage	Total
	Shares	Amount					
BALANCE, DECEMBER 31, 1998	4,254	$ 43	$ 19,603	$	$	$ (16,242)	$ 3,404
Issuance of common stock	162	2	532				534
Conversion of notes payable	80	1	994				995
Net loss						(5,679)	(5,679)
BALANCE, DECEMBER 31, 1999	4,496	46	21,129			(21,921)	(746)
Conversion of notes payable	63	1	1,073				1,074
Issuance of Series B preferred stock for cash							15,000
Issuance of common stock for cash, services and notes	4,690	46	33,945	(2,358)			31,633
Discount on notes below market rate				241			241
Accrued interest on notes				(117)			(117)
Purchase of Series A redeemable convertible preferred stock			(993)				(993)
Amount in excess of redemption obligation			999				999
Accretion to redemption value on Series A redeemable			(149)				(149)

convertible preferred stock							
Stock-based compensation			9,609				9,609
Net loss						(24,661)	(24,661)
BALANCE, DECEMBER 31, 2000	9,249	93	65,613	(2,234)		(46,582)	31,890
Issuance of common stock for cash	3,052	30	78,000				78,030
Cash received for common stock to be issued			3,900				3,900
Issuance of common stock for services	3		60				60
Exercise of stock options	1		13				13
Accrued interest on notes				(189)			(189)
Payments on notes receivable				28			28
Accretion to redemption value on Series A redeemable convertible preferred stock			(239)				(239)
Stock-based compensation			1,565				1,565
Issuance of put option by stockholder			(2,949)				(2,949)
Record merger of entities			171,154				171,154
Net loss						(48,245)	(48,245)
BALANCE, DECEMBER 31, 2001	12,305	123	317,117	(2,395)		(94,827)	235,018
Issuance of common stock for cash	3,922	40	58,775				58,815
Issuance of common stock for cash already received	234	2	(2)				
Issuance of stock award to employee	3		84				84
Cash received for common stock issuable			98				98
Accrued interest on notes				(229)			(229)

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (continued)
(in thousands)

	Series B convertible preferred stock		Series C convertible preferred stock		Series C convertible preferred stock issuable	Series C convertible preferred stock subscriptions receivable
	Shares	Amount	Shares	Amount		
Payments on notes receivable		$		$	$	$
Beneficial conversion feature of Series B convertible preferred stock						
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock						
Accretion to redemption value on Series A redeemable convertible preferred stock						
Stock-based compensation						
Put option redemption by stockholder						
Net loss						
BALANCE, DECEMBER 31, 2002	193	15,000				
Issuance of Series C convertible preferred stock subscriptions					50,000	(50,000)
Cash collected on Series C convertible preferred stock subscriptions						31,847
Issuance of common stock for cash						
Non-cash compensation expense of officer resulting from stockholder contribution						
Issuance of common stock for cash already received						
Notes receivable by stockholder issued to officers						
Accrued interest on notes						
Beneficial conversion feature of Series B convertible preferred						

stock						
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock						
Accretion to redemption value on Series A redeemable convertible preferred stock						
Stock-based compensation						
Put shares sold to majority stockholder						
Net loss						
BALANCE, DECEMBER 31, 2003	193	$15,000		$	$50,000	$(18,153)

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Common stock		Additional paid-in capital	Notes receivable from stockholders	Notes receivable from officers	Deficit accumulated during the development stage	Total
	Shares	Amount					
Payments on notes receivable		$	$	$ 1,314	$	$	$ 1,314
Beneficial conversion feature of Series B convertible preferred stock			1,421				1,421
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock			(1,421)				(1,421)
Accretion to redemption value on Series A redeemable convertible preferred stock			(251)				(251)
Stock-based compensation			268				268
Put option redemption by stockholder			1,921				1,921
Net loss						(206,265)	(206,265)
BALANCE, DECEMBER 31, 2002	16,464	165	378,010	(1,310)		(301,092)	90,773
Issuance of Series C convertible preferred stock							

subscriptions							
Cash collected on Series C convertible preferred stock subscriptions							31,847
Issuance of common stock for cash	3,494	35	49,965				50,000
Non-cash compensation expense of officer resulting from stockholder contribution			70				70
Issuance of common stock for cash already received	17						
Notes receivable by stockholder issued to officers			225		(225)		
Accrued interest on notes				(102)	(3)		(105)
Beneficial conversion feature of Series B convertible preferred stock			1,017				1,017
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock			(1,017)				(1,017)
Accretion to redemption value on Series A redeemable convertible preferred stock			(253)				(253)
Stock-based compensation			4,501				4,501
Put shares sold to majority stockholder			623				623
Net loss						(65,879)	(65,879)
BALANCE, DECEMBER 31, 2003	19,975	$200	$433,141	$(1,412)	$(228)	$(366,971)	$ 111,577

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (continued)
(in thousands)

	Series B convertible preferred stock		Series C convertible preferred stock		Series C convertible preferred stock issuable	Series C convertible preferred stock subscriptions receivable
	Shares	Amount	Shares	Amount		
Issuance of Series C convertible preferred stock for cash		$	356	$18,153	$(18,153)	$18,153
Issuance of Series C convertible preferred stock for cash already received			624	31,847	(31,847)	
Exercise of stock options						
Accrued interest on notes						
Repayment of notes receivable by stockholder issued to officers						
Beneficial conversion feature of Series B convertible preferred stock						
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock						
Accretion to redemption value on Series A redeemable convertible preferred stock						
Stock-based compensation						
Net loss						
BALANCE, MARCH 31, 2004 (UNAUDITED)	193	$15,000	980	$50,000	$	$

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Common stock		Additional paid-in capital	Notes receivable from stockholders	Notes receivable from officers	Deficit accumulated during the development stage	Total
	Shares	Amount					
Issuance of Series C convertible preferred stock for cash		$	$	$	$	$	$ 18,153
Issuance of Series C convertible preferred							

stock for cash already received							
Exercise of stock options			5				5
Accrued interest on notes				(26)			(26)
Repayment of notes receivable by stockholder issued to officers			(75)		75		
Beneficial conversion feature of Series B convertible preferred stock			612				612
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock			(612)				(612)
Accretion to redemption value on Series A redeemable convertible preferred stock			(64)				(64)
Stock-based compensation			1,195				1,195
Net loss						(16,409)	(16,409)
BALANCE, MARCH 31, 2004 (UNAUDITED)	19,975	$200	$434,202	$(1,438)	$(153)	$(383,380)	$114,431

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,			Cumulative period from February 14, 1991 (date of inception) to December 31,	Three months ended March 31,		Cumulative period from February 14, 1991 (date of inception) to March 31,
	2001	2002	2003	2003	2003	2004	2004
					(unaudited)		(unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:							
Net loss	$(48,245)	$(206,265)	$(65,879)	$(366,971)	$(20,336)	$(16,409)	$(383,380)
Adjustments to reconcile net loss to net cash used in operating activities:							
Depreciation and amortization	1,350	5,072	7,657	16,067	2,113	1,769	17,836
In-process research and development	19,726			19,726			19,726
Stock-based compensation expense	1,565	352	4,501	16,689	2,984	1,195	17,884
Discount on stockholder notes below market rate				241			241
Non-cash compensation expense of officer resulting from stockholder contribution			70	70	70		70
Stock issued for services	60			747			747
Loss (gain) on sale and abandonment/disposal of property and equipment	(7)	27	2,803	2,823	648	42	2,865
Accrued interest expense on notes payable to stockholders				1,538			1,538
Accrued interest on notes	(189)	(229)	(105)	(640)	(25)	(26)	(666)
Goodwill impairment		151,428		151,428			151,428
(Gain) loss on available-for-sale securities, net		67	76	143	12	25	168
Changes in assets and liabilities:							
Prepaid expenses and other current assets	(266)	1,402	(910)	(1,859)	218	(58)	(1,917)
Restricted cash			(559)	(559)			(559)
Other assets	(227)	254	(93)	(190)	4	86	(104)
Accounts payable	5,034	(1,157)	(2,283)	1,926	(869)	404	2,330
Accrued expenses and other current liabilities	56	387	2,258	4,015	387	932	4,947
Other liabilities	(21)		(87)	120	(32)	42	162
Payment of deferred compensation		(5)	(220)	1,644			1,644
Net cash used in operating activities	(21,164)	(48,667)	(52,771)	(153,042)	(14,826)	(11,998)	(165,040)

CASH FLOWS FROM INVESTING ACTIVITIES:							
Purchase of marketable securities		(71,055)	(50,060)	(121,115)	(13,341)	(1,394)	(122,509)
Sales of marketable securities		59,853	59,294	119,147	20,238		119,147
Purchase of property and equipment	(39,673)	(34,147)	(5,183)	(86,305)	(2,734)	(1,369)	(87,674)
Proceeds from sale of property and equipment	17		75	92	71		92
Net cash (used in) provided by investing activities	(39,656)	(45,349)	4,126	(88,181)	4,234	(2,763)	(90,944)
CASH FLOWS FROM FINANCING ACTIVITIES:							
Cash received for common stock to be issued	3,900			3,900			3,900
Repurchase of common stock			(1,028)	(1,028)	(1,028)		(1,028)
Issuance of common stock for cash	78,043	58,913	50,000	235,840	20,000	5	235,845
Put shares sold to majority stockholder			623	623			623
Borrowings under lines of credit	84			4,220			4,220
Proceeds from notes receivables	28	1,314		1,742			1,742
Principal payments on notes payable	(2,558)	(24)		(1,667)			(1,667)
Payable to stockholder			1,406	1,406		(1,406)	
Issuance of Series B convertible preferred stock for cash				15,000			15,000
Collection of Series C convertible preferred stock subscriptions receivable			31,847	31,847		18,153	50,000
Borrowings on notes payable				3,460			3,460
Net cash provided by financing activities	79,497	60,203	82,848	295,343	18,972	16,752	312,095

