MANNKIND CORP
Form S-3
September 02, 2005

As filed with the Securities and Exchange Commission on September 2, 2005 Registration No. 33-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3
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 Number)**

28903 North Avenue Paine
Valencia, CA 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, CA 91355
(661) 775-5300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

David Thomson, Esq.	**D. Bradley Peck, Esq.**
MannKind Corporation	**Cooley Godward LLP**
28903 North Avenue Paine	**4401 Eastgate Mall**
Valencia, CA 91355	**San Diego, CA 92121**
(661) 775-5300	**(858) 550-6000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.
If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:o
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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:þ

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 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	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock, $0.01 par value per share	17,131,682 shares	$12.38	$212,090,223	$24,963
Common Stock, $0.01 par value per share, issuable upon the exercise of warrants	3,426,340 shares	$12.38	$42,418,089	$4,993
Total	20,558,022 shares		$254,508,312	$29,956

(1) Based upon the estimated maximum number of shares of common stock that may be sold by the selling stockholders. Pursuant to Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, this registration statement also registers such additional shares of the Registrant s common stock as may hereafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) of the Securities Act. The price per share and aggregate offering price are based upon the average of the high and low sales prices of the Registrant s common stock on August 26, 2005, as reported on The Nasdaq National Market.

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.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell the securities under this prospectus until the Registration Statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the registrant is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 2, 2005

PROSPECTUS

20,558,022 Shares

Common Stock

The selling stockholders identified in this prospectus are offering for sale from time to time up to 20,558,022 shares of our common stock, $0.01 par value per share, which includes 17,131,682 shares of our common stock held by the selling stockholders and 3,426,340 shares of our common stock issuable to the selling stockholders upon the exercise of warrants. The selling stockholders acquired their shares and the warrants from us in a private placement that closed on August 5, 2005 and is more fully described on page 23 of this prospectus under the heading Selling Stockholders. We will not receive any of the proceeds from the sale of the shares of our common stock by the selling stockholders.

The selling stockholders or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions, at prevailing market prices or at privately negotiated prices, or through any other means described in this prospectus under Plan of Distribution.

Our common stock is quoted on the Nasdaq National Market under the symbol MNKD. On September 1, 2005, the last reported sale price for our common stock on the Nasdaq National Market was $12.83 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISKS.
SEE RISK FACTORS BEGINNING ON PAGE 3 OF THIS PROSPECTUS TO READ ABOUT FACTORS YOU
SHOULD CONSIDER IN CONNECTION WITH PURCHASING OUR COMMON STOCK.

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

The date of this prospectus is , 2005.

You should rely only on the information contained or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not, and the selling stockholders have not, authorized anyone to provide you with additional information or information different from that contained or incorporated by reference in this prospectus and any applicable prospectus supplement. The selling stockholders 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 and information appearing in any applicable prospectus supplement is accurate only as of the date of the applicable prospectus supplement. Additionally, information from other documents incorporated by reference in this prospectus or any applicable prospectus supplement is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of the prospectus or prospectus supplement or any sale of our common stock.

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Technosphere® and MedTone® are our registered trademarks in the United States. We have also applied for or registered company trademarks in other jurisdictions, including Europe and Japan. This document also contains trademarks and service marks of other companies that are the property of their respective owners.

PROSPECTUS SUMMARY

The following summary provides an overview of selected information relating to this offering and does not contain all the information that you should consider before investing in our common stock. You should carefully read this prospectus, especially the risks of investing in our common stock discussed under the section RISK FACTORS below, all documents incorporated by reference, any prospectus supplement, and the additional information described under the caption WHERE YOU CAN FIND MORE INFORMATION, beginning on page 32, before buying securities in this offering. Reference to we, us, our, our company and MannKind refers to MannKind Corporation and its subsidiary, unless the context requires otherwise.

We are a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. We are currently in Phase 3 clinical trials in the United States and Europe of our lead product, the Technosphere Insulin System, to study its safety and efficacy in the treatment of diabetes. This therapy consists of a proprietary dry powder Technosphere formulation of insulin that is inhaled into the deep lung using our proprietary MedTone inhaler. We believe that the combination of unique performance characteristics, including the rapid transfer of the insulin into the blood and the significantly higher bioavailability, and the convenience and ease of use of the Technosphere Insulin System may have the potential to change the way diabetes is treated.

Our other products candidates are in research and pre-clinical development. We are developing additional applications for our proprietary Technosphere platform technology by formulating other drugs for pulmonary delivery, primarily for metabolic and immunological diseases. We are also developing therapies for the treatment of solid-tumor cancers.

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. Our filings with the Securities and Exchange Commission, or SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports are available free of charge through our website as soon as reasonably practicable after being filed with or furnished to the SEC. The information on our website and other information that can be accessed through our website are not part of this prospectus.

RISK FACTORS

An investment in our common stock involves a high degree of risk. Prior to making a decision about investing in our common stock, you should carefully consider the following risks factors and the risk factors described in any applicable prospectus supplement, together with all of the other information contained in this prospectus and any prospectus supplement or appearing or incorporated by reference in the registration statement of which this prospectus is a part. The risks described below are not the only risks we face. Additional risks that we do not currently think are material may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could suffer, the trading price of our common stock could decline and you might lose all or part of your investment in our common stock.

RISKS RELATED TO OUR BUSINESS

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

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

We have never been profitable, and, as of June 30, 2005, we had an accumulated deficit of $492.3 million. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing 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.

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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 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 net proceeds from our private placement in August 2005, will enable us to continue planned operations into the third quarter of 2006. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Accordingly, we expect that we will need to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration or the establishment of other funding facilities, in order to continue the development and commercialization of our Technosphere Insulin System and other product candidates and to support our other ongoing activities. The amount of additional funds we need will depend on a number of factors, including:

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

We have raised capital in the past primarily through the sale of equity securities. We may in the future pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact your rights as a holder of our common stock, may dilute your ownership percentage and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and 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.

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

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

We have expended significant time, money and effort in the development of our lead product candidate, the Technosphere Insulin System, which has not yet received regulatory approval and which may never be commercialized. Before we can market and sell our Technosphere Insulin System, we will need to advance our Technosphere Insulin System through Phase 3 clinical trials and demonstrate in these trials that our Technosphere Insulin System is safe and effective. We currently anticipate conducting several pivotal Phase 3 clinical trials as well as several special population studies involving, in total, more than 3,000 patients, which will require the expenditure of additional time and resources. We must also receive the necessary approvals from the FDA and similar foreign regulatory agencies before this product can be marketed in the United States or elsewhere. Even if we were to receive regulatory approval, we ultimately may be unable to gain market acceptance of our Technosphere Insulin System for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and cost effectiveness. If we fail to commercialize our Technosphere Insulin System, our business, financial condition and results of operations will be materially and adversely affected.

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

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

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

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

- the rate of progress, costs and results of our clinical trial and research and development activities, which will be impacted by the level of proficiency and experience of our clinical staff;

product candidates, including insulin and other materials for our Technosphere Insulin System; and

the costs of expanding and maintaining manufacturing operations, as necessary.

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

We face substantial competition in the development of our product candidates and may not be able to compete successfully, and our product candidates may be rendered obsolete by rapid technological change.

We initially are focusing on the development of the Technosphere Insulin System for the treatment of diabetes, and we face intense competition in this area. Pfizer, Inc. and Sanofi-Aventis, in collaboration with Nektar Therapeutics, have been conducting Phase 3 clinical trials for the Exubera product. In March 2004, these collaborators filed a submission seeking regulatory approval in Europe, and in March 2005, their new drug application, or NDA, was accepted by the FDA. Novo Nordisk A.S. has a pulmonary insulin product in development. In July 2005, Eli Lilly and Company, in collaboration with Alkermes, Inc., initiated a Phase 3 clinical trial required for registration of their inhaled insulin system and to define the safety and efficacy of the Lilly/Alkermes product. In addition, a number of established pharmaceutical companies have or are developing proprietary technologies or have entered into arrangements with, or acquired, companies with technologies for the treatment of diabetes. We also face substantial competition for the development of our other product candidates.

