MANNKIND CORP
Form 424B5
November 27, 2006

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The information in this prospectus supplement and the accompanying prospectus is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

This filing is made pursuant to Rule 424(b)(5)
Under the Securities Act of 1933
In connection with Registration No. 333-138373

Subject to Completion,
Preliminary Prospectus Supplement dated November 27, 2006

PROSPECTUS SUPPLEMENT
(To Prospectus dated November 7, 2006)

$100,000,000

MannKind Corporation
% Senior Convertible Notes due 2013

The Offering:

The notes will bear interest at the rate of % per year on the principal amount of the notes, payable in cash semiannually in arrears on June and December of each year, beginning June , 2007. The notes will mature on December , 2013. The notes will be our general, unsecured, senior obligations and will rank equally in right of payment with our other senior unsecured debt and will effectively rank junior in right of payment to all of our secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other liabilities of our subsidiaries.

Convertibility of the Notes:

Holders may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding notes into shares of our common stock. The notes are convertible at a conversion rate of shares per $1,000 principal amount of notes, which is equal to a conversion price of approximately $ per share, subject to adjustment. If a holder elects to convert notes in connection with a fundamental change, such holder will also be entitled to receive a make-whole premium upon conversion in certain circumstances. Our common stock is quoted on the Nasdaq Global Market under the symbol MNKD. On November 24, 2006, the last sale price for our common stock as reported on the Nasdaq Global Market was $17.44 per share.

Purchase of the Notes at the Option of the Holder:

Upon a fundamental change of our company, each holder may require us to purchase all or a portion of such holder s notes at a price equal to the principal plus accrued and unpaid interest, if any.

The underwriters have reserved up to $50,000,000 of the notes in this offering for sale to our chairman, chief executive officer and principal stockholder, Alfred E. Mann. The underwriters will not receive any underwriting discount on the sale of notes sold directly to Mr. Mann. The amount of notes that Mr. Mann will be allocated in this

offering will depend on market conditions, and we cannot provide any assurance as to the exact amount of notes that Mr. Mann will be allocated, if any.

In addition, concurrently with this offering, we are offering 17,500,000 shares (or 20,125,000 shares if the underwriters exercise their over-allotment option in full) of our common stock in a public offering pursuant to a separate prospectus supplement. Although this note offering is not contingent upon the common stock offering and the common stock offering is not contingent upon this note offering, we currently anticipate raising approximately $405,200,000 in aggregate gross proceeds from the two offerings. However, amounts sold in each offering may vary based on market conditions relating to that particular security.

Investing in our notes involves risks, including those described in the Risk Factors section beginning on page S-9 of this prospectus supplement and incorporated by reference in this prospectus supplement and the accompanying prospectus.

	Per Note	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to MannKind, before expenses	$	$

(1) The underwriters will not receive any underwriting discount on the sale of notes to Alfred E. Mann.

We have granted the underwriters a 13-day option to purchase up to an additional $15,000,000 principal amount of notes to cover over-allotments, if any.

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

The notes will be ready for delivery in book entry form only through The Depository Trust Company on or about December , 2006.

Merrill Lynch & Co. **JPMorgan**

The date of this prospectus supplement is December , 2006.

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Prospectus Supplement

Prospectus

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we authorize to be distributed to you. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with

different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus is accurate only as of the date on those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus when making your investment decision. You should also read and consider the information in the documents we have referred you to in the sections of the prospectus entitled Where You Can Find More Information and Incorporation by Reference.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. This prospectus supplement provides you with the specific details regarding this offering, including the principal amount, conversion ratio and ranking of our notes, and the risks of investing in our notes. The accompanying prospectus provides you with more general information, some of which does not apply to the offering of our notes. To the extent information in this prospectus supplement is inconsistent with the accompanying prospectus or any of the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, you should rely on this prospectus supplement. You should read and consider the information in this prospectus supplement, the accompanying prospectus and any free writing prospectus, together with the additional information described under the headings Where You Can Find More Information and Incorporation by Reference in the accompanying prospectus.