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MannKind Corporation and Subsidiary (A Development Stage Company)

STATEMENTS OF CASH FLOWS (continued)
(in thousands)

	Years ended December 31,			Cumulative period from February 14, 1991 (date of inception) to December 31,	Three months ended March 31,		Cumulative period from February 14, 1991 (date of inception) to March 31,
	2001	2002	2003	2003	2003	2004	2004
					(unaudited)		(unaudited)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 18,677	$(33,813)	$34,203	$ 54,120	$ 8,380	$ 1,991	$ 56,111
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	35,053	53,730	19,917		19,917	54,120	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 53,730	$ 19,917	$54,120	$ 54,120	$28,297	$56,111	$ 56,111
SUPPLEMENTAL CASH FLOWS DISCLOSURES:							
Cash paid for income taxes	$ 2	$ 2	$ 1	$ 14	$	$	$ 14
Interest paid in cash	55	16	4	75			75
Accretion on redeemable convertible preferred stock	(239)	(251)	(253)	(892)	(60)	(64)	(956)
Issuance of common stock upon conversion of notes payable				3,331			3,331
Increase in additional paid-in capital resulting from merger	171,154			171,154			171,154
Issuance of common stock for notes receivable				2,758			2,758
Issuance of put option by stockholder	(2,949)			(2,949)			(2,949)
Put option redemption by stockholder		1,921		1,921			1,921
Notes receivable by stockholder issued to officers			225	225	225	(75)	150
Issuance of Series C convertible preferred stock subscriptions			50,000	50,000			50,000
Issuance of Series A redeemable convertible preferred stock				4,296			4,296

See notes to financial statements.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

1. Description of business and basis of presentation

Business MannKind Corporation (the Company) is a biopharmaceutical company focused on the development and commercialization of therapeutic products for diseases such as diabetes, cancer, inflammatory and autoimmune diseases. The Company s 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.

Basis of Presentation The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. Since its inception through March 31, 2004 the Company has reported accumulated net losses of $383,380,000 which include a goodwill impairment charge of $151,428,000 (see Note 2), and negative cash flow from operations of $165,040,000. It is costly to develop therapeutic products and conduct clinical trials for these products. Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations through the third quarter of 2004. Management plans to raise additional funds through the issuance of equity securities in an initial public offering of its common stock. Management believes the Company s existing capital resources together with proceeds anticipated from the initial public offering will enable it to continue planned operations into the second quarter of 2005. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. If planned operating results are not achieved or the Company is not successful in raising additional equity financing, management believes that planned expenditures could be reduced substantially; extending the time period over which the Company s currently available capital resources will be adequate to fund the Company s operations.

On December 12, 2001, the stockholders of AlleCure Corp. (AlleCure) and CTL ImmunoTherapies Corp. (CTL) voted to exchange their shares for shares of Pharmaceutical Discovery Corporation (PDC). Upon approval of the merger, PDC then changed its name to MannKind Corporation. PDC was incorporated in the State of Delaware on February 14, 1991. The stockholders of PDC did not vote on the merger. At the date of the merger, Mr. Alfred Mann owned 76% of PDC, 59% of AlleCure and 69% of CTL. Accordingly, only the minority interest of AlleCure and CTL was stepped up to fair value using the purchase method of accounting. As a result of this purchase accounting, in-process research and development of $19,726,000 and goodwill of $151,428,000 were recorded at the entity level. The historical basis of PDC and the historical basis relating to the ownership interests of Alfred Mann in AlleCure and CTL have been reflected in the financial statements. For periods prior to December 12, 2001, the results of operations have been presented on a combined basis. All references in the accompanying financial statements and notes to the financial statements to number of shares, sales price and per share amounts of the Company s capital stock have been retroactively restated to reflect the share exchange ratios for each of the entities that participated in the merger.

For periods subsequent to December 12, 2001, the accompanying financial statements have been presented on a consolidated basis and include the wholly-owned subsidiaries, AlleCure and CTL. On December 31, 2002, AlleCure and CTL merged with and into MannKind and ceased to be separate entities.

Reverse Stock Split On May 27, 2004, the Company s board of directors approved a one-for-three reverse stock split which was effected on July 22, 2004.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

All common share and per common share amounts in the consolidated financial statements have been 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.

2. Summary of significant accounting policies

Unaudited Interim Financial Statements The consolidated financial statements as of March 31, 2004 and for the three months ended March 31, 2003 and 2004, and the cumulative period from February 14, 1991 (date of inception) to March 31, 2004, are unaudited. In the opinion of management, the unaudited financial statements have been prepared on the same basis as the annual financial statements and include all adjustments necessary for a fair presentation of the financial statements. Results of interim periods are not necessarily indicative of the results to be expected for the entire fiscal year.

Reclassifications Certain reclassifications have been made to the prior years financial statements to conform to the 2003 presentation.

Unaudited Pro Forma Stockholders Equity and Net Loss Per Share The unaudited pro forma stockholders equity at March 31, 2004 reflects the conversion, upon closing of an initial offering of the Company s common stock, 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, each outstanding as of March 31, 2004, at an assumed initial public offering price of $14.00 per shares, into 6,166,372 shares of common stock.

The Company s Series A, B and C preferred stock automatically convert, based on the criteria described in Note 9, into common stock upon the closing of an initial public offering of the Company s common stock. The unaudited pro forma net loss per share for the year ended December 31, 2003 and the three months ended March 31, 2004 is computed using the weighted average number of common shares outstanding during the respective periods, including the pro forma effects of the assumed 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 proposed 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 effective issuance date of the

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

Series C preferred stock. The following table summarizes the components of the unaudited pro forma net loss per share:

	Year ended December 31, 2003	Three months ended March 31, 2004
		(unaudited)
Net loss	$(65,879,000)	$(16,409,000)
Deemed dividend related to beneficial conversion features of convertible preferred stock	(1,017,000)	(612,000)
Accretion to preferred stockholders	(253,000)	(64,000)
Net loss attributable to common stockholders	$(67,149,000)	$(17,085,000)
Weighted average shares used in computing basic and diluted net loss per share	18,487,521	19,974,812
Adjusted to reflect the effect of the assumed conversion of convertible preferred stock	1,619,076	4,243,506
Weighted average shares used in computing pro forma basic and diluted net loss per share	20,106,597	24,218,318
Pro forma basic and diluted net loss per share attributable to common stockholders	$ (3.34)	$ (0.71)

Financial Statement Estimates 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 amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents The Company considers all highly liquid investments with a purchased maturity date of 90 days or less to be cash equivalents.

Concentration of Credit Risk Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and marketable securities. Cash and cash equivalents consist primarily of interest-bearing accounts and are regularly monitored by management and held in high credit quality institutions.

Marketable Securities The Company accounts for marketable securities as available for sale, in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Debt and Equity Securities*. Unrealized holding gains and losses for available-for-sale securities are reported as a separate component of stockholders equity until realized.

Deferred Offering Costs In connection with its proposed initial public offering, the Company has $464,216 and $645,794 of deferred offering costs included in prepaid expenses and other current assets in the accompanying balance sheet at December 31, 2003 and March 31, 2004.

Fair Value of Financial Instruments The carrying amounts of financial instruments, which include cash equivalents, marketable securities, accounts payable, accrued expenses and other current liabilities and payable to stockholder, approximate their fair values due to their relatively short maturities. The carrying amounts of the notes receivable from stockholders and officers reflect market rates of interest for similar loans of similar amounts and terms available from a third party (see Notes 6 and 7).

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

Goodwill and Identifiable Intangibles As of December 31, 2001, the Company s balance sheet included goodwill of $151,428,000, which resulted from the merger with AlleCure and CTL on December 12, 2001, as described in Note 1. Upon adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*, on January 1, 2002, the Company, under the initial transitional test, determined there was no impairment of goodwill, principally because as of the date of the transitional impairment test management believed the basis to initially record the goodwill remained appropriate and did not indicate the goodwill was impaired. In connection with the implementation of SFAS No. 142, the Company adopted a policy of testing goodwill and intangible assets with indefinite lives for impairment at least annually, as of December 31, with any related impairment losses being recognized in earnings when identified. Toward the end of the third quarter of 2002, the Company initiated an internal study to assess whether the product development programs acquired in the merger with AlleCure and CTL were meeting their objectives. As a result of the internal study, the Company s management concluded in December 2002 that the major AlleCure product development program should be terminated and that the clinical trials of the CTL product should be halted and returned to the research stage. As a result of this determination, during the first quarter of 2003, the Company closed the CTL facility and reduced headcount for AlleCure and CTL by approximately 50%. In connection with the annual test for impairment of goodwill as of December 31, 2002, the Company determined that on the basis of the internal study the goodwill recorded for the AlleCure and CTL units was potentially impaired. The Company performed the second step of the annual impairment test as of December 31, 2002 for each of the potentially impaired reporting units and estimated the fair value of the AlleCure and CTL programs using the expected present value of future cash flows which were expected to be negligible. Accordingly, the goodwill balance of $151,428,000 was determined to be fully impaired and an impairment loss was recorded in the fourth quarter of 2002.