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, production and sales and marketing resources than we do and have a greater depth and number of experienced managers. As a result, our competitors may be better equipped than we are to develop, manufacture, market and sell competing products.

The rapid rate of scientific discoveries and technological changes could result in one or more of our products becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that would render our technology and our Technosphere Insulin System less competitive, uneconomical or obsolete. The fact that another company will likely be the first to commercialize a pulmonary insulin system may give that company an advantage in terms of being able to gain reputation and market share as well as set parameters for the pulmonary insulin market such as pricing. Our future success will depend not only on our ability to develop our products but to improve them and to keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

We also expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the areas of diabetes and cancer. These institutions are becoming increasingly aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

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

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

If we are not able to enter into a collaboration on terms that are favorable to us for our products, we could be required to undertake and fund product development, clinical trials, manufacturing and marketing activities solely at our own expense. For example, we are currently evaluating potential collaborations with respect to our Technosphere Insulin System. We currently estimate that the cost of a self-funded Phase 3 program over the next 12 months would be in the range of $150 to $175 million. However, this estimate may change based on how the program proceeds. Failure to enter into a collaboration with respect to our Technosphere Insulin System following initial Phase 3 clinical trials or

with respect to any other product candidate could substantially increase our

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requirements for capital, which might not be available on favorable terms, if at all. Alternatively, we would have to substantially reduce our development efforts, which would delay or otherwise impede the commercialization of our product candidates.

If we enter into collaborative agreements and if our third-party collaborators do not perform satisfactorily or if our collaborations fail, development or commercialization of our product candidates may be delayed and our business could be harmed.

We currently rely on clinical research organizations and hospitals to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates, including our Technosphere Insulin System. Further, we may also enter into license agreements, partnerships or other collaborative arrangements to support financing, development and marketing of our Technosphere Insulin System. We may also license technology from others to enhance or supplement our technologies. These various collaborators may enter into arrangements that would make them potential competitors. These various collaborators also may breach their agreements with us and delay our progress or fail to perform under their agreements, which could harm our business.

If we enter into collaborative arrangements, we will have less control over the timing, planning and other aspects of our clinical trials, and the sale and marketing of our product candidates. We cannot assure you that we will be able to enter into satisfactory arrangements with third parties as contemplated or that any of our existing or future collaborations will be successful.

Testing of a particular product candidate may not yield successful results, and even if it does, we may still be unable to commercialize that product candidate.

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

- safety and efficacy results obtained in our preclinical and initial clinical testing may be inconclusive or may not be predictive of results obtained in later-stage clinical trials or following long-term use, and we may as a result be forced to stop developing product candidates that we currently believe are important to our future;

- the data collected from clinical trials of our product candidates may not be sufficient to support FDA or other regulatory approval;

- after reviewing test results, we or any potential collaborators may abandon projects that we previously believed were promising; and

- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

We have initiated the second of our Phase 3 studies, a pivotal safety study of our Technosphere Insulin System, primarily to evaluate pulmonary function during long term use. Our Technosphere Insulin System is intended for multiple uses per day. Due to the size and time frame over which the clinical trials are conducted, the results of clinical trials may not be indicative of the effects of long-term use. If long-term use of our product results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell our Technosphere Insulin System, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical trials, which may be time-consuming and expensive, and may not produce favorable results.

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

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

Our revenues and profitability may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing

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or profitability of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any healthcare reform proposals or legislation. Such reforms may make it difficult to complete the development and testing of our product candidates, and therefore may limit our ability to generate revenues from sales of our product candidates and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of other companies that are prospective collaborators for some of our product candidates, our ability to commercialize our product candidates under development may be adversely affected.

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

If we are unable to transition successfully from an early-stage development company to a company that commercializes therapeutics, our operations will suffer.

We are reaching a critical juncture in our development, transitioning from an early-stage development company to one with multiple Phase 3 clinical trials moving toward commercializing a product. Phase 3 development of the Technosphere Insulin System will be far more complex than the earlier phases. Overall, we plan to support a significant number of studies in the near term. We have not previously implemented the range of studies contemplated for our Phase 3 clinical program. Moreover, as a company, we have no previous experience in the Phase 3-through-NDA stage of product development.

We require a well-structured plan to make this transition. We are in the process of implementing the following measures, among others, to accommodate our transition and successfully implement our commercialization strategy for our Technosphere Insulin System:

- add a significant number of new personnel, particularly in clinical development, regulatory and manufacturing production, including personnel with significant Phase 3-to-commercialization experience;
- expand our manufacturing capabilities;
- develop comprehensive and detailed commercialization, clinical development and regulatory plans;
- implement standard operating procedures, including those for protocol development; and
- align our management structure to accommodate the increasing complexity of our operations.

If we are unable to accomplish these measures in a timely manner, we would be at considerable risk of failing to:

- complete our Phase 3 clinical trial program in a deliberate fashion, on time and within budget; and

We have never manufactured any of our product candidates in commercial quantities, and if we fail to develop an effective manufacturing capability for our product candidates or to engage third-party manufacturers with this capability, we may be unable to commercialize these products.

We currently use our Danbury, Connecticut facility to manufacture raw Technosphere material, formulate Technosphere Insulin, fill plastic cartridges with Technosphere Insulin and blister package the cartridges for our clinical trials. We presently intend to increase our formulation, fill and finishing capabilities at Danbury in order to

accommodate our activities through initial commercialization. This expansion will involve a number of third-party

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suppliers of equipment and materials as well as engineering and construction services. Our suppliers may not deliver all of the required equipment, materials and services in a timely manner or at reasonable prices. If we encounter difficulties in our relationships with these suppliers, or if a supplier becomes unable to provide us with goods or services at the agreed-upon price, our facilities expansion could be delayed or its costs increased.

We have never manufactured any of our product candidates in commercial quantities. As our product candidates move through the regulatory process, we will need to either develop the capability of manufacturing on a commercial scale or engage third-party manufacturers with this capability, and we cannot assure you that we will be able to do either successfully. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. In addition, before we would be able to produce commercial quantities of Technosphere Insulin at our Danbury facility, it will have to undergo a pre-approval inspection by the FDA. The expansion process and preparation for the FDA s pre-approval inspection for commercial production at the Danbury facility could take an additional six months or longer. If we use a third-party supplier to formulate Technosphere Insulin or produce its raw material, the transition could also require significant start-up time to qualify and implement the manufacturing process. If we engage a third-party manufacturer, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if we or our potential third-party manufacturers fail to deliver the required commercial quantities of our products on a timely basis and at commercially reasonable prices, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenues.

If our suppliers fail to deliver materials and services needed for the production of our Technosphere Insulin System in a timely and sufficient manner, or they fail to comply with applicable regulations, our business and results of operations will be harmed and the market price of our common stock may decline.