This prospectus supplement and the accompanying prospectus have not been approved by the Financial Services Authority. The notes may not be offered or sold to any person in the United Kingdom except where the offer is exempt from the general prohibition against the offer of securities to the public under section 85 of the Financial Services and Markets Act 2000, or FMSA, by virtue of one or more of the criteria set out in section 86 of FMSA.

This prospectus supplement and the accompanying prospectus is directed only at (i) persons outside the United Kingdom, (ii) persons who have professional experience in matters relating to investments and who are investment professionals within the meaning of Article 19(5) of FMSA (Financial Promotion) Order 2005 of the United Kingdom (the Financial Promotion Order), (iii) persons who fall within Article 49(2)(a) through (d) (high net worth companies, unincorporated associations, etc.) of the Financial Promotion Order, or (iv) any other persons to whom this prospectus supplement and the accompanying prospectus for the purposes of Section 21 of FSMA can otherwise lawfully be made (all such persons together being referred to as Relevant Persons), and must not be acted on or relied upon by persons other than Relevant Persons.

Unless the context otherwise requires, references to MannKind or the company, we, us, and our in this prospectu supplement and the accompanying prospectus mean MannKind Corporation and its wholly owned subsidiaries.

Technosphere® and MedTone® are registered trademarks of MannKind Corporation. We have also applied for or registered company trademarks in other jurisdictions, including Europe and Japan. This prospectus supplement also include references to registered service marks and trademarks of other entities.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus, including the documents that we incorporate by reference herein and therein, contain statements that are not strictly historical in nature and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are subject to the safe harbor created by Section 27A of the Securities Act and Section 21E of the Exchange Act and may 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;

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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; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing;

scientific studies and the conclusions we draw from them; and

our ability to successfully enter into strategic business collaborations.

In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, goal, intends, may, plans, potential, predicts, projects, should, will, would, the negativ words or similar expressions intended to identify forward-looking statements. These statements reflect our views as of the date on which they were made with respect to future events and are based on assumptions and subject to risks and uncertainties. The underlying information and expectations are likely to change over time. Given these uncertainties, you should not place undue reliance on these forward-looking statements as actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the heading Risk Factors in this prospectus supplement, in the accompanying prospectus and in our SEC filings. These forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should rely only on the information contained, or incorporated by reference, in this prospectus supplement, the accompanying prospectus, the registration statement of which this prospectus supplement is a part, the documents incorporated by reference herein, and any applicable prospectus supplement and understand that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. Before deciding to purchase our securities, you should carefully consider the risk factors discussed here or incorporated by reference, in addition to the other information set forth in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement. This summary does not contain all the information that you should consider before investing in our notes. You should read the entire prospectus supplement, the accompanying prospectus and any free writing prospectus carefully, including Risk Factors, the financial statements and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus before making an investment decision. This prospectus supplement contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results anticipated in these forward-looking statements as a result of factors described under the Risk Factors section and elsewhere in this prospectus supplement and in the risk factors set forth under Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2005 and each of our Quarterly Reports on Form 10-Q for the periods ended March 31, 2006, June 30, 2006 and September 30, 2006, and elsewhere in the documents incorporated by reference.

MannKind Corporation

Overview

MannKind Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead investigational product candidate, the Technosphere Insulin System, is currently in Phase 3 clinical trials in the United States, Europe and Latin America to study its safety and efficacy in the treatment of diabetes. This therapy consists of a proprietary dry powder formulation of insulin that is inhaled into the deep lung using our proprietary inhaler. We believe that the performance characteristics, unique kinetics, convenience and ease of use of the Technosphere Insulin System may have the potential to change the way diabetes is treated. According to the Centers for Disease Control, diabetes affects approximately 20.8 million patients in the United States. Furthermore, we believe that not one diabetes drug is included among the top 20 best-selling drugs in the United States. We believe there is a large unmet medical need to treat diabetes patients with a convenient and effective insulin regimen.