Property and Equipment Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the term of the lease or the service lives of the improvements, whichever is shorter. Assets under construction are not depreciated until placed into service.

Impairment of Long-Lived Assets The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If the estimated future cash flows from the use of an asset are less than the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. For the year ended December 31, 2003, the Company recorded a write-down of long-lived assets of approximately $2,154,000.

Income Taxes Deferred income tax assets and liabilities are recorded for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized.

Stock-Based Compensation At December 31, 2003 and March 31, 2004 the Company has three stock-based compensation plans, which are described more fully in Note 10. The Company accounts for employee stock options using the intrinsic value method in accordance with Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and its interpretations, and has adopted the disclosure-only alternative of SFAS No. 123, *Accounting for Stock-Based Compensation*. Stock options issued to consultants are accounted for in accordance with the provisions of Emerging Issues Task Force Issue (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling,*

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

Goods or Services, and FASB Interpretation No. 28 (FIN 28), *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*.

Under SFAS No. 123 the Company estimates the fair value of each stock option at the grant date or modification date, if any, by using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year ended December 31,			Three months ended March 31,	
	2001	2002	2003	2003	2004
				(unaudited)	
Risk-free interest rate	4.94%	3.53%	2.90%	2.71%	2.28%
Expected lives	8 years	8 years	4 years	8 years	4 years
Volatility	100%	100%	100%	100%	100%

The weighted-average expected lives for the year ended December 31, 2003 decreased to approximately 4 years from 8 years for each of the years ended December 31, 2001 and 2002 primarily because options granted during 2003 under the re-pricing program described in Note 10 have a 4-year term.

Had compensation cost been determined under the accounting provisions of SFAS No. 123, the Company s net loss would have been adjusted to the pro forma amounts indicated below (in thousands):

	Year ended December 31,			Three months ended March 31,	
	2001	2002	2003	2003	2004
				(unaudited)	
Net loss as reported	$(48,245)	$(206,265)	$(65,879)	$(20,336)	$(16,409)
Add: Stock-based employee compensation expense included in reported net loss	1,565	352	4,501	2,984	1,195
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards	(3,943)	(5,724)	(6,863)	(7,685)	(2,150)
Net loss pro forma	(50,623)	(211,637)	(68,241)	(25,037)	(17,364)
Deemed dividend related to beneficial conversion features of convertible preferred stock		(1,421)	(1,017)		(612)
Accretion on redeemable preferred stock	(239)	(251)	(253)	(60)	(64)
Net loss applicable to common stockholders pro forma	$(50,862)	$(213,309)	$(69,511)	$(25,097)	$(18,040)
Basic and diluted loss attributable to common stockholders per share, as reported	$ (4.60)	$ (15.43)	$ (3.63)	$ (1.24)	$ (0.86)

Basic and diluted loss attributable to common stockholders per share, pro forma	$ (4.83)	$ (15.83)	$ (3.76)	$ (1.52)	$ (0.90)

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

Research and Development Research and development expenses consist primarily of costs associated with the clinical trials of the Company s product candidates, manufacturing supplies and other development materials, compensation and other expenses for research and development personnel, costs for consultants and related contract research, facility costs and depreciation. Expenditures relating to research and development are expensed as incurred.

Net Loss Per Share Of Common Stock Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive.

Potentially dilutive securities outstanding are summarized as follows:

	December 31,			March 31,	
	2001	2002	2003	2003	2004
				(unaudited)	
Series A redeemable convertible preferred stock on an as converted basis	890,706	890,706	890,706	890,706	890,706
Series B convertible preferred stock on an as converted basis	642,060	702,867	746,408	702,867	772,623
Series C convertible preferred stock on an as converted basis					3,267,954
Stock warrants	282,108	289,401	174,917	170,983	175,227
Common stock options	775,268	1,904,603	2,099,824	2,145,561	2,149,953

Segment Information Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating entirely in the United States of America.

Exit or Disposal Activities SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities is effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. FAS No. 146 addresses financial accounting and reporting for the costs associated with exit or disposal activities and EITF Issue No. 94-3 Liability Recognition for Certain Employee Termination Benefits and Costs to Exit and Disposal Activity (Including Certain Costs Incurred in a Restructuring) . SFAS No. 146 requires that a liability for costs associated with an exit or disposal activity be recognized when the liability is incurred and establishes that fair value is the objective for initial measurements of the liability.

Included in general and administrative expense for the year ended December 31, 2003 are approximately $2,163,000 of costs related to the consolidation of the Company s separate California facilities into the Company s Valencia facility. The $2,163,000 consists of $1,077,000 in severance costs, $438,000 in office closure costs and $648,000 related to the abandonment of fixed assets. Payments of $1,406,000 have been made as of December 31, 2003. The remaining liability of $109,000 is included in accrued expenses and other current liabilities at December 31, 2003.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

Recently Issued Accounting Standards In January 2003, the Financial Accounting Standards Board (FASB) issued Financial Interpretation Number 46, *Consolidation of Variable Interest Entities* (FIN 46) with the objective of improving financial reporting by companies involved with variable interest entities. FIN 46 clarifies the application of Accounting Research Bulletin No. 51 to certain entities, defined as variable interest entities, in which equity investors do not have characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated support from other parties. In December 2003, the FASB issued a revision to FIN 46 (FIN 46R) to clarify some of the provisions of FIN 46. The Company currently has no entities which have the characteristics of a variable interest equity. Furthermore, the Company s adoption of the remaining provisions of FIN 46R in the quarter ended March 31, 2004 did not have an impact on the Company s financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatory redeemable financial instruments of nonpublic companies, which is effective for fiscal periods beginning after December 31, 2004. Adoption of this statement did not have a material impact on the Company s financial statements.

3. Investment in securities

The following is a summary of the available-for-sale securities classified as current assets (in thousands).

	December 31, 2002		December 31, 2003		March 31, 2004	
	Cost basis	Fair value	Cost basis	Fair value	Cost basis	Fair value
					(unaudited)	
US government securities	$ 9,336	$ 9,336	$ 518	$ 518	$1,937	$1,937
Corporate debt instruments	1,799	1,799	1,307	1,307	1,257	1,257
	$11,135	$11,135	$1,825	$1,825	$3,194	$3,194

The maturity dates for debt securities at December 31, 2002 and 2003, and March 31, 2004, is less than one year. Proceeds from the sale and maturities of available-for-sale securities amounted to approximately $59,853,000, $59,294,000 and zero for the years ended December 31, 2002 and 2003, and for the three months ended March 31, 2004, respectively. Gross realized losses for available-for-sale securities were approximately $(67,000), $(76,000) and zero for the year ended December 31, 2002 and 2003, and for the three months ended March 31, 2004, respectively. Gross realized gains for available-for-sale securities were insignificant for the years ended December 31, 2002 and 2003, and for the three months ended March 31, 2004. Gross realized gains and losses for available-for-sale securities are recorded as other income (expense). Unrealized gains and losses for available-for-sale securities for all periods presented were not material.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

4. Property and equipment

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

	Estimated useful life	December 31, 2002	December 31, 2003	March 31, 2004
	(years)			(unaudited)
Land		$ 5,273	$ 5,273	$ 5,273
Buildings	39	9,566	9,566	9,566
Building improvements	5 39	29,089	36,296	36,637
Machinery and equipment	3 10	17,304	16,530	17,615
Furniture, fixtures and office equipment	7 10	3,101	2,234	1,874
Computer equipment and software	3 5	2,181	3,048	3,092
Leasehold improvements		1,816	627	627
Construction in progress		4,630	789	989
Deposits on equipment		8,125	5,656	5,656
		81,085	80,019	81,329
Less accumulated depreciation and amortization		(8,410)	(12,696)	(14,448)
Property and equipment net		$72,675	$ 67,323	$ 66,881

Depreciation and amortization expense for the years ended December 31, 2001, 2002, 2003, three months ended March 31, 2003 and 2004, and the cumulative period from February 14, 1991 (date of inception) to March 31, 2004 was $1,350,000, $5,072,000, $7,657,000, $2,113,000, $1,769,000 and $17,836,000, respectively.

5. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities are comprised of the following (in thousands):

	December 31, 2002	December 31, 2003	March 31, 2004
			(unaudited)
Salary and related expenses	$ 846	$2,004	$2,403
Research and clinical trial costs	417	1,224	2,098
Other	494	787	446
Accrued expenses and other current liabilities	$1,757	$4,015	$4,947

6. Notes receivable from stockholders

During the year ended December 31, 2000, the Company issued an aggregate of 238,000 shares of common stock to an executive of CTL and a consultant of CTL in exchange for full recourse notes receivable of $1,179,000 each, for an aggregate amount of $2,358,000. The notes bear interest at fixed rates and are payable in five years. The notes are prepayable at the option of the note holder. The notes are collateralized by the underlying common stock. The note holders have no further obligation

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

to provide services to the Company under the terms of the stock purchases. The notes bear fixed rates of interest that were less than market rates of interest available for similar loans of similar amounts and terms from a third party; consequently, the Company recognized compensation expense equal to the discount on the notes based on market rates of interest and the terms of the notes. The total discount on the notes of $241,000 was expensed to general and administrative expense during the year ended December 31, 2000 as the note holders had no further obligation to the Company. During the year ended December 31, 2002, the executive of CTL paid his $1,179,000 note in full along with $135,000 of accrued interest.