For our Technosphere Insulin System to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our MedTone inhaler, the related cartridges and other materials. We currently have a long-term supply agreement with Diosynth B.V., an independent supplier of insulin and a subsidiary of Akzo Nobel, which is currently our sole supplier for insulin. We are aware of at least five other suppliers of bulk insulin but to date we have not entered into a commercial relationship with any of the five. Currently, we manufacture the raw Technosphere material, but we are in the process of qualifying a secondary manufacturer to supply us with commercial quantities of this raw material. We recently entered into a long-term supply agreement with Vaupell, Inc., the supplier of our MedTone inhaler and cartridges. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with current drug Good Manufacturing Practices, or cGMP, and the production of MedTone inhaler and related cartridges in accordance with device Quality System Regulations, or QSR. The supply of all of these materials may be limited or the manufacturer may not meet relevant regulatory requirements, and if we are unable to obtain these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we should encounter delays or difficulties in our relationships with manufacturers or suppliers, our development or manufacturing may be delayed. Any such events would delay the submission of our product candidates for regulatory approval or market introduction and subsequent sales and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

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

A broad base of physicians and specialists treat patients with diabetes. A large sales force will be required in order to educate and support these physicians and specialists. Therefore, we plan to enter into collaborations with one or more

pharmaceutical companies to sell, market and distribute our Technosphere Insulin System. If we fail to enter into collaborations, we will be required to establish our own direct sales, marketing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and we estimate that establishing a specialty sales force would cost more than $20 million. Because of our size, we would be at a disadvantage to our potential competitors, all of which have collaborated with large pharmaceutical companies that have substantially more resources than we do. As a result, we would not initially be able to field a sales force as large as our competitors or

provide the same degree of market research or marketing support. In addition, our competitors would have a greater ability to devote research resources toward expansion of the indications for their products. We cannot assure you that we will succeed in entering into acceptable collaborations, that any such collaboration will be successful or, if not, that we will successfully develop our own sales, marketing and distribution capabilities.

If our products do not become widely accepted by physicians, patients, third-party payors and the healthcare community, we may be unable to generate significant revenue, if any.

Our product candidates are new and unproven. Even if our product candidates obtain regulatory approvals, they may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of our product candidates will depend on many factors, including:

- the claims for which FDA approval can be obtained, including superiority claims;
- the perceived advantages and disadvantages of competitive products;
- the willingness and ability of patients and the healthcare community to adopt new technologies;
- the ability to manufacture the product in sufficient quantities with acceptable quality and at an acceptable cost;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of the product compared to those of competing products or therapies;
- the convenience and ease of administration of the products relative to existing treatment methods;
- the pricing and reimbursement of our products relative to existing treatment therapeutics and methods; and
- marketing and distribution support for our products.

Physicians will not recommend our products until clinical data or other factors demonstrate the safety and efficacy of our products as compared to other treatments. Even if the clinical safety and efficacy of our product candidates is established, physicians may elect not to recommend these product candidates for a variety of factors, including the reimbursement policies of government and third-party payors and the effectiveness of our competitors in marketing their therapies. Because of these and other factors, our products may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If product liability claims are brought against us, we may incur significant liabilities and suffer damage to our reputation.

The testing, manufacturing, marketing and sale of our various product candidates, including the Technosphere Insulin System, expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers and loss of revenues. We currently carry worldwide liability insurance in the amount of $5 million. We believe these limits are reasonable to cover us from potential damages arising from current and previous clinical trials of our Technosphere Insulin System. In addition, we carry local policies per trial in each country in which we conduct clinical trials that requires us to carry local coverage. We intend to obtain product liability coverage for commercial sales in the future. However, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will be able to obtain sufficient coverage at an acceptable cost, if at all. If losses from such claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product liability claim, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates

and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

10.

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development work involves the controlled storage and use of hazardous materials, including chemical, radioactive and biological materials. In addition, our manufacturing operations involve the use of CBZ-lysine, which is stable and non-hazardous under normal storage conditions, but may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations governing how we use, manufacture, store, handle and dispose of these materials. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to $1 million per occurrence and $2 million in the aggregate and is supplemented by an umbrella policy that provides a further $4 million of coverage; however, our insurance policy excludes pollution coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts.

When we purchased the facilities located in Danbury, Connecticut, there was a soil cleanup plan in process. As part of the purchase, we obtained an indemnification from the seller related to the remediation of the soil for all known environmental conditions that existed at the time the seller acquired the property. The seller is, in turn, indemnified for these known environmental conditions by the previous owner. We estimate that the cost to complete the soil cleanup plan for industrial use is $1.5 to $3.0 million over the next 18 to 24 months. We also received an indemnification from the seller for environmental conditions created during its ownership of the property and for environmental problems unknown at the time that the seller acquired the property. These additional indemnities are limited to the purchase price that we paid for the Danbury facilities. In the event that any cleanup costs are imposed on us and we are unable to collect the full amount of these costs and expenses from the seller or the party responsible for the contamination, we may be required to pay these costs and our business and results of operations may be harmed.

If we lose any key employees or scientific advisors, our operations and our ability to execute our business strategy could be materially harmed.

In order to commercialize our product candidates successfully, we will be required to expand our work force, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel. We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all.

The loss of the services of any principal member of our management and scientific staff could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are at will and we currently do not have employment agreements with any of the principal members of our management or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experience required to develop, gain regulatory approval of and commercialize our product candidates successfully. In May 2005, we terminated the employment of Dr. Wendell Cheatham, our former Chief Medical Officer. Although Mr. Edstrom has assumed Dr. Cheatham s management responsibilities while we search for a senior executive to lead our development operations, there can be no assurance that we will be able to recruit such an individual with the appropriate skills and experience.

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

harm our business. In addition, these advisors are not prohibited from, and may have arrangements with, other companies to assist those companies in developing technologies that may compete with our product candidates.

11.

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

Alfred Mann, our Chairman and Chief Executive Officer, is also serving as the Chairman and Co-Chief Executive Officer of Advanced Bionics Corporation, which was acquired by Boston Scientific Corporation. Mr. Mann is involved in many other business and charitable activities. As a result, the time and attention Mr. Mann devotes to the operation of our business varies and he may not expend the same time or focus on our activities as other, similarly situated chief executive officers. Mr. Mann typically devotes anywhere between 25 and 50 hours a week to our business. If Mr. Mann is unable to devote the time and attention necessary to running our business, we may not be able to execute our business strategy and our business could be materially harmed.

We have been sued by our former Chief Medical Officer. As a result of this litigation, we may incur material costs and suffer other consequences, which may adversely affect us.

In May 2005, Dr. Cheatham filed a complaint against us in the California Superior Court. The complaint alleges causes of action for wrongful termination in violation of public policy, breach of contract and retaliation in connection with the termination of Dr. Cheatham s employment. In the complaint, Dr. Cheatham seeks compensatory, punitive and exemplary damages in excess of $2.0 million as well as reimbursement of attorneys fees. In June 2005, we answered the complaint and also filed a cross-complaint against Dr. Cheatham, alleging claims for libel per se, trade libel, breach of contract, breach of the implied covenant of good faith and fair dealing and breach of the duty of loyalty. In July 2005, Dr. Cheatham filed a demurrer and motion to strike our cross-complaint under California s anti-SLAPP statute, the hearing for which is scheduled for September 28, 2005.

The litigation will result in costs and divert management s attention and resources, any of which could adversely affect our business, results of operations or financial position. We are also concerned that, despite the findings by an independent counsel following an investigation and despite the endorsement of the independent counsel s report by our board of directors, investors could give undue weight to Dr. Cheatham s allegations, resulting in damage to our reputation, or the FDA could begin an investigation, either of which could adversely affect the trading price of our common stock. If we are not successful in this litigation, we could be forced to make a significant settlement or judgment payment to Dr. Cheatham, which could adversely affect our business, results of operations or financial position.

Our facilities that are located in Southern California may be affected by natural disasters.

Our headquarters and some of our research and development activities are located in Southern California, where they are subject to an enhanced risk of natural and other disasters such as power and telecommunications failures, mudslides, fires and earthquakes. A fire, earthquake or other catastrophic loss that causes significant damage to our facilities or interruption of our business could harm our business. We do not carry insurance to cover losses caused by earthquakes, and the insurance coverage that we carry for fire damage and for business interruption may be insufficient to compensate us for any losses that we may incur.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which, beginning with our fiscal year ending December 31, 2005, will require annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent auditors that both addresses management s assessments and provides for the independent auditor s assessment of the effectiveness of our internal controls. During the course of our testing, we may identify deficiencies which we may not be able to remediate in time to meet the deadline for compliance with Section 404. Testing and maintaining internal controls also involves significant costs and can divert our management s attention from other matters that are important to our business. We may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404, and our independent auditors may not be able or willing to issue a favorable assessment of our conclusions. Failure to achieve and maintain an effective internal control environment could harm our operating results and could cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

12.