We believe our Technosphere Insulin System will address some of the shortcomings of traditional insulin therapies. In particular, we have observed in our clinical trials to date that the 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, but which is absent in patients with diabetes. Specifically, Technosphere Insulin is rapidly absorbed into the bloodstream following inhalation, reaching peak levels within 12 to 14 minutes. As a result of this rapid onset of action, most of the glucose-lowering activity of Technosphere Insulin occurs within the first three hours of administration which is generally when glucose becomes available from a meal instead of the much longer duration of action observed when insulin is injected subcutaneously. We believe that the relatively short duration of action of Technosphere Insulin reduces the need for patients to snack between meals in order to manage ongoing blood glucose excursions. Indeed, in our clinical trials, we have observed that patients using Technosphere Insulin have achieved significant reductions in post-meal glucose excursions and significant improvements in overall glucose control, as measured by decreases in glycosylated hemoglobin, or HbA1c, levels, without the weight gain typically associated with insulin therapy.

In our clinical trials to date, we have observed no difference in pulmonary function between patients treated with Technosphere Insulin and patients treated with standard diabetes care. However, the longest study that we have completed so far is a six-month trial. In September 2006, we completed patient enrollment in a pivotal, two-year, Phase 3, safety study of Technosphere Insulin that will compare the pulmonary function of diabetes patients

randomized to either Technosphere Insulin or standard diabetes care. We are continuing to enroll patients in three other major Phase 3 clinical trials, two of which are pivotal efficacy trials. Based on our discussions with the Food and Drug Administration, or FDA, we plan to accumulate two years of controlled safety data before we file a new drug application for the Technosphere Insulin System. We anticipate that our

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entire clinical trial program, including several special population studies, will involve more than 4,500 patients. Larger populations and longer durations of exposure may be necessary depending on the safety profile of our product.

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 also developing additional Technosphere-based products for the delivery of other drugs. In October 2006, we filed an investigational new drug application, or IND, in respect of our cancer immunotherapy program. This IND has received FDA clearance and we plan to initiate Phase 1 clinical trials of a therapeutic cancer vaccine by the end of 2006.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2006, we have incurred a cumulative net loss of $716.6 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities.

We do not anticipate sales of any product prior to regulatory approval and commercialization of our Technosphere Insulin System. We currently do not have the required approvals to market any of our product candidates, and we may not receive any approvals. We may not be profitable even if we succeed in commercializing any of our product candidates. We expect to make substantial and increasing expenditures and to incur additional operating losses for at least the next several years as we:

- continue the clinical development and commercialization of our Technosphere Insulin System for the treatment of diabetes;
- expand our manufacturing operations for our Technosphere Insulin System to meet our currently anticipated commercial production needs;
- expand our other research, discovery and development programs;
- expand our proprietary Technosphere platform technology and develop additional applications for the pulmonary delivery of other drugs; and
- enter into sales and marketing collaborations with other companies, if available on commercially reasonable terms, or develop these capabilities ourselves.

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

Recent Developments

On September 16, 2006, we announced the results of a Phase 3 clinical study of Technosphere Insulin in patients with type 2 diabetes. This study was designed to evaluate whether our Technosphere Insulin System demonstrated similar safety and efficacy compared to patients treated with insulin aspart, an injected rapid-acting insulin analog, or RAA. The study included 308 patients with type 2 diabetes who where randomized to receive either Technosphere Insulin or RAA at meal times, in each case together with insulin glargine, a long-acting insulin, as basal insulin. After six months of treatment, both patient groups achieved statistically significant reductions in HbA1c levels, with the Technosphere Insulin patient group achieving an average 1.05% reduction and the injected RAA patient group achieving an average 1.30% reduction. Significantly fewer patients experienced hypoglycemia in the Technosphere Insulin patient group than in the injected RAA patient group. Additionally, after six months of treatment, the

Technosphere Insulin patient group experienced average weight loss of 1.7 pounds compared with the injected RAA patient group, which experienced average weight gain of 0.5 pounds. Pulmonary function did not differ between the two patient groups after six months of treatment and after a six-month withdrawal period. These results are consistent with our previous studies on Technosphere Insulin that demonstrated improvement in glycemic control with no effect on lung function.