Notes receivable reflected in stockholders equity consist of the following:

	December 31,		March 31,
	2002	2003	2004
			(unaudited)
Principal	$1,179,000	$1,179,000	$1,179,000
Accrued interest	131,000	233,000	259,000
Total	$1,310,000	$1,412,000	$1,438,000

In December 2001, the Company s majority stockholder entered into an agreement (the Put agreement) with the executive of CTL that permits the executive to require the majority stockholder to purchase approximately 119,000 shares from the executive with the note receivable for a fixed price of approximately $2,949,000, or $24.75 per share. In accordance with SEC Staff Accounting Bulletin Topic 5.T, *Accounting for Expenses or Liabilities Paid by Principal Stockholder*, the Company recorded the Put obligation of the majority stockholder as common stock subject to repurchase and as a decrease in additional paid-in capital. In February 2002 the executive exercised a portion of the Put for approximately $1,921,000 (77,667 shares), which was paid in cash by the majority stockholder. The Company reflected the partial redemption of the Put by the majority stockholder as a decrease in common stock subject to repurchase and an increase in additional paid-in capital. The executive resigned in September 2002 and, pursuant to a post-employment agreement that was formalized and executed in January 2003, the Company modified the terms of options to purchase 30,317 shares of common stock held by the former executive (see Note 12 Severance agreements) and assumed the majority stockholder s remaining Put obligation of approximately $1,028,000. The remaining $1,028,000 of the Put (41,333 shares) was exercised in December 2002 and paid in cash by the Company in January 2003. During the year ended December 31, 2002, the estimated fair value per share of the Company s common stock declined below the exercise price of the Put. As a result, during the year ended December 31, 2002 the Company recorded $405,000 of stock-based compensation expense, which was the difference between the amount paid to the former executive and the amount received from the majority stockholder and represented the intrinsic value of the 41,333 shares subject to the Put. In December 2003, the majority stockholder purchased the 41,333 shares for an aggregate price of approximately $623,000.

The Company issued 110,000 shares of common stock to an executive of AlleCure in exchange for notes receivable, in the amounts of $1,214,000 during the year ended December 31, 2000 and $750,000 during the year ended December 31, 2001. The notes bear interest at fixed rates and are payable in five years. The notes are pre-payable at the option of the note holder. The notes are collateralized by the underlying common stock. The note holder has no further obligation to the Company under the terms of the stock purchase. During the first quarter of 2003, the executive was terminated by the Company (See Note 12 Severance agreements). The note-for-stock transactions are

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being accounted for as in-substance stock option grants to an employee. The in-substance stock option grants had no intrinsic value as of the transaction dates. The pre-payment feature of the notes results in the exercise price of the in-substance stock option being unknown until the notes are paid in full. Accordingly, the Company is required to measure the intrinsic value of the in-substance stock options on the balance sheet date of each financial reporting period. During 2001, the Company recorded approximately $815,000 of stock-based compensation expense, which is included in general and administrative expense, relating to the in-substance stock options. This amount was reversed in 2002 because the in-substance stock options had no intrinsic value as of December 31, 2002. There was no stock-based compensation expense recorded for the in-substance options in 2003 because they had no intrinsic value as of December 31, 2003.

During the year ended December 31, 2000 and during the year ended December 31, 2001, the Company issued an aggregate 701,333 shares of common stock to various consultants in exchange for notes receivable aggregating approximately $10,923,000. The notes bear interest at fixed rates and are payable in five years. The notes are pre-payable at the option of the note holders. The notes are collateralized by the underlying common stock. The note holders have no further obligation to the Company under the terms of the stock purchases. The note-for-stock transactions are being accounted for as in-substance stock option grants to non-employees. Since the in-substance stock options were 100% vested and nonforfeitable upon issuance, a measurement date is deemed to have occurred on the issuance date. Accordingly, the Company recorded stock-based compensation expense equal to the estimated fair value of the in-substance options of $8,372,000 in 2000 and $15,000 in 2001. These amounts, which are included in research and development expense in the accompanying statements of operations, were estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: volatility of 100%, term of five years, interest rate of 5.06%.

7. Notes receivable from officers

In March 2003, a limited liability company controlled by the Company s majority stockholder loaned the aggregate principal sum of $225,000 to two officers pursuant to promissory notes and purchased the principal residence owned by one officer as part of his relocation to California. In accordance with SEC Staff Accounting Bulletin Topic 5.T, *Accounting for Expenses or Liabilities Paid by Principal Stockholder*, the Company recorded the loans from the majority stockholder as an increase in additional paid-in capital and as a note receivable, which is classified within stockholders equity. In addition, $70,000 was recorded as compensation expense with a corresponding credit to additional paid-in capital representing the amount of the residential purchase price paid to one officer that exceeded the appraised value. This $70,000 is included in general and administrative expenses on the Company s statement of operations for the year ended December 31, 2003. The notes bear fixed rates of interest that were less than market rates of interest available for similar loans of similar amounts and terms from a third party. Consequently, the Company also recognized a non-cash compensation expense equal to the discount on the notes. The total discount on the notes of approximately $14,000 was amortized to compensation expense over the term of the note. The notes are secured by the officers title and interest in future bonus payments, if any, from the Company. As of March 31, 2004, the amount owed to the lender pursuant to the notes receivable was $153,000, including accrued interest. As of April 15, 2004, both notes had been fully repaid.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

8. Deferred compensation

Certain stockholders and officers elected to defer part or all of their compensation from 1991 through 1998 due to cash flow difficulties in those years. The amounts due for deferred compensation are non interest-bearing with no repayment terms.

Deferred compensation consists of the following (in thousands):

	December 31,		March 31,
	2002	2003	2004
			(unaudited)
Deferred compensation to stockholders and officers	$1,864	$1,644	$1,644
Less non-current portion		(284)	(284)
Deferred compensation current	$1,864	$1,360	$1,360

In February 2003, pursuant to a settlement agreement with one of the officers, the Company agreed to pay the deferred compensation amount outstanding to the former officer in the amount of approximately $775,000 in three payments. As of December 31, 2003 the Company has paid approximately $220,000 of this amount. An additional $271,000 is due in April 2004 and the remaining $284,000 is due in April 2005. The settlement also obligated the Company to make certain severance related payments which are more fully described in Note 12 Severance agreements.

9. Common and preferred stock

Common Stock The Company is authorized to issue 100,000,000 shares of common stock. As of March 31, 2004, 19,975,089 shares of common stock are issued and outstanding.

The Company had reserved shares of common stock for issuance as follows:

	December 31, 2003	March 31, 2004
		(unaudited)
Common stock options	2,099,825	2,149,953
Conversion of Series A preferred stock	890,706	890,706
Conversion of Series B preferred stock	746,408	772,622
Conversion of Series C preferred stock		3,267,954
Exercise of warrants	174,917	175,227
	3,911,856	7,256,462

Preferred Stock The Company is authorized to issue 5,000,000 shares of preferred stock.

Liquidation Preferences of Preferred Stock In the event of liquidation, dissolution or winding-up of the Company, the Series C convertible preferred stockholders shall be entitled to receive in preference to the common stockholders, Series A redeemable convertible preferred

stockholders and the Series B convertible preferred stockholders, a per share amount equal to $51.00 plus all declared and unpaid dividends. After such distributions have been made, the Series A redeemable convertible preferred stockholders and the Series B convertible preferred stockholders shall be entitled to receive on an equal basis, in the case of the Series A redeemable convertible preferred stockholders, a per share amount equal to $16.22, plus all accrued and unpaid dividends (whether or not declared) and, in the case of

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the Series B convertible preferred stockholders, a per share amount equal to $77.88, plus all declared and unpaid dividends. After such distributions have been made, the Series C convertible preferred stockholders and the common stockholders shall be entitled to receive on a pro rata basis a distribution per share equivalent to that made to the Series A redeemable convertible preferred stockholders. After such distributions have been made, any remaining assets of the Company will be distributed pro rata among the Series A redeemable convertible preferred stockholders, Series C convertible preferred stockholders and the common stockholders based on the number of common shares held by each, assuming conversion of all convertible preferred stock at the then applicable conversion rate.

Series A Redeemable Convertible Preferred Stock As of December 31, 2003, the Company had outstanding 267,212 shares of 5.12% cumulative dividend Series A redeemable convertible preferred stock. The rights, preferences and privileges of the holders of Series A redeemable convertible preferred stock are as follows:

Each share of Series A redeemable convertible preferred stock is convertible into approximately 3.3 shares of common stock (subject to adjustment in the event of the issuance of common stock below a price per share of $4.86 and subject to proportionate adjustment for stock dividends, stock subdivisions, stock redivisions, reverse stock splits and stock consolidations). Shares will automatically be converted in the event of a public offering of common stock in which the aggregate net proceeds equal or exceed $20 million, the price paid in such offering reflects a pre-offering valuation of at least $30 million and the common stock is approved for quotation on the Nasdaq National Market or certain other stock exchanges. The Series A convertible preferred stock offering was determined not to contain a beneficial conversion feature on the offering commitment date. However, if the conversion price is adjusted downward at a future date a beneficial conversion charge would be recorded by the Company as a reduction in retained earnings or, in the absence of retained earnings, additional paid-in capital, and an increase in additional paid-in capital. In the period of the charge, if any, net income applicable to common stockholders and net income per share would be reduced.