RISKS RELATED TO REGULATORY APPROVALS

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

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

- product design, development, manufacture and testing;
- product labeling;
- product storage and shipping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We expect, based on our discussions with the FDA and on our understanding of the interactions between the FDA and other pharmaceutical companies developing pulmonary insulin delivery systems, that we will need safety data covering at least two years from patients treated with our Technosphere Insulin System and that we must complete a two-year carcinogenicity study of Technosphere Insulin in rodents to obtain approval, among other requirements. We cannot be certain when or under what conditions we will undertake further clinical trials. The clinical trials of our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates, including our Technosphere Insulin System. Even if we believe the data collected from our clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

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

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. To our knowledge, no pulmonary insulin product has yet been approved for marketing, and we are not aware of any precedent for the successful commercialization of products based on our technology or technologies similar to ours. However, an application for approval for another pulmonary insulin product candidate was recently filed in the United States, and we believe a decision could be made by the FDA in early 2006. The FDA has advised us that it will regulate our Technosphere Insulin System as a combination product because of the complex nature of the system that includes the combination of a new drug (Technosphere Insulin) and a new medical device (the

MedTone inhaler used to administer the insulin). The FDA indicated that the review of a future drug marketing application for our Technosphere Insulin System will involve three separate review groups of the FDA: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health within the FDA that reviews medical devices. We currently understand that the Metabolic and Endocrine Drug Products Division will be the lead group and will obtain consulting reviews from the other two FDA groups. The FDA has not made an official final decision in this regard, however, and we can make no assurances at this time about what impact FDA review by multiple groups will have on the review and approval of our product or whether we are correct in our understanding of how the Technosphere Insulin System will be reviewed and approved.

Also, recent events regarding questions about the safety of marketed drugs, including pertaining to the lack of adequate labeling, may result in increased cautiousness by the FDA in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing

requirements as conditions of approval, which may significantly affect the marketability of our drug products. FDA review of our Technosphere Insulin System as a combination product therapy may lengthen the product development and regulatory approval process, increase our development costs and delay or prevent the commercialization of our Technosphere Insulin System.

We are developing our Technosphere Insulin System as a new treatment for diabetes utilizing unique, proprietary components. 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 NDA for our Technosphere Insulin System. No assurances exist that we will not be required to obtain separate device clearances or approval for use of our inhaler with our Technosphere Insulin System. This may result in our being subject to medical device review user fees and to other device requirements to market our inhaler and may result in significant delays in commercialization. Even if the device component is approved as part of our NDA for the Technosphere Insulin System, numerous device regulatory requirements still apply to the device part of the drug-device combination.

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

We will not be able to commercialize our Technosphere Insulin System and other product candidates until we have obtained regulatory approval. We have no experience as a company in late-stage regulatory filings, such as preparing and submitting NDAs, which may place us at risk of delays, overspending and human resources inefficiencies. Any delay in obtaining, or inability to obtain, regulatory approval could harm our business.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to criminal prosecution, fined or forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval.

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing trials. In addition, if we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and a reformulation of our products, additional clinical trials, changes in labeling of, or indications of use for, our products and/or additional marketing applications may be required. If we encounter any of the foregoing problems, our business and results of operations will be harmed and the market price of our common stock may decline.

Even if we obtain regulatory approval for our product candidates, such approval may be limited and we will be subject to stringent, ongoing government regulation.

Even if regulatory authorities approve any of our product candidates, they could approve less than the full scope of uses or labeling that we seek or otherwise require special warnings or other restrictions on use or marketing. Regulatory authorities may limit the segments of the diabetes population to which we or others may market our Technosphere Insulin System or limit the target population for our other product candidates. Based on currently available clinical studies, we believe that our Technosphere Insulin System may have certain advantages over currently approved insulin products or pulmonary insulin products in development, including its approximation of the natural first-phase insulin release spike. Nonetheless, there are no assurances that these and other advantages, if any, of the Technosphere Insulin System have clinical significance or can be confirmed in head-to-head clinical trials against appropriate approved comparator insulin drug products. Such comparative clinical trials are required to make these types of superiority claims in labeling or advertising. These aforementioned observations and others may therefore not be capable of substantiation in comparative clinical trials prior to our NDA submission, if at all, or otherwise may not be suitable for inclusion in product labeling or advertising and, as a result, our Technosphere Insulin System may not have competitive advantages when compared to other insulin products.

The manufacture, marketing and sale of these product candidates will be subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning safety or efficacy of

14.

the product occur following approval. In response to recent events regarding questions about the safety of certain approved prescription products, including the lack of adequate warnings, the FDA and Congress are currently considering new regulatory and legislative approaches to advertising, monitoring and assessing the safety of marketed drugs, including legislation providing the FDA with authority to mandate labeling changes for approved pharmaceutical products, particularly those related to safety. We also cannot be sure that the current Congressional and FDA initiatives pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

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

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

We can make no assurances that our insulin supplier will be acceptable to the FDA. If we were required to find a new or additional supplier of insulin, we would be required to evaluate the new supplier s ability to provide insulin that meets our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of our Technosphere Insulin System. We also depend on suppliers for other materials that comprise our Technosphere Insulin System, including our MedTone inhaler and cartridges. All of our device suppliers must comply with relevant regulatory requirements including QSR. It also is likely that major suppliers will be subject to FDA preapproval inspections before the agency will approve a future marketing application for our Technosphere Insulin System. At the present time our insulin supplier is certified to the ISO9001:2000 Standard. There can be no assurance, however, that if the FDA were to conduct a preapproval inspection of our insulin supplier or other suppliers, that the agency would find that the supplier substantially comply with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the indicated uses for which the product candidate may be marketed or contain requirements for potentially costly post-marketing follow-up clinical trials.

Reports of side effects or safety concerns in related technology fields or in other companies clinical trials could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates.

At present, there are a number of clinical trials being conducted by us and other pharmaceutical companies involving insulin delivery systems. If we discover that our product is associated with a significantly increased frequency of adverse events, or if other pharmaceutical companies announce that they observed frequent adverse events in their

trials involving the pulmonary delivery of insulin, we could encounter delays in the timing of our clinical trials or difficulties in obtaining the approval of our Technosphere Insulin System. As well, the public perception of our products might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company s product.

For example, in August 2004, an analyst reported that the United Kingdom Committee on the Safety of Medicines had expressed concern that a European application for approval of a drug for the treatment of diabetes was not

licensable at the time. Earlier in 2004, Sanofi-Aventis, on behalf of Pfizer and Nektar, filed for regulatory approval in Europe of Exubera. Although the identity of the drug was not disclosed in the analyst s report, the news nonetheless triggered temporary but sharp declines in the market prices of Nektar s common stock as well as our common stock. There are also a number of clinical trials being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical trials could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business and results of operations and cause the market price of our common stock to decline.

RISKS RELATED TO INTELLECTUAL PROPERTY

If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably.

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets, know-how and confidentiality agreements. We own a number of domestic and international patents, have a number of domestic and international patent applications pending and have licenses to additional patents. We cannot assure you that our patents and licenses will successfully preclude others from using our technologies, and we could incur substantial costs in seeking enforcement of our proprietary rights against infringement. Even if issued, the patents may not give us an advantage over competitors with similar technologies.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents if we attempt to enforce them and they are challenged in court or in other proceedings, such as oppositions, which may be brought in US or foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the US Patent and Trademark Office, or USPTO.