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Company 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. MannKind Corporation and the MannKind Corporation logo are our service marks. 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

The following is a brief summary of the terms of this offering. For a complete description of the terms of the notes, see Description of Notes in this prospectus supplement.

Issuer	MannKind Corporation
Notes to be offered	$100,000,000 aggregate principal amount, or $115,000,000 if the underwriters exercise their option to purchase additional notes in full.
Maturity date	December , 2013.
Interest and payment dates	% per year on the principal amount, payable semiannually in arrears in cash on June and December of each year, beginning June , 2007.
Conversion rights	The notes are convertible, at the option of the holder, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date, into shares of our common stock at a conversion rate of shares per $1,000 principal amount of notes per share, which is equal to a conversion price of approximately $ per share. The conversion rate is subject to adjustment as set forth in Description of Notes Adjustment of Conversion Rate.
Make-whole premium upon a fundamental change	If a fundamental change (as described in this prospectus supplement) occurs, other than a fundamental change described under the third or fourth bullet points under the definition of a change in control described in Description of Notes Repurchase at Option of Holders Upon a Fundamental Change, we will pay a make-whole premium on notes converted in connection with a fundamental change by increasing the conversion rate on such notes. The amount of the make-whole premium, if any, will be based on our common stock price and the effective date of the fundamental change. A description of how the make-whole premium will be determined and a table showing the make-whole premium that would apply at various common stock prices and fundamental change effective dates is set forth under Description of Notes Make-Whole Premium Upon a Fundamental Change.
Repurchase of notes by us at the option of the holders upon a fundamental change	If we undergo a fundamental change, except in certain circumstances, each holder will have the option to require us to repurchase all or any portion of that holder s notes. The fundamental change repurchase price will be 100% of the principal amount of the notes to be repurchased plus accrued and unpaid interest, if any.
Ranking	The notes:

will be our general, unsecured, senior obligations and will rank equally in right of payment with our other unsecured senior debt;

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	will effectively rank junior in right of payment to any of our existing and future secured debt, to the extent of the value of the assets securing such debt; and will effectively rank junior in right of payment to any existing and future debt and other liabilities of our subsidiaries, including trade payables. As of September 30, 2006, after giving effect to this offering of notes and the use of proceeds therefrom, we would have had no outstanding secured debt, and our subsidiaries would have had no outstanding liabilities to which the notes would rank effectively junior. The terms of the supplemental indenture and the indenture under which the notes are issued do not limit our ability to incur additional debt, including secured debt.
Use of proceeds	We intend to use the net proceeds to us from this offering and the concurrent common stock offering to fund the costs of our clinical trials programs and other research and development activities, to expand our manufacturing operations, both on-going and planned, and for general corporate purposes, including working capital and repayment of $70.0 million in principal amount of indebtedness, plus accrued interest, owed to Alfred E. Mann pursuant to an outstanding note. We may also use a portion of the net proceeds to in-license, invest in or acquire businesses or technologies that we believe are complementary to our own, although we have no current plan, commitments or agreements with respect to any acquisitions as of the date of this prospectus supplement. This offering is not contingent on the concurrent common stock offering. See Use of Proceeds.
Form and denomination	The notes will be issued in minimum denominations of $1,000 and any integral multiple of $1,000. The notes will be issued in book-entry form and will be represented by permanent global certificates deposited with, or on behalf of, The Depository Trust Company, or DTC, and registered in the name of a nominee of DTC. Beneficial interests in any of the notes will be shown on, and transfers will be effected only through, records maintained by DTC or its nominee and any such interest may not be exchanged for certificated securities, except in limited circumstances. See Description of Notes Book-Entry System. The notes will not be listed on any securities exchange or included in any automated quotation system. The notes will be new securities for which there is currently no public market.
Nasdaq symbol for common stock	Our common stock is quoted on the Nasdaq Global Market under the symbol MNKD.