At any time following September 30, 2002, within 30 days of a written request by a Series A redeemable convertible preferred stockholder, the Company shall redeem for cash a sum equal to the redemption value of $16.22 per share, together with all unpaid cumulative dividends. The cumulative dividends for Series A redeemable convertible preferred stock are accrued annually so that the carrying value will equal the redemption amount on September 30, 2002 and thereafter. In addition, differences between the redemption amount and the net proceeds received (i.e., the costs of financing) were accreted through September 30, 2002.

Each share of Series A redeemable convertible preferred stock has the same voting rights as the common stock into which it is convertible.

Dividends may be declared at the discretion of the board of directors and are cumulative. Per annum dividends of $0.83 per share of Series A redeemable convertible preferred stock must be declared and paid before any dividends on common stock may be declared or paid.

Series B Convertible Preferred Stock As of December 31, 2003, the Company had outstanding 192,618 shares of Series B convertible preferred stock. The rights, preferences and privileges of the holders of Series B convertible preferred stock are as follows:

Each share of Series B convertible preferred stock was initially convertible into approximately 3.3 shares of common stock, adjusted for dilution as defined. The holders of the Series B

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convertible preferred stock will be entitled to a weighted-average antidilution adjustment to the conversion price in the event that the Company issues equity securities for an effective purchase price of less than $23.37 per share (on an as-if-converted-to-common stock basis) in an equity financing. The conversion price will also be subject to proportionate adjustment for stock subdivisions, stock combinations and stock dividends. Shares will automatically be converted on the date of an underwritten public offering in which the gross proceeds are at least $15 million. The Series B convertible preferred stock offering was determined not to contain a beneficial conversion feature on the offering commitment date. However, during the years ended December 31, 2002 and 2003 and the three months ended March 31, 2004, the conversion price was adjusted downward to $21.33 per share as of December 12, 2002, $20.10 per share as of approximately December 31, 2003, and $19.41 per share as of approximately March 31, 2004 resulting in a beneficial conversion charge to common stockholders of approximately $1,421,000, $1,017,000, and $612,000, respectively. These charges have been reflected by the Company as both a reduction and increase in additional paid-in capital during the respective periods. Although the charges have no net effect on stockholders equity, they increase the net loss applicable to the common stockholders and net loss per share. If the conversion price is adjusted downward at a future date a beneficial conversion charge would be recorded by the Company as a reduction in retained earnings or, in the absence of retained earnings, additional paid-in capital, and an increase in additional paid-in capital. In the period of the charge, if any, net income applicable to common stockholders and net income per share would be reduced.

Each share of Series B convertible preferred stock has the same voting rights as the common stock into which it is convertible.

Dividends may be declared at the discretion of the board of directors. Dividends are not cumulative but must be simultaneously declared and paid with dividends declared and paid on common stock.

Series C Convertible Preferred Stock In December 2003, the Company issued stock subscriptions receivable in the aggregate amount of $50,000,000 for 980,392 shares of Series C convertible preferred stock. All of the 980,392 shares of Series C convertible preferred stock were issued in the first quarter of 2004. Approximately $31,847,000 of the $50,000,000 in stock subscriptions were collected in December 2003. The remaining stock subscription receivable of approximately $18,153,000 as of December 31, 2003 was collected during the first quarter of 2004. The rights, preferences and privileges of the holders of Series C convertible preferred stock are as follows:

Each share of Series C is convertible into approximately 3.3 shares of common stock, adjusted for dilution as defined. Shares will automatically be converted on the date of an underwritten public offering of common stock in which the Company receives gross proceeds of $60 million or upon the affirmative election of the holders of a majority of the outstanding shares of the Series C convertible preferred stock. The holders of the Series C convertible preferred stock will be entitled to a weighted-average antidilution adjustment to the conversion price in the event that the Company issues equity securities for an effective purchase price of less than $15.30 per share (on an as-if-converted-to-common stock basis) in an equity financing. In addition, if, on or before May 1, 2005, the Company issues equity securities in one or more financings and the consideration to the Company in such financings, in the aggregate, is $60,000,000 or greater, then the conversion price of the Series C convertible preferred stock will automatically adjust to an adjusted price equal to 80% of the volume weighted-average sale price per share of all of the securities issued in such financing(s) (on an as-if-converted-to-common stock basis) if such adjusted

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NOTES TO FINANCIAL STATEMENTS (continued)

price is less than the then-effective conversion price of the Series C convertible preferred stock. The conversion price will also be subject to proportional adjustment for stock splits, stock dividends and the like. The Series C convertible preferred stock was determined not to have any beneficial conversion value upon issuance since the initial effective conversion price of $15.30 per share on an as-if-converted-to-common stock basis was greater than the estimated fair value per share of the common stock into which the Series C convertible preferred stock was convertible offering commitment date. However, if the conversion price is adjusted downward at a future date a beneficial conversion charge would be recorded by the Company as a reduction in retained earnings or, in the absence of retained earnings, additional paid-in capital, and an increase in additional paid in-capital. In the period of the charge, if any, net income applicable common stockholders and net income per share would be reduced.

Each share of Series C has the same voting rights as the common stock into which it is convertible.

Dividends may be declared at the discretion of the board of directors. Dividends are not cumulative but must be simultaneously declared and paid with dividends declared and paid on common stock.

10. Stock option plans

The Company s 2001 Stock Awards Plan (the Plan) provides for the granting of stock options to directors, employees and consultants. The Company has reserved 5,000,000 shares of common stock for issuance under the Plan. During 2002, the Board approved the issuance of 3,333 shares of common stock to an employee. These shares, which were valued at $84,000 and recorded as compensation expense in 2002, reduced the number of shares available for issuance under the Plan. As of December 31, 2003, 1,299,262 options were outstanding under the Plan. As of March 31, 2004, 1,356,043 options were outstanding under the plan. The Company has two other stock award plans: the 1991 Stock Option Plan (the 1991 Plan) and the 1999 Stock Plan (the 1999 Plan). Both of these plans provide for the granting of stock options to directors, employees and consultants. As of both December 31, 2003 and March 31, 2004, 126,500, and 126,099, respectively, options were outstanding under the 1991 Plan and 305,430 options were outstanding under the 1999 Plan. There are no additional shares available for issuance under the 1991 Plan and the 1999 Plan at December 31, 2003 or March 31, 2004.

Prior to the merger of CTL and AlleCure into the Company, CTL had granted options to purchase shares of its common stock under its 2000 Stock Option and Stock Plan (the CTL Plan). Similarly, AlleCure had granted options to purchase shares of its common stock under its 2000 Stock Option and Stock Plan (the AlleCure Plan). Pursuant to the plans of reorganization and agreements of merger between the Company and each of CTL and AlleCure, the Company has assumed the obligation to issue shares of the Company s common stock, at the exchange ratio agreed to in the merger agreement, upon the exercise of options granted under the CTL Plan and the AlleCure Plan. After the merger date, no further options were granted under either the CTL Plan or AlleCure Plan. As of December 31, 2003 there were an aggregate of 127,661 options outstanding under these plans. As of March 31, 2004 there were an aggregate of 121,409 options outstanding under these plans. The assumption of options issued by CTL and AlleCure by the Company in connection with the merger on December 12, 2001 resulted in a new measurement date. On this date, the outstanding options had an intrinsic value of approximately $2,528,000. Approximately $632,000 of the $2,528,000 related to vested options and was therefore recorded immediately as compensation expense. The remaining amount of the $2,528,000 related to unvested options and is being amortized to stock-based

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

compensation expense over the remaining vesting period. During the years ended December 31, 2001, 2002, 2003, the cumulative period from February 14, 1991 (date of inception) to December 31, 2003 and the three months ended March 31, 2004, $632,038, $632,038, $274,532, $1,538,608 and $53,727, respectively, was recognized as stock-based compensation expense related to these options. As of March 31, 2004, assuming no options are cancelled or expired in future periods, the remaining intrinsic value to be amortized is approximately $161,000.

The Company s Board of Directors approved certain option grants outside of the Company s 2001 Stock Awards Plan. During the year ended December 31, 2002, an employee who is also a majority stockholder was granted 240,972 options at an exercise price of $25.23 per share. The options vest annually over four years. These options were outstanding at December 31, 2003 and March 31, 2004 and are included in the tables below.

The following table summarizes information about stock options outstanding:

	Year ended December 31,						Three months ended March 31, 2004	
	2001		2002		2003			
	Options	Weighted average exercise price	Options	Weighted average exercise price	Options	Weighted average exercise price	(unaudited) Options	(unaudited) Weighted average exercise price
Options outstanding at the beginning of the period	632,589	7.23	775,268	10.53	1,904,603	17.52	2,099,825	10.29
Granted	174,172	23.28	1,222,675	22.11	1,664,886	9.36	74,333	8.61
Exercised	(1,549)	8.49	(17,771)	5.49			(526)	7.80
Canceled	(29,944)	15.12	(75,569)	20.58	(1,469,664)	18.57	(23,679)	14.40
Options outstanding at the end of the period	775,268	10.53	1,904,603	17.52	2,099,825	10.29	2,149,953	10.20
Options exercisable at the end of the period	644,899	9.06	636,937	10.08	728,590	9.96	765,464	10.74

The weighted-average exercise prices and weighted-average fair values of options granted are as follows:

	Year ended December 31,						Three months ended March 31, 2004	
	2001		2002		2003			
	Weighted average exercise price	Weighted average fair value	Weighted average exercise price	Weighted average fair value	Weighted average exercise price	Weighted average fair value	(unaudited) Weighted average exercise price	(unaudited) Weighted average fair value
Option Price equal to estimated fair value	23.34	19.14	25.23	21.42				
Option Price greater than estimated fair value	25.23	20.22						
Option Price less than estimated fair value	13.23	20.22	12.75	13.11	9.36	11.55	8.61	11.07