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

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

Competitors may infringe our patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

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

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

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

A third party may claim that we are using inventions covered by such third party s patents and may go to court to stop us from engaging in our normal operations and activities. These lawsuits can be expensive and would consume time and other resources. There is a risk that a court would decide that we are infringing a third party s patents and would order us to stop the activities covered by the patents, including the commercialization of our products. In addition, there is a risk that we would have to pay the other party damages for having violated the other party s patents (which damages may be increased, as well as attorneys fees ordered paid, if infringement is found to be willful), or that we will be required to obtain a license from the other party in order to continue to commercialize the affected products, or to design our products in a manner that does not infringe a valid patent. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms or at all, requiring cessation of activities that were found to infringe a valid patent. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Although we own a number of domestic and foreign patents and patent applications relating to our Technosphere Insulin System and cancer vaccine products under development, we have identified certain third-party patents that a court may interpret to restrict our freedom to operate (that is, to cover our products) in the areas of Technosphere formulations, pulmonary insulin delivery and the treatment of cancer. Specifically, we have identified certain third-party patents having claims relating to chemical compositions of matter and pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of our Technosphere Insulin System. We have also identified third-party patents disclosing methods of use and compositions of matter related to DNA-based vaccines that also may trigger an allegation of infringement upon the commercial manufacture and sale of our cancer therapy. If a court were to determine that our insulin products or cancer therapies were infringing any of these patent rights, we would have to establish with the court that these patents were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in an infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business would be harmed and our profitability could be materially adversely impacted.

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

Patent litigation is costly and time-consuming. Among other things, such litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Although patent and intellectual property disputes in the

pharmaceutical area have often been settled for licensing or similar arrangements, associated costs may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business and results of operations and cause the market price of our common stock to decline.

17.

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

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

RISKS RELATED TO OUR COMMON STOCK

We expect that our stock price will fluctuate significantly.

We completed our initial public offering on August 2, 2004. Prior to that, our stockholders could not buy or sell our common stock publicly. An active public market for our common stock may not continue to develop or be sustained. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks. Since August 2, 2004, the high and low sales price of our common stock has varied significantly, from a low of $8.42 to a high of $24.31. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

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

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

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

Public companies in general and companies included on The Nasdaq National Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock to decline, regardless of our operating

performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

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

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

Mr. Mann has been our primary source of financing to date. Following the close of our private placement on August 5, 2005, Mr. Mann beneficially owned approximately 48.7% of our outstanding shares of capital stock. Members of Mr. Mann s family beneficially owned at least an additional 1.6% of our outstanding shares of common stock, although Mr. Mann does not have voting or investment power with respect to these shares. By virtue of his holdings, Mr. Mann can and will continue to be able to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

Subject to compliance with federal and state securities laws, Mr. Mann is free to sell the shares of our stock he holds at any time. Upon his death, we have been advised by Mr. Mann that his shares of our capital stock will be left to the Alfred E. Mann Medical Research Organization, or AEMMRO, and AEM Foundation for Biomedical Engineering, or AEMFBE, not-for-profit medical research foundations that serve as funding organizations for Mr. Mann s various charities, including the Alfred Mann Foundation, or AMF, and the Alfred Mann Institute for Biomedical Engineering at the University of Southern California, and that may serve as funding organizations for any other charities that he may establish. The AEMMRO is a membership foundation consisting of six members, including Mr. Mann, four of his children and Dr. Joseph Schulman, the director of AMF. The AEMFBE is a membership foundation consisting of five members, including Mr. Mann and the same four of his children. Although we understand that the members of AEMMRO and AEMFBE have been advised of Mr. Mann s objectives for these foundations, once Mr. Mann s shares of our capital stock become the property of the foundations, we cannot assure you as to how those shares will be distributed or how they will be voted.

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

As of August 15, 2005, we had approximately 50.2 million shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations and, in the case of the shares covered by the registration statement of which this prospectus is a part, to compliance with prospectus delivery requirements.

If our common stockholders, including the selling stockholders identified in this prospectus, 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. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registrations rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and bylaws include anti-takeover provisions, such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or

combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us,

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even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements include, but are not limited to, statements about: the progress or success of our research, development and clinical programs, the timing of the development and 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, may, plans, potential, predicts, projects, goal, and similar expressions intended to identify forward-looking statements. For these statements, we claim the protection of the safe harbors for forward-looking statements as provided in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. 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 caption RISK FACTORS, beginning on page 3, and elsewhere in this prospectus and any applicable prospectus supplement. Because the factors discussed in this prospectus or incorporated by reference could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any such forward-looking statements.

Any forward-looking statement speaks only as of the date on which it is made, or if no date is stated, as of the date of this prospectus. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should read this prospectus, the registration statement of which this prospectus is a part, and the documents incorporated by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements. **EXCEPT AS REQUIRED BY LAW, WE UNDERTAKE NO OBLIGATION TO PUBLICLY UPDATE OR REVISE ANY FORWARD-LOOKING STATEMENTS, WHETHER AS A RESULT OF NEW INFORMATION, FUTURE EVENTS OR ANY OTHER REASON.**

USE OF PROCEEDS

We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders. The proceeds from the sale of the common stock offered pursuant to this prospectus are solely for the accounts of the selling stockholders.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq National Market listing fees and fees and expenses of our counsel and our accountants.

A portion of the shares covered by this prospectus are issuable upon exercise of warrants to purchase our common stock. Upon any exercise for cash of the warrants, the selling stockholders will pay us the exercise price of the warrants. The cash exercise price of the warrants is $12.228 per share of our common stock. The warrants are also exercisable on a cashless basis. We will not receive any cash payment from the selling stockholders upon any exercise of the warrants on a cashless basis.

SELLING STOCKHOLDERS

We issued an aggregate of 17,131,682 shares of our common stock and issued warrants to purchase up to 3,426,340 shares of our common stock to the selling stockholders named in the selling stockholder table below in a private placement of securities that closed on August 5, 2005. The warrants issued to the selling stockholders are exercisable at any time in whole or in part beginning February 2, 2006 and ending August 5, 2010 at an exercise price of $12.228 per share. The private placement transaction was exempt from the registration requirements of the Securities Act.

We agreed with each selling stockholder to file the registration statement of which this prospectus is a part to register for resale the shares of our common stock sold in the private placement transaction, and the shares of our common stock underlying the warrants we issued in the private placement transaction. Throughout this prospectus, when we refer to the selling stockholders, we mean the persons listed in the table below, as well as the pledgees, donees, assignees, transferees, successors and others who later hold any of the selling stockholders interests, and when we refer to the shares of our common stock being registered on behalf of the selling stockholders, we are referring to the shares of our common stock sold and the shares of our common stock issuable upon the exercise of the warrants issued in the private placement transaction, collectively, unless otherwise indicated.

The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them. We currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares other than the securities purchase agreement pursuant to which the selling stockholders purchased their shares from us. The shares offered by this prospectus may be offered from time to time by the selling stockholders, although the warrant shares will not be eligible to be offered pursuant to this prospectus until the related warrants become exercisable and are exercised.

The following table sets forth the name of each selling stockholder, the number of shares owned by each selling stockholder prior to this offering (including shares that such selling stockholder can acquire upon exercise of the warrants issued in the private placement), the number of shares that may be offered under this prospectus and the number of shares of our common stock to be owned by each selling stockholder after this offering is completed, assuming that all offered shares are sold as contemplated herein and thereafter none of the offered shares will be held by the selling stockholders.

Except as noted in the footnotes below, none of the selling stockholders has held any position or office with us or any of our predecessors or affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years other than as a result of the ownership of our shares or other securities.