Material U.S. federal income tax consequences	The notes and the shares of our common stock issuable upon conversion of the notes will be subject to certain U.S. federal income tax consequences. Holders are encouraged to consult their tax advisors as to the U.S. federal, state, local or other tax consequences of

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	acquiring, owning and disposing of the notes. See Material U.S. Federal Income Tax Consequences.
Risk factors	See Risk Factors and other information included in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in our notes.

Unless otherwise noted, the information in this prospectus supplement assumes that the underwriters over-allotment option will not be exercised.

Sale of Notes in this Offering to Alfred E. Mann

The underwriters have reserved up to $50.0 million of the notes in this offering for sale to our chairman, chief executive officer and principal stockholder, Alfred E. Mann.

Concurrent Common Stock Offering

Concurrently with this offering of notes, we are offering 17,500,000 shares (or 20,125,000 shares if the underwriters exercise their over-allotment option in full) of our common stock to the public at an assumed price of $17.44 per share, based on the closing price of our common stock on the Nasdaq Global Market on November 24, 2006. We refer to that offering herein as the common stock offering. As part of the common stock offering, the underwriters have reserved up to 8,750,000 shares for sale to Alfred E. Mann, at a price equal to the greater of the public offering price in the common stock offering or the market value of our common stock immediately preceding the pricing of the common stock offering as determined by applicable Nasdaq rules.

Note and Concurrent Common Stock Offering

The concurrent common stock offering is being conducted as a separate public offering by means of a separate prospectus supplement. Although this note offering is not contingent upon the common stock offering and the common stock offering is not contingent upon this note offering, we currently anticipate raising approximately $405.2 million in aggregate gross proceeds from the two offerings. However, amounts sold in each offering may vary based on market conditions relating to that particular security.

Unless otherwise noted, for presentation purposes, the information in this prospectus supplement assumes Alfred E. Mann will purchase $50.0 million of the notes offered in this offering and 8,750,000 shares of our common stock in the concurrent common stock offering. The underwriters will not receive any underwriting discount on the sale of notes or common stock to Mr. Mann. The number of shares or amount of notes that Mr. Mann will be allocated in the offerings will depend on market conditions and the number of shares could be more or less than the amount initially reserved for allocation. We cannot provide any assurance as to the exact number of shares of common stock or notes that Mr. Mann will be allocated, if any. Any notes or shares of our common stock not allocated by the underwriters to Mr. Mann in the offerings may be sold by the underwriters to the public on the terms set forth in applicable prospectus supplements.

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risk factors described below and all other information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus before deciding to invest in our securities. If any of the following risks actually occur, they may materially harm our business, financial condition, operating results and cash flow. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

Certain risks related to regulatory approvals

Our product candidates must undergo rigorous preclinical and clinical testing and we must obtain regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any products.

Our research and development activities, as well as the manufacturing and marketing of our product candidates, including our Technosphere Insulin System, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulation of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

product design, development, manufacture and testing;

product labeling;

product storage and shipping;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We expect, based on our discussions with the FDA and on our understanding of the interactions between the FDA and other pharmaceutical companies developing inhaled insulin delivery systems, that we will need safety data covering at least two years from patients treated with our Technosphere Insulin System and that we must complete a two-year carcinogenicity study and an additional six-month carcinogenicity study of Technosphere Insulin in rodents to obtain approval, among other requirements. We cannot be certain when or under what conditions we will undertake further clinical trials. The clinical trials of our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates, including our Technosphere Insulin System. Even if we believe the data collected from our clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with our interpretation of the data. For example, even if we obtain statistically significant results with respect to the primary endpoint in a pivotal clinical study (102) of the

Technosphere Insulin System, the FDA may deem the results uninterpretable because of issues related to the open-label, non-inferiority design of the study. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