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

The following table summarizes information about stock options outstanding at December 31, 2003:

Grant price range	Options outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Options exercisable	Weighted-average exercise price
$0.33 $7.95	1,636,568	5.66	$7.29	478,792	$5.70
$9.90 $12.75	136,223	3.12	$12.18	120,966	$12.21
$12.99 $15.57	4,744	7.62	$14.64	3,460	$14.40
$21.12 $25.23	322,290	7.41	$24.69	125,372	$23.97
	2,099,825	5.77	$10.29	728,590	$9.96

The following table summarizes information about stock options outstanding at March 31, 2004 (unaudited):

Grant price range	Options outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Options exercisable	Weighted-average exercise price
$0.33 $7.95	1,657,914	5.50	$7.29	478,559	$5.70
$9.18 $12.75	174,351	4.35	$11.49	120,119	$12.21
$12.99 $15.57	4,744	7.37	$14.64	3,460	$14.40
$21.12 $25.23	312,944	7.19	$24.75	163,326	$24.42
	2,149,953	5.66	$10.20	765,464	$10.74

For employee options, the difference between the estimated fair value of the underlying stock and the option exercise price is recognized as compensation expense over the vesting period in accordance with APB Opinion No. 25. For non-employee options, the Company recognizes stock-based compensation expense for the estimated fair value of the options, determined using the Black-Scholes option-pricing model, in accordance with EITF No. 96-18 and FIN 28. During the year ended December 31, 2001, non-employee stock-based compensation expense of approximately $75,000 was recognized for outstanding non-employee options. During the year ended December 31, 2002, previously recorded non-employee stock-based compensation expense of approximately $14,000 was reversed because of a decline in the estimated fair value of the Company s common stock underlying the non-employee options. During the year ended December 31, 2003, non-employee stock based compensation expense of approximately $277,000 was recognized for outstanding non-employee options. During the three months ended March 31, 2004, previously recorded non-employee stock based compensation expense of approximately $1,000 was reversed. As of December 31, 2003, non-employee options to purchase 36,837 shares of the Company s common stock at a weighted-average exercise price of $6.39 per share were outstanding and are reflected in the tables above. The in-substance stock options disclosed in Note 6, which resulted from the issuance of stock to certain individuals, are excluded from the tables above.

In January 2003, pursuant to a post-employment agreement with a former CTL executive, options to purchase 30,317 shares of common stock for $21.12 per share remain fully exercisable through January 2006. The change in option terms resulted in a new measurement date. Since the stock option

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was modified in connection with the former executive s post-employment activities to be provided through September 2003, stock-based compensation expense was recorded in 2003 in the amount of approximately $255,000, which was estimated using the Black-Scholes options pricing model.

In October 2003, pursuant to a settlement agreement with MannKind s former Chief Executive Officer, options to purchase 83,333 shares of common stock were immediately vested and remain fully exercisable through April 2005. The change in option terms resulted in a new measurement date. On the date of the agreement, the outstanding options had an intrinsic value of approximately $153,000 that was recorded immediately as compensation expense.

In November 2003, pursuant to a settlement agreement with a former employee, options to purchase 5,000 shares of common stock were immediately vested and remain fully exercisable through May 2004. The change in option terms resulted in a new measurement date. On the date of the agreement, the outstanding options had an intrinsic value of approximately $25,000 that was recorded immediately as compensation expense.

During the year ended December 31, 2003, the Company extended the exercise period for certain employee options to purchase 174,855 shares of common stock at an exercise price of $6.24 per share. Also, in February 2003, pursuant to a settlement agreement with a former executive, the Company agreed that options to purchase 124,553 shares of common stock would remain exercisable at least until April 2006 (see Note 12). The Company recorded compensation expense of approximately $2,502,000 in the year ended December 31, 2003 associated with all of these options. No additional compensation expense was incurred in the three months ended March 31, 2004.

On October 7, 2003, the Company s board of directors approved a re-pricing program for certain outstanding options to purchase shares of the Company s common stock granted under each of its stock plans. Under the re-pricing program, each holder of outstanding options granted under the stock plans who was an employee of the Company on November 5, 2003 could elect to exchange up to all of their outstanding options with an exercise price greater than $7.95 for re-priced stock options with an exercise price of $7.95 per share and a term of four years. The option re-pricing became effective on November 5, 2003. Vesting restarted immediately with 50% vesting in November 2004 and the remaining 50% vesting monthly until fully vested in November 2005. Employees who voluntarily resign in the 12-month period beginning November 5, 2003 will forfeit their re-priced options. Employees who are involuntarily terminated in the 12-month period beginning November 5, 2003 will vest 50% upon termination. In accordance with the terms of the re-pricing program, on November 5, 2003 the Company canceled 781,572 outstanding stock options with a weighted average exercise price of $19.83 per share and issued, in exchange for the canceled options, 781,572 new options with an exercise price of $7.95 per share. Compensation cost for all options re-priced under the re-pricing program will be re-measured, using the intrinsic value method proscribed by APB No. 25, on a quarterly basis until the options are exercised, canceled or expire. Compensation cost for these options are recognized in accordance with the method prescribed by FIN 28. Since the amount of compensation cost attributable to the re-priced options is dependent on the fair value of the Company s common stock underlying the options on the future re-measurement dates, the amount of stock-based compensation recognized in any given future period cannot be predicted and may have a material impact on the Company s results of operations. For the year ended December 31, 2003, the Company recorded $595,000 in stock-based compensation expense related to the re-pricing program. For the three months ended March 31, 2004, the Company recorded approximately $955,000 in stock based compensation expense relating to the re-pricing program.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

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

	Year ended December 31,			Three months ended March 31,	
	2001	2002	2003	2003	2004
				(unaudited)	
Employee related	$1,445	$366	$4,224	$3,060	$1,196
Consultant related	120	(14)	277	(76)	(1)
Total	$1,565	$352	$4,501	$2,984	$1,195

Total stock-based compensation expense recognized in the accompanying statements of operations is included in the following categories (in thousands):

	Year ended December 31,			Three months ended March 31,	
	2001	2002	2003	2003	2004
				(unaudited)	
Research and development	$ 562	$ 602	$ 961	$ 444	$ 386
General and administrative	1,003	(250)	3,540	$2,540	809
Total	$1,565	$ 352	$4,501	$2,984	$1,195

11. Warrants

Warrants were issued during the years ended December 31, 1995 and 1996 to purchase shares of common stock. As of December 31, 2003 and March 31, 2004, warrants to purchase 175,227 shares of common stock were outstanding and exercisable at a weighted average exercise price of $12.54 per share. The outstanding warrants range in price from $12.53 to $12.70 per share and expire at various dates through 2007. Each warrant contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event the Company declares any stock dividends or effects any stock split, reclassification or consolidation of its common stock. The warrants also contain a provision that provides for an adjustment to the exercise price and the number of shares issuable in the event that the Company issues securities for a per share price less than a specified price. In addition to these provisions, holders of warrants to purchase 39,899 shares of the Company s common stock have rights to convert the warrants into shares of common stock.

On March 30, 2001, CTL issued a warrant to its majority stockholder in conjunction with the purchase of the Company s common stock. Pursuant to the plan of reorganization and agreement of merger between the Company and CTL, the Company assumed an obligation to issue 118,424 shares of its common stock upon the exercise of this warrant. The exercise price of the warrant, as adjusted by the merger, is $21.12 per share of common stock. The warrants remained outstanding as of December 31, 2002 and expired unexercised on March 31, 2003.

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NOTES TO FINANCIAL STATEMENTS (continued)

12. Commitments and contingencies

Operating Leases The Company leases certain facilities and equipment under various operating leases, which expire at various dates through December 31, 2005. Future minimum rental payments, required under operating leases, are as follows at December 31, 2003 (in thousands):

Year ending December 31,	
2004	$596
2005	61
2006	36
Total minimum lease payments	$693

Rent expense under all operating leases for the years ended December 31, 2001, 2002 and 2003, was approximately $849,000, $851,000 and $1,241,195, respectively.

Capital Leases The Company s capital leases were not material for the years ended December 31, 2001, 2002 and 2003.

Litigation The Company is subject to various claims and legal actions that arise in the ordinary course of business. In the opinion of management, the ultimate resolution of such matters will not have a material adverse impact on the Company s financial position or results of operations.

Guarantees and Indemnifications 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 Company may terminate the indemnification agreements with its officers and directors upon 90 days written notice, but termination will not affect claims for indemnification relating to events occurring prior to the effective date of termination. 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. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2003.

Severance Agreements In February 2003, pursuant to a settlement agreement, the Company is obligated to pay a former executive approximately $1,049,000 over three years, comprised of approximately $775,000 in deferred compensation (see Note 8) from prior years and the remainder comprised of other severance-related items. As of December 31, 2003 the Company has paid approximately $451,000 of this amount. An additional $271,000 is due in April 2004, $43,000 is due in September 2004 and the remaining $284,000 is due in April 2005. The settlement agreement further provides that the options held by the former executive to purchase up to 46,585 shares of the Company s common stock remain fully exercisable through April 2007, and options to purchase up to 124,553 shares of the Company s common stock remain fully exercisable until at least April 2006. The change in option terms resulted in a new measurement date. On the date of the agreement, the outstanding options had an intrinsic value of approximately $1,091,000, which was immediately expensed as part of the $2,502,000 charge more fully described in Note 10.