The information in the table below is based on information provided by or on behalf of the selling stockholders, Schedules 13D and 13G and other public documents filed with the SEC. This information is only accurate as of the date that such information was provided to us or the SEC and may change. Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting or investment power with respect to the securities. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that could be issued upon the exercise of outstanding options and warrants held by that person that are currently exercisable or exercisable within 60 days of August 15, 2005 are considered outstanding. These shares, however, are not considered outstanding as of August 15, 2005 when computing the percentage ownership of each other person. Although the warrants held by the selling stockholders are not exercisable until February 2, 2006, the shares of our common stock issuable upon the exercise of such warrants are shown as beneficially owned by the selling stockholders included in the table below since those shares of our common stock are being offered in this prospectus. Each selling stockholder s percentage of shares owned after the offering is based on 50,190,600 shares of our common stock outstanding as of August 15, 2005. Unless otherwise indicated in the footnotes to this table, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

The selling stockholders may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of their shares since the date on which the information in the table is presented. Information about the selling stockholders may change over time.

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Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering	
			Number	Percentage
Adage Capital Partners, L.P. (1)	1,292,218	1,292,218		
Alfred E. Mann and affiliates (2)	26,314,392	10,260,537	16,053,855	29.8%
Amaranth LLC (3)	4,870,045	370,045	4,500,000	8.4%
Amaranth Global Equities Master Fund Limited (3)	541,116	41,116	500,000	*
Atlas Master Fund, Ltd. (4)	352,423	352,423		
Brookside Capital Partners Fund, L.P. (5)	1,527,167	1,527,167		
D3 Capital Management, LLC and affiliates (6)	234,949	234,949		
Deerfield International Limited (7)	488,694	488,694		
Deerfield Partners, L.P. (8)	451,102	451,102		
FMR Corp. and affiliates (9)	3,351,225	2,525,698	825,527	1.5%
Hakan Edstrom (10)	330,090	5,874	324,216	*
Kent Kresa (11)	50,100	12,600	37,500	*
Kings Road Investments Ltd. (12)	469,898	469,898		
Narragansett I, L.P. and affiliates (13)	939,796	939,796		
Oracle U.S. Partners LLC (14)	873,465	528,635	344,830	*
Aries Domestic Fund, L.P. and affiliates (15)	323,055	176,212	146,843	*
T. Rowe Price Associates, Inc. and affiliates (16)	813,009	646,109	166,900	*
Tang Capital Partners, LP (17)	234,949	234,949		

* Less than one percent.

(1) Comprises 1,076,848 shares of common stock and 215,370 shares of common stock underlying a warrant, all of which shares are being offered pursuant to this prospectus.

(2) Includes the following

securities held
by the following
selling
stockholders:

Alfred E. Mann Living Trust: 17,980,598 shares of common stock (including 6,944,963 shares of common stock being offered pursuant to this prospectus) and 1,388,993 shares of common stock underlying warrants (all being offered pursuant to this prospectus); and

Biomed Partners, LLC: 4,025,979 shares of common stock (including 1,605,483 shares of common stock being offered pursuant to this prospectus) and 321,098 shares of common stock underlying warrants (all being offered pursuant to this prospectus).

Also includes the following securities held by the following stockholders:

Alfred E. Mann: 180,729 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2005;

Mannco LLC: 10,968 shares of common stock; and

Biomed Partners II, LLC: 2,406,027 shares of common stock.

The Alfred E. Mann Living Trust and Minimed Infusion, Inc. are the managing members of each of Biomed Partners, LLC and Biomed Partners II, LLC. Alfred E. Mann, as trustee of the Alfred E. Mann Living Trust and through his control of Mannco LLC and Minimed Infusion, Inc., has voting and dispositive power over the shares held by the Alfred E. Mann Living Trust, Biomed Partners, LLC, Biomed Partners II, LLC and Mannco LLC. Alfred E. Mann is our Chief Executive Officer and Chairman of our Board of Directors.

(3) Comprises the following securities held by the following selling stockholders:

Amaranth Global Equities Master Fund Limited: 534,263 shares of common stock (including 34,263 shares of common stock being offered pursuant to this prospectus) and 6,853 shares of common stock underlying warrants (all being offered pursuant to this prospectus); and

Amaranth LLC: 4,808,371 shares of common stock (including 308,371 shares of common stock being offered pursuant to this prospectus) and 61,674 shares of common stock underlying warrants (all being offered pursuant to this prospectus).

Amaranth Advisors L.L.C. is the trading advisor to both Amaranth Global Equities Master Fund Limited and Amaranth LLC and has voting and investment control over the securities held by both entities. Nicholas M. Maounis is the managing member of Amaranth Advisors L.L.C. Each of Amaranth Securities L.L.C. and Amaranth Global Securities Inc. is a broker-dealer registered pursuant to Section 15(b) of the Exchange Act and is a member of the National Association of Securities Dealers, Inc. (the NASD). Each such broker-dealer may be deemed to be an affiliate of Amaranth Advisors L.L.C. Neither Amaranth Securities L.L.C. nor Amaranth Global Securities Inc. is authorized by the NASD to engage in securities offerings either as an underwriter or as a selling group participant and neither Amaranth Securities L.L.C. nor Amaranth Global Securities Inc. actually engages in any such activity. See Footnote 18.

(4) Comprises 293,686 shares of common stock and 58,737 shares of common stock underlying warrants, all of which shares are being offered pursuant to this prospectus. Balyasny Asset Management and Jacob Gottlieb share voting and investment control over the securities held by Atlas Master Fund, Ltd.

(5) Comprises 1,272,639 shares of common stock and 254,528 shares of common stock underlying warrants, all of which shares are being offered pursuant to this prospectus. Domenic Ferrante is the sole managing member of Brookside Capital Management, LLC, which in turn, is the general partner of Brookside Capital Investors, L.P., which in turn, is the sole general partner of Brookside Capital Partners Fund, L.P. Mr. Ferrante, Brookside Capital Management, LLC and Brookside Capital Investors, L.P. may each be deemed to share voting or investment control over the securities held by Brookside Capital Partners Fund, L.P. and disclaim beneficial ownership of such securities except to the extent of their pecuniary interests therein.

(6) Comprises the following securities held by the following selling stockholders, all of which are being offered pursuant to this prospectus:

D3 LifeScience Ltd.: 105,554 shares of common stock and 21,111 shares of common stock underlying warrants;

D3 LifeScience Market Neutral Ltd.: 58,900 shares of common stock and 11,780 shares of common stock underlying warrants; and

D3 LifeScience Select Ltd.: 31,337 shares of common stock and 6,267 shares of common stock underlying warrants.

D3 Capital Management, LLC is the investment manager of each of D3 LifeScience Ltd., D3 LifeScience Market Neutral Ltd. and D3 LifeScience Select Ltd. and has voting and investment control over the securities held by each of the foregoing entities. Nathan Fischel, MD, CFA is the managing member of D3 Capital Management, LLC.

(7) Includes 407,245 shares of common stock and 81,449 shares of common stock underlying warrants, all of which shares are being offered pursuant to this prospectus.

(8) Includes 375,918 shares of common stock and 75,184 shares of common stock underlying warrants, all of which shares are being offered pursuant to this prospectus.

(9) Comprises the following securities held by the following selling stockholders:

Fidelity Contrafund (Contrafund): 2,118,528 shares of common stock (including 1,521,689 shares of common stock being offered pursuant to this prospectus) and 304,338 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

Fidelity Contrafund: Fidelity Advisor New Insights Fund (New Insights Fund): 208,006 shares of common stock (including 149,406 shares of common stock being offered pursuant to this prospectus) and 29,881 shares of common stock underlying warrants (all being offered pursuant to this prospectus); and

Variable Insurance Products Fund II: Contrafund Portfolio (Variable Insurance Fund): 603,741 shares of common stock (including 433,653 shares of common stock being offered pursuant to this prospectus) and 86,731 shares of common stock underlying warrants (all being offered pursuant to this prospectus).