The requirements governing the conduct of clinical trials and manufacturing and marketing of our product candidates, including our Technosphere Insulin System, outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes

include all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products for government reimbursement. 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. We are not aware of any precedent for the successful commercialization of products based on our technology. On January 26, 2006, the FDA approved the first inhaled insulin product, Exubera. This may impact the development and registration of our Technosphere Insulin System in many ways, including: the approval of Exubera may increase the difficulty of enrolling patients in our clinical trials; Exubera may be viewed as standard of care by the FDA and used as a reference for the safety/efficacy evaluations of our Technosphere Insulin System; and the approval standards set for Exubera may be applied to other products that follow including our Technosphere Insulin System. The FDA has advised us that it will regulate our Technosphere Insulin System as a combination product because of the complex nature of the system that includes the combination of a new drug (Technosphere Insulin) and a new medical device (the MedTone inhaler used to administer the insulin). The FDA indicated that the review of a future drug marketing application for our Technosphere Insulin System will involve three separate review groups of the FDA: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health within the FDA that reviews medical devices. We currently understand that the Metabolic and Endocrine Drug Products Division will be the lead group and will obtain consulting reviews from the other two FDA groups. The FDA has not made an official final decision in this regard, however, and we can make no assurances at this time about what impact FDA review by multiple groups will have on the review and approval of our product or whether we are correct in our understanding of how the Technosphere Insulin System will be reviewed and approved.

Also, questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by the FDA in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products. FDA review of our Technosphere Insulin System as a combination product therapy may lengthen the product development and regulatory approval process, increase our development costs and delay or prevent the commercialization of our Technosphere Insulin System.

We are developing our Technosphere Insulin System as a new treatment for diabetes utilizing unique, proprietary components. As a combination product, any changes to either the MedTone inhaler, the Technosphere material or the insulin, including new suppliers, could possibly result in FDA requirements to repeat certain clinical studies. This means, for example, that switching to an alternate delivery system could require us to undertake additional clinical trials and other studies, which could significantly delay the development and commercialization of our Technosphere Insulin System. Our product candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.

We currently expect that our inhaler will be reviewed for approval as part of the New Drug Application, or NDA, for our Technosphere Insulin System. No assurances exist that we will not be required to obtain separate device clearances or approval for use of our inhaler with our Technosphere Insulin System. This may result in our being subject to medical device review user fees and to other device requirements to market our inhaler and may result in significant delays in commercialization. Even if the device component is approved as part of our NDA for the Technosphere Insulin System, numerous device regulatory requirements still apply to the device part of the

drug-device combination.

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Risks Related to the Notes and Our Common Stock

The effective subordination of the notes may limit our ability to satisfy our obligations under the notes.

The notes will be our senior unsecured obligations and will rank equally in right of payment with all of our other senior unsecured indebtedness. However, the notes will be effectively subordinated in right of payment to all of our secured indebtedness, including any secured indebtedness we may incur in the future, to the extent of the value of the collateral securing such indebtedness. As of September 30, 2006, we had no outstanding secured indebtedness. The indenture governing the notes does not prohibit us from incurring secured indebtedness in the future. Consequently, in the event of a bankruptcy, liquidation, dissolution, reorganization or similar proceeding with respect to us, the holders of any secured indebtedness will be entitled to proceed directly against the collateral that secures such indebtedness. Therefore, the collateral will not be available for satisfaction of any amounts owed under our unsecured indebtedness, including the notes, until the secured indebtedness is satisfied in full.

The notes also will be effectively subordinated in right of payment to all unsecured and secured liabilities of our subsidiary. In the event of a bankruptcy, liquidation, dissolution, reorganization or similar proceeding with respect to our subsidiary, we, as an equity owner of the subsidiary, and therefore you, as holders of our debt, including the notes, will be subject to the prior claims of the subsidiary s creditors, including trade creditors and preferred equity holders. As of September 30, 2006, our subsidiaries had no indebtedness (exclusive of intercompany debt, trade payables, distribution payables, accrued expenses and other liabilities). The indenture governing the notes does not prohibit our subsidiaries from incurring indebtedness in the future.

We may not have the ability to repurchase notes for cash pursuant to their terms.