In February 2003, pursuant to a settlement agreement, the Company became obligated to pay a former employee his base salary at the rate of approximately $22,000 per month through December 2003, and a lump sum payment of $67,000 in February 2005, which is included in accrued expenses in the accompanying balance sheet at December 31, 2003.

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

In October 2003, under the terms of a severance agreement with its former Chief Executive Officer, the Company paid a severance payment of $165,000 and agreed to pay his base salary at the rate of approximately $28,000 per month through April 2005. The agreement also provides for accelerated vesting of an option held by the former executive permitting him to purchase up to 83,333 shares of the Company s common stock until April 7, 2005 (see Note 10).

13. Employee benefit plans

During 1999, CTL established a 401(k) Savings Retirement Plan (the CTL Retirement Plan) for CTL. The CTL Retirement Plan covered substantially all full-time employees who met the CTL Retirement Plan s eligibility requirements and provides for employee elective contributions with a Company-match provision. For the year ended December 31, 2001, the Company contributed $60,000 to the CTL Retirement Plan.

During 2000, AlleCure established a 401(k) Savings Retirement Plan (the AlleCure Retirement Plan) for AlleCure. The AlleCure Retirement Plan covered substantially all full-time employees who met the AlleCure Retirement Plan s eligibility requirements and provided for employee elective contributions with a Company-match provision. For the year ended December 31, 2001, the Company contributed $29,000 to the AlleCure Retirement Plan.

During the year ended December 31, 2002, PDC established a 401(k) Savings Retirement Plan (the PDC Retirement Plan) for PDC. Immediately after its establishment, the PDC Retirement Plan, CTL Retirement Plan and AlleCure Retirement Plan were converted to the 401(k) Savings Retirement Plan (the MannKind Retirement Plan) for the Company. For the years ended December 31, 2003 and 2002 and three months ended March 31, 2004, the Company contributed $235,000, $224,000, and $62,000, respectively, to the MannKind Retirement Plan.

14. Income taxes

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. A valuation allowance is established when uncertainty exists as to whether all or a portion of the net deferred tax assets will be realized. Components of the net deferred tax asset as of December 31, 2002 and 2003, are approximately as follows (in thousands):

	2002	2003
Deferred Tax Assets:		
Net operating loss carryforwards	$ 44,962	$ 66,921
Research and development credits	3,357	3,494
Accrued expenses	2,066	7,592
Start-up costs deduction	12	
Non-qualified stock option expense	532	2,442
Depreciation	(232)	(416)
Total gross deferred tax assets	50,697	80,033
Valuation allowance	(50,697)	(80,033)
Net deferred tax assets	$	$

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

The Company s effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2002 and 2003:

	December 31,	
	2002	2003
Federal tax benefit rate	34.0%	34.0%
State tax benefit, net of federal benefit		
Permanent items	(24.9)	(0.1)
Other		1.6
Valuation allowance	(9.1)	(35.5)
Effective income tax rate	0.0%	0.0%

As required by SFAS No. 109, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, the deferred tax assets have been fully reserved. Management reevaluates the positive and negative evidence on an annual basis. During the years ended December 31, 2002 and 2003, the change in the valuation allowance was $24,216,000 and $29,336,000, respectively, for income taxes.

At December 31, 2003, the Company had federal and state net operating loss carryforwards of approximately $172,507,000 and $97,008,000 available, respectively, to reduce future taxable income and which will expire at various dates beginning in 2013 through 2023. At December 31, 2003, the Company had research and development credits of $3,494,000 that expire at various dates through 2017. Ownership changes, as defined in the Internal Revenue Code, including those resulting from the issuance of common stock in connection with the Company s planned initial public offering, may limit the amount of net operating loss and tax credit carryforwards that can be utilized to offset future taxable income or tax liability. The amount of the limitation is determined in accordance with Section 382 of the Internal Revenue Code. Approximately $16,579,000 of the federal and state net operating loss carryforwards is estimated to be limited under Internal Revenue Code Section 382.

15. Related party transactions

The Company issued 1,773,234 shares of its common stock to related parties during the year ended December 31, 2002 for proceeds of approximately $27,450,000. The Company issued 3,016,834 shares of its common stock to its majority stockholder during the year ended December 31, 2001 for proceeds of approximately $76,000,000. In connection with certain of these issuances, the board of directors approved the issuance of a warrant to purchase 118,424 shares of the Company s common stock at $21.12 per share, which expired unexercised on March 31, 2003.

During the years ended December 31, 2001, 2002 and 2003, the Company paid $426,000, $406,000, and $497,000, respectively, to certain universities to conduct sponsored research programs, including clinical research. Certain stockholders of the Company are employees of these universities and oversee the sponsored research programs.

One stockholder was paid $242,000 and $48,000 for consulting services during the years ended December 31, 2002 and 2001, respectively.

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NOTES TO FINANCIAL STATEMENTS (continued)

In December 2001, the Company s majority stockholder entered into an agreement with an executive of CTL that permitted the executive to require the majority stockholder to purchase shares of the Company s stock held by the executive, for a fixed price of approximately $2,949,000 (see Note 6).

From September 2001 to December 2002, the Company leased property located in Sylmar, California from Sylmar Biomedical Park LLC, a company controlled by the Company s majority stockholder. During the years ended December 31, 2002 and 2003 and for the period from February 14, 1991 (date of inception) to December 31, 2003, approximately $39,000, $20,000 and $59,000, respectively, was expensed to general and administrative in the accompanying statements of operations in connection with the property leased from Sylmar Biomedical Park LLC.

During the year ended December 31, 2002, while he was one of the Company s directors, MannKind s former Chief Executive Officer provided the Company with consulting services relating to its research and development programs. The Company paid the executive approximately $124,000 for his services.

In connection with certain meetings of the Company s board of directors and on other occasions when the Company s business necessitated air travel for the Company s majority stockholder and other Company employees, the Company utilized the majority stockholder s private aircraft and the Company paid the charter company that manages the aircraft on behalf of the Company s majority stockholder approximately $441,000 and $321,000, respectively, for the years ended December 31, 2002 and 2003.

In 2004, the Company engaged one of its directors to provide consulting services related to seeking potential partners in the development and commercialization of the Company s technology. As of March 31, 2004, the Company paid approximately $37,000 for consulting services rendered.

The Company has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws (see Note 12 Guarantees and indemnifications).

16. Selected quarterly financial data (unaudited)

	Quarter ended			
	Mar 31	Jun 30	Sep 30	Dec 31
	(in thousands, except per share data)			
2002				
Net loss	$ (9,985)	$(12,262)	$(15,560)	$(168,458)
Net loss attributable to common stockholders	$(10,046)	$(12,913)	$(15,790)	$(169,188)
Basic and diluted net loss per share	$ (0.82)	$ (1.03)	$ (1.10)	$ (11.48)
Weighted average common shares used to compute net loss per share	12,305	12,491	14,324	14,732

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MannKind Corporation and Subsidiary (A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS (continued)

	Mar 31	Jun 30	Sep 30	Dec 31
	(in thousands, except per share data)			
2003				
Net loss	$(20,336)	$(13,109)	$(13,870)	$(18,564)
Net loss attributable to common stockholders	$(20,396)	$(14,046)	$(14,078)	$(18,629)
Basic and diluted net loss per share	$ (1.24)	$ (0.79)	$ (0.71)	$ (0.93)
Weighted average common shares used to compute net loss per share	16,466	17,760	19,697	19,975

	Mar 31
	(in thousands, except per share data)
2004	
Net loss	$(16,409)
Net loss attributable to common stockholders	$(17,085)
Basic and diluted net loss per share	$ (0.86)
Weighted average common shares used to compute net loss per share	19,975

17. Subsequent events

On March 23, 2004, the following actions were approved by the stockholders:

An amendment and restatement of the Company s 2001 Stock Awards Plan as the 2004 Equity Incentive Plan, which would become effective upon the closing of the IPO.

The adoption of the 2004 Employee Stock Purchase Plan, which would become effective upon the closing of the IPO.

The adoption of the 2004 Non-Employee Directors Stock Option Plan, which would become effective upon the closing of the IPO.

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INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other expenses of issuance and distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by the Registrant in connection with the sale of the common stock being registered. All the amounts shown are estimates except for the SEC registration fee, the NASD filing fee and The Nasdaq National Market listing fee.

Description	Amount to be paid
SEC registration fee	$12,021
NASD filing fee	9,988
Nasdaq Stock Market Listing Application fee	125,000
Blue sky qualification fees and expenses	20,000
Printing and engraving expenses	310,000
Legal fees and expenses	775,000
Accounting fees and expenses	535,000
Transfer agent and registrar fees	5,000
Miscellaneous	7,991
Total	$1,825,000

Item 14. Indemnification of directors and officers.

We were incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law, or DGCL, generally provides that a Delaware corporation may indemnify any person who is, or is threatened to be made, a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may also indemnify any person who is, or is threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation s best interests, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful

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on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. The Registrant s amended and restated certificate of incorporation and amended and restated bylaws provide for the indemnification of directors and officers of the Registrant to the fullest extent permitted under the DGCL and other applicable laws.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability:

for any transaction from which the director derives an improper personal benefit;

for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

for improper payment of dividends or redemptions of shares; or

for any breach of a director s duty of loyalty to the corporation or its stockholders.

The Registrant s amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by the Registrant upon delivery to the Registrant of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Registrant.