Contrafund, New Insights Fund and Variable Insurance Fund (collectively the Funds and each individually a Fund) are each a registered investment fund advised by Fidelity Management & Research Company (Fidelity), a wholly owned subsidiary of FMR Corp. and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940. Fidelity is the beneficial owner of 3,351,225 shares of our common stock as a result of acting as investment advisor to various investment companies registered under Section 8 of the Investment Company Act of 1940, including each of the Funds. Edward C. Johnson 3d, FMR Corp. through its control of Fidelity and each Fund, each has sole power to dispose of the securities owned by each Fund. Neither FMR Corp. nor Mr. Johnson has the sole power to vote or direct the voting of the shares owned directly by each Fund, which power resides with the applicable Fund s Board of Trustees. Each Fund is an affiliate of a broker-dealer. See Footnote 18.

(10) Comprises:

14,895 shares of common stock held by the Edstrom Family Trust (including 4,895 shares of common stock being offered pursuant to this prospectus) and 979 shares of common stock underlying warrants held by the Edstrom Family Trust (all being offered pursuant to this prospectus);

3,228 shares of common stock held by Hakan Edstrom; and

310,988 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2005 by Hakan Edstrom.

Hakan Edstrom is our President and Chief Operating Officer and voting and investment control over the securities held by the Edstrom Family Trust.

(11) Comprises:

30,500 shares of common stock (including 10,500 shares of common stock being offered pursuant to this prospectus) held by the Kresa Family Trust and 2,100 shares of common stock underlying warrants held by the Kresa Family Trust (all being offered pursuant to this prospectus); and

17,500 shares of common stock issuable upon the exercise of options within 60 days of August 15, 2005 by Kent Kresa.

Kent Kresa is a member of the Compensation Committee of our Board of Directors. As trustee of the Kresa Family Trust, Mr. Kresa has voting and investment control over the securities held by the trust.

(12) Comprises 391,582 shares of common stock and 78,316 shares of common stock underlying warrants, all of which shares are being offered pursuant to this prospectus. Kings Road Investments Ltd. is a wholly-owned subsidiary of Polygon Global Opportunities Master Fund. Polygon Investment Partners LLP, Polygon Investment Partners LP and Polygon Investments Ltd., as investment managers; Polygon Global Opportunities

Master Fund; Alexander Jackson; Reade Griffith; and Paddy Dear share voting and investment control over the securities held by Kings Road Investments Ltd. Alexander Jackson, Reade Griffith and Paddy Dear control Polygon Investment Partners LLP, Polygon Investment Partners LP and Polygon Investments Ltd. Polygon Investment Partners LLP, Polygon Investment Partners LP and Polygon Investments Ltd. disclaim beneficial ownership of the securities held by Kings Road Investments Ltd.

(13) Comprises the following securities held by the following selling stockholders, all of which are being offered pursuant to this prospectus:

Narragansett I, LP: 297,602 shares of common stock and 59,521 shares of common stock underlying warrants; and

Narragansett Offshore, Ltd: 485,561 shares of common stock and 97,112 shares of common stock underlying warrants.

Narragansett Management, LP is the investment manager of Narragansett I, LP and Narragansett Offshore, Ltd. and has voting and investment control over the securities held by each of the foregoing entities. Joseph L. Dowling, III is the managing member of the general partner of Narragansett Management, LP.

(14) Includes 785,359 shares of common stock (including 440,529 shares of common stock being offered pursuant to this prospectus) held by Oracle U.S. Partners, LLC and 88,106 shares of common stock underlying warrants held by Oracle U.S. Partners, LLC (all being offered pursuant to this prospectus). Larry N. Feinberg is the managing member of Oracle U.S. Partners, LLC and has voting and investment control over the securities held by Oracle U.S. Partners, LLC. Alfred E. Mann is an investor in Oracle U.S. Partners, LLC.

(15) Comprises the following securities held by the following selling stockholders, all of which are being offered pursuant to this prospectus:

Aries Domestic Fund, L.P.: 41,850 shares of common stock and 8,370 shares of common stock underlying warrants;

Aries Domestic Fund II, L.P.: 7,342 shares of common stock and 1,468 shares of common stock underlying warrants;

Aries Master Fund II: 24,229 shares of common stock and 4,846 shares of common stock underlying warrants; and

RAQ, LLC: 73,422 shares of common stock and 14,685 shares of common stock underlying warrants.

Lindsay A. Rosenwald, M.D. is the sole stockholder, Chairman and Chief Executive Officer of Paramount BioCapital Asset Management, Inc. and managing member of RAQ, LLC. Paramount BioCapital Asset Management, Inc. is the general partner to each of Aries Domestic Fund, L.P. and Aries Domestic Fund II, L.P., and investment manager of the Aries Master Fund II. Dr. Rosenwald has voting and investment control over the securities held by Aries Domestic Fund, L.P., Aries Domestic Fund II, L.P., Aries Master Fund II and RAQ, LLC. Dr. Rosenwald is also Chairman, Chief Executive Officer and sole stockholder of Paramount BioCapital, Inc., a NASD member broker-dealer. See Footnote 18.

(16) Comprises the following securities held by the following selling stockholders:

John Hancock Trust Health Sciences Trust: 37,700 shares of common stock (including 21,000 shares of common stock being offered pursuant to this prospectus) and 4,200 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

Raytheon Company Combined DB/DC Master Trust Health Sciences: 8,800 shares of common stock (including 4,900 shares of common stock being offered pursuant to this prospectus) and 980 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

T. Rowe Price New Horizons Fund, Inc.: 314,000 shares of common stock and 62,800 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

T. Rowe Price Health Sciences Fund, Inc.: 230,000 shares of common stock (including 130,000 shares of common stock being offered pursuant to this prospectus) and 26,000 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

T. Rowe Price Health Sciences Portfolio, Inc.: 1,600 shares of common stock (including 900 shares of common stock being offered pursuant to this prospectus) and 180 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

TA IDEX T. Rowe Price Health Sciences: 55,124 shares of common stock (including 30,624 shares of common stock being offered pursuant to this prospectus) and 6,125 shares of common stock underlying warrants (all being offered pursuant to this prospectus);

TD Mutual Funds TD Health Sciences Fund: 30,800 shares of common stock (including 22,000 shares of common stock being offered pursuant to this prospectus) and 4,400 shares of common stock underlying warrants (all being offered pursuant to this prospectus); and

VALIC Company I Health Sciences Fund : 27,300 shares of common stock (including 15,000 shares of common stock being offered pursuant to this prospectus) and 3,000 shares of common stock underlying warrants (all being offered pursuant to this prospectus).

T. Rowe Price Associates, Inc. serves as investment advisor with power

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to direct investments and/or sole power to vote the shares owned by the foregoing funds, as well as shares owned by certain other individual and institutional investors. For purposes of the reporting requirements of the Exchange Act, T. Rowe Price Associates, Inc. may be deemed to be the beneficial owner of all of the shares set forth next to name on the table above; however, T. Rowe Price Associates, Inc. expressly disclaims all beneficial ownership of such securities. T. Rowe Price Associates, Inc. is a wholly owned subsidiary of T. Rowe Price Group, Inc., which is a publicly traded financial services holding company.

(17) Comprises 195,791 shares of common stock and 39,158 shares of common stock underlying warrants, all of which shares are being offered pursuant to this prospectus. Kevin C. Tang, as managing member, has voting and investment control over the securities held by Tang Capital Partners, LP.