In connection with a fundamental change, you may require us to repurchase all or a portion of your notes in cash. If you were to require us to repurchase your notes, we may not be able to pay the amount required in cash. Our ability to repurchase the notes is subject to our liquidity position at the time, and may be limited by law, by the indenture, and by indebtedness and agreements that we may enter into in the future which may replace, supplement or amend our existing or future debt. In addition, if we did not have sufficient cash to meet our obligations, while we could seek to obtain third-party financing to pay for any amounts due in cash upon such events, third-party financing may not be available on commercially reasonable terms, if at all. Our failure to repurchase the notes would constitute an event of default under the indenture under which we issued the notes, which might constitute an event of default under the terms of our other indebtedness at that time.

The notes contain no financial covenants, therefore, the note holders will not have protection against adverse changes in our business.

The indenture does not contain any financial covenants, restrict our ability to repurchase our securities other than the notes in accordance with their terms, pay dividends or make restricted payments or contain any covenants or other provisions to afford holders protection in the event of a transaction that substantially increases the level of our indebtedness. Furthermore, the indenture will contain only limited protections in the event of a change in control. We could also engage in many types of transactions, such as acquisitions, refinancings or recapitalizations, that could substantially affect our capital structure and the value of the notes and our common stock.

Because your right to require us to repurchase the notes is limited, the market price of the notes may decline if we enter into a transaction that is not a fundamental change under the indenture.

The term fundamental change is limited and may not include every event that might cause the market price of the notes to decline. The term fundamental change does not apply to transactions in which 90% of the consideration paid

for our common stock, excluding cash payments for fractional shares and cash payments made in respect of dissenters appraisal rights, in a merger or similar transaction is publicly traded

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common stock. Our obligation to repurchase the notes upon certain fundamental changes may not preserve the value of the notes in the event of a highly leveraged transaction, reorganization, merger or similar transaction. See Description of Notes Repurchase at Option of Holders Upon a Fundamental Change.

The make-whole premium that may be payable upon conversion in connection with certain fundamental changes may not adequately compensate you for the lost option time value of your notes as a result of such change in control.

If you convert notes in connection with certain fundamental changes, we may be required to pay a make-whole premium by increasing the conversion rate. The make-whole payment is described under Description of Notes Make-Whole Premium Upon a Fundamental Change. While the make-whole premium is designed to compensate you for the lost option time value of your notes as a result of certain fundamental changes, the make-whole amount is only an approximation of such lost value and may not adequately compensate you for such loss. In addition, in some other cases described under Description of Notes Make-Whole Premium Upon a Fundamental Change, there will be no such make-whole premium.

Conversion of the notes may dilute the ownership interest of existing stockholders.

The conversion of some or all of the notes may dilute the ownership interests of existing stockholders, including holders who have previously converted their notes. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants, because the conversion of the notes could depress the price of our common stock.

The conversion rate of the notes may not be adjusted for all dilutive events.

The conversion rate of the notes is subject to adjustment for certain events, including, among others, the issuance of stock dividends on our common stock, the issuance of rights or warrants to acquire shares of our common stock or securities convertible into shares of our common stock, subdivisions and combinations of our common stock, dividends of our capital stock, certain cash dividends and certain tender or exchange offers. See Description of Notes Adjustment of Conversion Rate. The conversion rate will not be adjusted for other events, such as an issuance of shares of common stock for cash, that may adversely affect the trading price of the notes or our common stock. It is also possible that an event that adversely affects the value of the notes, but does not result in an adjustment to the conversion rate, could occur.

If you hold notes, you are not entitled to any rights with respect to our common stock, but you are subject to all changes made with respect to our common stock.

If you hold notes, you are not entitled to any rights with respect to our common stock, including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock, but you are subject to all changes affecting the common stock. You will only be entitled to rights on the common stock if and when we deliver shares of common stock to you in exchange for your notes and in limited cases under the anti-dilution adjustment provisions of the notes. For example, in the event that an amendment is proposed to our restated certificate of incorporation or amended and restated bylaws requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to delivery of the common stock, you will not be entitled to vote on the amendment, although you will nevertheless be subject to any changes in the powers or rights of our common stock.