As permitted by Delaware law, the Registrant has entered into indemnity agreements with each of its directors and executive officers that require the Registrant to indemnify such persons against any and all expenses (including attorneys fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of the Registrant or any of its affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Registrant and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving a director, officer or key employee of the Registrant as to which indemnification is being sought, nor is the Registrant aware of any threatened litigation that may result in claims for indemnification by any officer or director of the Registrant.

The Registrant has an insurance policy covering its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or otherwise.

In connection with this offering, the Registrant entered into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify the Registrant s directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

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Reference is made to the following documents filed as exhibits to this Registration Statement regarding relevant indemnification provisions described above and elsewhere herein:

Exhibit document	Number
Form of Underwriting Agreement	1.1
Amended and Restated Certificate of Incorporation	3.1
Amended and Restated Bylaws	3.3
Form of Indemnity Agreement	10.1

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all securities sold by us since January 2001. All share amounts give effect to the one-for-three reverse stock split of our common stock effected on July 22, 2004.

(1) In June and August 2001 we issued and sold an aggregate of 1,351,909 shares of our common stock to the Alfred E. Mann Living Trust for aggregate consideration of $34 million.

(2) In December 2001, in connection with our acquisition of CTL, we issued 2,504,928 shares of our common stock to former common stockholders of CTL and 267,212 shares of our Series A preferred stock to the Alfred E. Mann Living Trust and McLean Watson Advisory Inc. in exchange for all of the outstanding shares of Series A preferred stock of CTL ImmunoTherapies Corp. Upon the closing of this offering at an assumed initial public offering price of $14.00 per share, these shares of Series A preferred stock will be converted into 890,706 shares of our common stock.

(3) In December 2001, in connection with our acquisition of AlleCure, we issued 3,697,275 shares of our common stock to former common stockholders of AlleCure and 192,618 shares of our Series B preferred stock to the Alfred E. Mann Living Trust in exchange for all of the outstanding shares of Series A preferred stock of AlleCure Corp. Upon the closing of this offering at an assumed initial public offering price of $14.00 per share, these shares of Series B preferred stock will be converted into 811,400 shares of our common stock.

(4) In May 2002 we issued and sold an aggregate of 233,849 shares of our common stock to ten accredited investors for aggregate consideration of $5.9 million.

(5) In June through December 2002 we issued and sold an aggregate of 3,921,767 shares of our common stock to 93 accredited investors for aggregate consideration of $58 million.

(6) In May 2003 we issued and sold an aggregate of 2,838,315 shares of our common stock to Biomed Partners and Biomed Partners II for aggregate consideration of $40 million.

(7) In August 2003 we issued and sold an aggregate of 654,879 shares of our common stock to Biomed Partners and Biomed Partners II for aggregate consideration of $10 million.

(8) In December 2003 we issued 41,534 shares of our common stock to the Alfred E. Mann Living Trust for aggregate consideration of $0.6 million.

(9) In January to March 2004 we issued and sold an aggregate of 980,392 shares of our Series C preferred stock to 38 accredited investors for aggregate consideration of $50 million. Upon the closing of this offering at an assumed initial public offering price of $14.00 per share, these shares will be converted into 4,464,266 shares of our common stock.

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(10) On July 22, 2004, we issued an aggregate of 22,309 shares of our common stock upon the conversion of warrants originally issued in 1996 and held by six warrantholders. We relied upon the exemption contained in Section 3(a)(9) of the Securities Act for this issuance.

(11) Since January 2001, we have granted options under our equity incentive plans to purchase 1,537,210 shares of common stock (net of expirations and cancellations) to employees, directors and consultants, having exercise prices ranging from $7.95 to $25.23 per share. Of these, options to purchase 19,846 shares of common stock have been exercised for aggregate consideration of $115,018, at exercise prices ranging from $4.95 to $21.12 per share.

The offers, sales, and issuances of the securities described in paragraphs (1) through (10) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act and/or Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

The offers, sales and issuances of the securities described in paragraph (11) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit number	Description of document
1.1(a)	Form of Underwriting Agreement.
3.1(a)	Registrant s Restated Certificate of Incorporation, as currently in effect.
3.2(a)	Registrant s Certificate of Designation, Preferences and Rights of Series A Preferred Stock, as currently in effect.
3.3(a)	Registrant s Certificate of Designation, Preferences and Rights of Series B Preferred Stock, as currently in effect.
3.4(a)	Registrant s Certificate of Designation, Preferences and Rights of Series C Preferred Stock, as currently in effect.
3.5(a)	Form of Registrant s Amended and Restated Certificate of Incorporation, to be effective upon completion of the offering.
3.6(a)	Amended and Restated By-Laws, as currently in effect.
3.7(a)	Form of Registrant s Amended and Restated Bylaws, to be effective upon completion of the offering.
4.1(a)	Form of Common Stock Certificate.
4.2(a)	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.
5.1	Opinion of Cooley Godward LLP.

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Exhibit number	Description of document
10.1(a)(b)	Form of Indemnity Agreement entered into between the Registrant and its directors and officers.
10.2(a)(b)	2004 Equity Incentive Plan and Form of Stock Option Agreement thereunder.
10.3(a)	2004 Non-Employee Directors Stock Option Plan and Form of Stock Option Agreement thereunder.
10.4(a)(b)	2004 Employee Stock Purchase Plan and Form of Offering Document thereunder.
10.5(a)(b)	Executive Severance Agreement, dated August 1, 2003, between the Registrant and Wendell Cheatham.
10.6(a)(b)	Executive Severance Agreement, dated August 1, 2003, between the Registrant and Hakan Edstrom.
10.7(a)(b)	Executive Severance Agreement, dated August 1, 2003, between the Registrant and David Thomson.
10.8(a)(b)	Executive Severance Agreement, dated August 1, 2003, between the Registrant and Dick Anderson.
10.9(a)(b)	Executive Severance Agreement, dated August 1, 2003, between the Registrant and Dan Burns.
10.10(a)(b)	Change of Control Agreement, dated August 1, 2003, between the Registrant and Wendell Cheatham.
10.11(a)(b)	Change of Control Agreement, dated August 1, 2003, between the Registrant and Hakan Edstrom.
10.12(a)(b)	Change of Control Agreement, dated August 1, 2003, between the Registrant and David Thomson.
10.13(a)(b)	Change of Control Agreement, dated August 1, 2003, between the Registrant and Dick Anderson.
10.14(a)(b)	Change of Control Agreement, dated August 1, 2003, between the Registrant and Dan Burns.
10.15(c)	Supply Agreement made on January 1, 2000 by and between Diosynth B.V. and Pharmaceutical Discovery Corporation.
10.16(a)	Pharmaceutical Discovery Corporation 1991 Stock Option Plan.
10.17(a)	Pharmaceutical Discovery Corporation 1999 Stock Plan and Form of Stock Option Plan thereunder.
10.18(a)	AlleCure Corp. 2000 Stock Option and Stock Plan.
10.19(a)	CTL Immunotherapies Corp. 2000 Stock Option and Stock Plan.
10.20(a)	2001 Stock Awards Plan.
21.1(a)	Subsidiary of the Registrant.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Accounting Firm.
23.2	Consent of Cooley Godward LLP. Reference is made to Exhibit 5.1.
24.1(a)	Power of Attorney. Reference is made to the signature page.

(a) *Previously filed.*

(b) *Indicates management contract or compensatory plan.*

(c) *Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.*

(b) Financial Statement Schedules.

All schedules are omitted because they are not required, are not applicable or the information is included in the financial statements or notes thereto.

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Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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Signatures

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 4 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Valencia, State of California, on the 26th day of July, 2004.

MANNKIND CORPORATION

By: /s/ ALFRED E. MANN

Alfred E. Mann
Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 4 to Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ALFRED E. MANN Alfred E. Mann	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	July 26, 2004
/s/ HAKAN S. EDSTROM Hakan S. Edstrom	President, Chief Operating Officer and Director	July 26, 2004
/s/ RICHARD L. ANDERSON Richard L. Anderson	Corporate Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	July 26, 2004
* Kathleen Connell, Ph.D.	Director	July 26, 2004
* Ronald Consiglio	Director	July 26, 2004
* Llew Keltner M.D., Ph.D.	Director	July 26, 2004
* Michael Friedman, M.D.	Director	July 26, 2004
* Kent Kresa	Director	July 26, 2004
* David MacCallum	Director	July 26, 2004
*By: /s/ HAKAN S. EDSTROM Hakan S. Edstrom *Attorney-in-fact*		

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10.13(a)(b)	Change of Control Agreement, dated August 1, 2003, between the Registrant and Dick Anderson.
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10.15(c)	Supply Agreement made on January 1, 2000 by and between Diosynth B.V. and Pharmaceutical Discovery Corporation.

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Part II

Exhibit number	Description of document
10.16(a)	Pharmaceutical Discovery Corporation 1991 Stock Option Plan.
10.17(a)	Pharmaceutical Discovery Corporation 1999 Stock Plan and Form of Stock Option Plan thereunder.
10.18(a)	AlleCure Corp. 2000 Stock Option and Stock Plan.
10.19(a)	CTL Immunotherapies Corp. 2000 Stock Option and Stock Plan.
10.20(a)	2001 Stock Awards Plan.
21.1(a)	Subsidiary of the Registrant.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Accounting Firm.
23.2	Consent of Cooley Godward LLP. Reference is made to Exhibit 5.1.
24.1(a)	Power of Attorney. Reference is made to the signature page.

(a) *Previously filed.*

(b) *Indicates management contract or compensatory plan.*

(c) *Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.*