(18) Selling stockholders who are registered broker-dealers are deemed to be underwriters within the meaning of the Securities Act. In addition, selling stockholders who are affiliates of registered broker-dealers may be deemed to be underwriters within the meaning of the Securities Act if such selling stockholder (a) did not acquire its shares being offered in the ordinary course of business or (b) had any agreement or understanding, directly or indirectly, with any person to distribute the securities. To our knowledge, no selling stockholder who is a registered broker-dealer or an affiliate of a registered broker-dealer received any securities as underwriting compensation. Each selling stockholder purchased the shares of common stock and the warrants in the private placement in the ordinary course of such stockholder s business and, at the time of the purchase of such securities did not have any agreements or understandings, directly or indirectly, with any person to distribute the shares or warrants.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, automated interdealer quotation system, market or trading facility on which the shares are traded, in the over-the-counter market, or in private transactions. These dispositions may be at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to prevailing market prices, at varying prices determined at the time of sale or at prices otherwise negotiated. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The selling stockholders may sell the securities using one or more, or a combination of the following methods:

on The Nasdaq National Market (or any other exchange on which the shares may be listed);

on the over-the-counter market;

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker or dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

through the distribution of the common stock by any selling stockholders to its partners, members or stockholders;

through one or more underwritten offerings on a firm commitment or best efforts basis;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law

In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under a supplement to this prospectus under Rule 424(b) or under any applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors-in-interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances,

in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus. To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

In connection with distributions of the shares of our common stock or interests therein, the selling stockholders, other than entities affiliated with Alfred E. Mann, may enter into hedging transactions with broker-dealers or other financial institutions, which institutions may, in turn, engage in short sales of shares of our common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders may also sell the shares of our common stock

short and redeliver these shares to close out the selling stockholders short positions, or loan or pledge shares of our common stock to broker-dealers that may in turn sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares of our common stock offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the shares of common stock offered by them will be the purchase price of the shares less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders may engage brokers and dealers, and any brokers or dealers may arrange for other brokers or dealers to participate in effecting sales of the securities. These brokers, dealers or underwriters may act as principals, or as an agent of a selling securityholder. Broker-dealers may agree with a selling stockholder to sell a specified number of the securities at a stipulated price per security. If the broker-dealer is unable to sell securities acting as agent for a selling stockholder, it may purchase as principal any unsold securities at the stipulated price. Broker-dealers who acquire securities as principals may thereafter resell the securities from time to time in transactions in any stock exchange or automated interdealer quotation system on which the securities are then listed, at prices and on terms then prevailing at the time of sale, at prices related to the then-current market price or in negotiated transactions. Broker-dealers may use block transactions and sales to and through broker-dealers, including transactions of the nature described above.

To the extent required under the Securities Act of 1933, the aggregate amount of selling stockholders securities being offered and the terms of the offering, the names of any agents, brokers, dealers or underwriters and any applicable commission with respect to a particular offer will be set forth in an accompanying prospectus supplement. Any underwriters, dealers, brokers or agents participating in the distribution of the securities may receive compensation in the form of underwriting discounts, concessions, commissions or fees from a selling stockholder and/or purchasers of selling stockholders securities of securities, for whom they may act (which compensation as to a particular broker-dealer might be in excess of customary commissions).

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the shares of common stock or interests therein may be underwriters within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are underwriters within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We will bear substantially all of the costs, expenses and fees in connection with the registration of the shares of common stock, other than any commissions, discounts or other fees payable to broker-dealers in connection with any sale of shares, which will be borne by the selling stockholder selling such shares of common stock. We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

In order to comply with the securities laws of some states, if applicable, the shares of common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the shares may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares of our common stock in the market and to the activities of the selling stockholders. These rules may limit the timing of purchases and sales of the shares by such selling stockholders.

We will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act.

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We have agreed with each selling stockholder to keep the registration statement of which this prospectus constitutes a part effective with respect to its shares of our common stock until the earlier of (1) August 5, 2007 and (2) the date on which all shares purchased from us, or acquirable upon exercise of warrants purchased from us, during any 90 day period by such selling stockholder in the private placement may be sold pursuant to Rule 144 of the Securities Act.

LEGAL MATTERS

Cooley Godward LLP, San Diego, California, has given its opinion to us as to certain legal matters relating to the validity of the shares of our common stock offered by the selling stockholders in this prospectus

EXPERTS

The financial statements as of December 31, 2004 and 2003 and for each of the three years ending in the period ended December 31, 2004 and for the period from February 14, 1991 (date of inception) to December 31, 2004, incorporated in this prospectus by reference from the Company s Annual Report on Form 10-K for the year ended December 31, 2004 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and we file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement under the Securities Act with respect to the common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules which are part of the registration statement. For further information with respect to us and the common stock offered by this prospectus by the selling stockholders, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. You may read and copy any document we file at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available to the public from the SEC s website at *http://www.sec.gov*. We maintain a website at www.mannkindcorp.com.

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the following documents we filed with the SEC pursuant to Section 13 of the Exchange Act:

Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2005 Annual Meeting of Stockholders);

Quarterly Reports on Form 10-Q for the quarters ended June 30, 2005 and March 31, 2005;

Current Reports on Form 8-K filed on February 23, 2005, March 21, 2005, June 8, 2005, June 23, 2005, August 5, 2005, and August 18, 2005;

Description of our common stock contained in our registration statement on Form 8-A dated July 23, 2004; and

All documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering.

You may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statement, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at the SEC s website or our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website does not constitute incorporation by reference of the information contained in our website. We do not consider information contained on, or that can be accessed through, our website to be part of this prospectus.

You may request a copy of our SEC filings at no cost, by writing or telephoning us at the following address:

Investor Relations
MannKind Corporation
28903 North Avenue Paine
Valencia, CA 91355
(661) 775-5300

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the various costs and expenses, payable by us in connection with the offering of common stock being registered. All the amounts shown are estimates except for the SEC registration fee.

	Amount to Be Paid
Registration fee	$ 29,956
Legal fees and expenses	30,000
Accounting fees and expenses	40,000
Printing and engraving expenses	5,500
Miscellaneous	4,544
Total	$ 110,000

Item 15. Indemnification of Directors and Officers.

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 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.

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;

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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.

Item 16. Exhibits.

Exhibit Number	Description
4.1	Form of common stock certificate of registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-115020).
4.2	Form of Warrant to Purchase Common Stock issued to purchasers in private placement on August 5, 2005 (incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed August 5, 2005).
5.1	Opinion of Cooley Godward LLP.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Cooley Godward LLP is contained in Exhibit 5.1 to this Registration Statement on Form S-3.
24.1	Power of Attorney is contained on the signature page of this Registration Statement on Form S-3.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Securities

Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

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 Securities 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 Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

MANNKIND CORPORATION

By: /s/ Alfred E. Mann

Alfred E. Mann
Chief Executive Officer and
Chairman

Date: September 2, 2005

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hakan S. Edstrom, Richard L. Anderson and David Thomson, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all pre-effective and post-effective amendments to this registration statement, and any other documents in connection therewith, and to file the same, with all exhibits thereto, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below 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*)	September 1, 2005
/s/ Hakan S. Edstrom Hakan S. Edstrom	President, Chief Operating Officer and Director	September 1, 2005
/s/ Richard L. Anderson Richard L. Anderson	Corporate Vice President and Chief Financial Officer (*Principal Financial and Accounting Officer*)	September 1, 2005
/s/ Kathleen Connell, Ph.D. Kathleen Connell, Ph.D.	Director	September 1, 2005
/s/ Ronald Consiglio Ronald Consiglio	Director	September 1, 2005
/s/ Llew Keltner M.D., Ph.D.	Director	September 1, 2005

Llew Keltner M.D., Ph.D.		
/s/ Michael Friedman, M.D.	Director	September 1, 2005
Michael Friedman, M.D.		

Signature	Title	Date
/s/ Kent Kresa Kent Kresa	Director	September 1, 2005
/s/ David H. MacCallum David H. MacCallum	Director	September 1, 2005
/s/ Henry L. Nordoff Henry L. Nordoff	Director	September 1, 2005

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