You may have to pay taxes with respect to distributions on our common stock that you do not receive.

The conversion rate of the notes is subject to adjustment for certain events arising from stock splits and combinations, stock dividends and other actions by us that modify our capital structure. See Description of Notes Adjustment of Conversion Rate. The conversion rate is also subject to adjustment for other events such as certain fundamental changes resulting in the payment of a make-whole premium by us. See Description of Notes Make-Whole Premium Upon a Fundamental Change. If the conversion rate is

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adjusted, under certain circumstances you may be deemed to have received a constructive dividend from us, resulting in ordinary income to you for U.S. federal income tax purposes, even though you would not receive any cash related to that adjustment and even though you might not exercise your conversion right. See Material U.S. Federal Income Tax Consequences.

An active trading market for the notes may not develop, and you may not be able to sell your notes at attractive prices or at all.

The notes are a new issue of our securities for which there is currently no public market, and no active trading market might ever develop. If the notes are traded after their initial issuance, they may trade at a discount from their initial offering price, depending on prevailing interest rates, the market for similar securities, the price, and volatility in the price, of shares of our common stock, our performance and other factors. In addition, we do not know whether an active trading market will develop for the notes and even if one develops, that it will be maintained. To the extent that an active trading market does not develop or is maintained, the liquidity and trading prices for the notes may be harmed.

We have no plans to list the notes on a securities exchange. We have been advised by the underwriters that they presently intend to make a market in the notes. However, the underwriters are not obligated to do so. Any market-making activity, if initiated, may be discontinued at any time, for any reason or for no reason, without notice. If the underwriters cease to act as the market makers for the notes, we cannot assure you another firm or person will make a market in the notes.

The liquidity of any market for the notes will depend upon the number of holders of the notes, our results of operations and financial condition, the market for similar securities, the interest of securities dealers in making a market in the notes and other factors. An active or liquid trading market of the notes may not develop.

An adverse rating of the notes may cause their trading prices to fall.

If a rating agency rates the notes, it may assign a rating that is lower than investors expectations. Rating agencies also may lower ratings on the notes in the future. If rating agencies assign a lower-than-expected rating or reduce, or indicate that they may reduce, their ratings in the future, the trading price of the notes could significantly decline.

We may issue additional shares of common stock and thereby materially and adversely affect the price of our notes.

We are not restricted from issuing additional shares of common stock during the life of the notes. If we issue additional shares of common stock, the price of our common stock, and in turn, the price of the notes may decline.

Our management will have broad discretion in how we use the net proceeds of this offering and the common stock offering.

We have not determined the specific allocation of the net proceeds from this offering and the concurrent common stock offering. Our management will have broad discretion over the use and investment of the net proceeds, and, accordingly, investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds, with only limited information concerning management s specific intentions. Our management may spend a portion or all of the new proceeds in ways that our securityholders may not desire or that may not yield a favorable return. The failure of our management to apply the net proceeds from this offering and the concurrent common stock offering effectively could harm our business, financial condition and results of operations.

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Our stock price is volatile and may affect the trading price of the notes.

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- the progress and results of our clinical trials;
- announcements by us or our competitors concerning their clinical trial results, acquisitions, strategic alliances, technological innovations and newly approved commercial products;
- the availability of critical materials used in developing and manufacturing our Technosphere Insulin System or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- developments in our litigation with our former Chief Medical Officer;
- 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;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- 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; and
- general economic, political or stock market conditions.

Any of these risks, as well as other factors, could cause the market price of our common stock to decline.

Because the notes are convertible into shares of our common stock, volatility or depressed prices for our common stock could have a similar effect on the trading price of the notes. This may result in greater volatility in the trading price of the notes than would be expected for any non-convertible debt securities we may issue. Holders who receive our common stock upon conversion of the notes will also be subject to the risk of volatility and depressed prices of our common stock.

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 Global 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.