MANNKIND CORP
Form 10-K
March 15, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 000-50865.

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

Registrant s telephone number, including area code

(661) 775-5300

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:

None

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No þ

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer þ	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No þ

As of June 30, 2011, the aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the last sale price of such stock as of such date on the NASDAQ Global Market, was approximately $197,471,688.

As of March 2, 2012, there were 167,465,888 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement, or the Proxy Statement, for the 2012 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III of this Annual Report on Form 10-K.

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MANNKIND CORPORATION

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2011

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Forward-Looking Statements

Statements in this report that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements about: the progress or success of our research, development and clinical programs, including the application for and receipt of regulatory clearances and approvals, and the timing or success of the commercialization of AFREZZA, if approved, or any other products or therapies that we may develop; our ability to market, commercialize and achieve market acceptance for AFREZZA, 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; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; and scientific studies and the conclusions we draw from them. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, goal, intends, may, plans, predicts, projects, should, will, would, and similar expressions intended to identify forward-looking statements. These statements are only predictions or conclusions 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 Risks and Uncertainties That May Affect Results and elsewhere in this report. 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 otherwise.

AFREZZA®, MedTone®, Dreamboat and Technosphere® are our trademarks in the United States. We have also applied for or have 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.

PART I

Item 1. ***Business***

Unless the context requires otherwise, the words MannKind, we, company, us and our refer to MannKind Corporation and its subsidiaries. Unless explicitly stated otherwise, AFREZZA refers to the combination of AFREZZA inhalation powder and the AFREZZA inhaler.

MannKind Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead product candidate, AFREZZA (insulin human [rDNA origin]) inhalation powder, is an ultra rapid-acting insulin that is in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. Diabetes is a significant health concern. According to the Centers for Disease Control and Prevention, in the United States in 2011, approximately 25.8 million people had diabetes and if current trends continue, one in three adults in the United States are expected to have diabetes by 2050. The International Diabetes Federation has estimated that approximately 366 million people have diabetes today; by 2030 this is expected to have risen to approximately 552 million.

PRODUCT PIPELINE

Our lead product candidate, AFREZZA, has a time-action profile unlike other insulin products. In our clinical trials to date, we have consistently observed that AFREZZA inhalation powder is rapidly absorbed into the bloodstream following inhalation, reaching peak levels within 12 to 14 minutes. In this manner, AFREZZA produces a profile of insulin levels in the bloodstream that closely approximates the early insulin secretion normally seen in healthy individuals immediately following the beginning of a meal, but which is absent in patients with diabetes.

The AFREZZA inhalation powder is centered on a class of pH-sensitive organic molecules that self-assemble into small particles under acidic conditions. We refer to these particles as Technosphere particles. Certain drugs,

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such as insulin, can be loaded onto these particles by combining an acidic solution of the drug with a suspension of Technosphere material, which is then dried to a powder. This powder is then filled into plastic cartridges and packaged. To administer AFREZZA inhalation powder, a patient loads a cartridge into our inhaler. By inhaling through this device, air is pulled through the cartridge, which aerosolizes the powder and pulls the particles into the air current and out through the mouthpiece. The individual particles within this aerosol are small and have aerodynamic properties that enable them to fly efficiently deep into the lungs. When the particles contact the moist lung surface with its neutral pH, the Technosphere particles dissolve immediately, releasing the insulin molecules to diffuse across a thin layer of cells into the bloodstream. We believe that the insulin absorption step is a passive process that occurs without any active assistance or enhancement and without disruption of either cell membranes or the tight junctions between cells.

To date, the AFREZZA clinical program has involved 61 different studies of AFREZZA and over 5,600 adult patients. In our clinical studies, we observed that AFREZZA produces the following clinical benefits:

Consistent decreases in A1C levels, comparable to current insulin therapies. In a number of clinical studies involving patients with type 1 and type 2 diabetes, we have evaluated levels of glycosylated hemoglobin, or A1C, which is a measure of average blood glucose. A consistent finding was that AFREZZA produced decreases in A1C levels that were essentially comparable to the decreases observed in the control arm of these studies, including studies that compared AFREZZA to rapid-acting insulin analogs, to pre-mixed insulin analogs and to metformin in combination with a sulfonylurea.

Superior post-meal glucose control. Because AFREZZA inhalation powder has a shorter duration of action we believe that its glucose-lowering effect better meets a patient s needs following a meal than other available insulin therapies. Specifically, AFREZZA treatment produces lower blood glucose levels than comparators in the first hour following meal ingestion with comparable levels after two hours. Importantly, AFREZZA does not remain active for an extended period of time, thereby reducing the risk of hypoglycemia between meals.

Improved fasting glucose control. In clinical trials of both type 1 and type 2 diabetes, AFREZZA has consistently provided lower fasting blood glucose levels than comparator insulin therapies. As we reported with external authors in a report of one of our earlier Phase 3 studies that was reported in The Lancet in 2010, this observation might be the result of greater suppression of endogenous glucose production with AFREZZA plus a basal insulin than with a conventional insulin regimen.

Less hypoglycemia due to better synchronization with glucose absorption from meals. In clinical trials involving patients with type 2 diabetes, we observed that the incidence and frequency of hypoglycemia was significantly reduced. Similar results were observed in patients with type 1 diabetes. The overall hypoglycemic event rate was lower for AFREZZA at all times of the day, but in particular, there were fewer nocturnal hypoglycemic events, a condition much feared by patients with diabetes.

Little or no weight gain. In our clinical trials, patients treated with AFREZZA experienced weight reduction or significantly less weight gain compared to other insulin therapies.

There are no assurances, however, that these or any other advantages of AFREZZA will be agreed to by the US Food and Drug Administration, or FDA, or otherwise included in final product labeling or advertising.

To date, our clinical trials have indicated that AFREZZA has a favorable safety profile. The most common adverse event associated with AFREZZA therapy was a transient, mild and non-productive cough, which occurred early in about 25-30% of subjects and diminished within the first few weeks after initiation of AFREZZA therapy. The occurrence of mild cough is well recognized with inhaled medications. In our studies, the incidence of cough leading to the discontinuation of AFREZZA was low.

After a two-year Phase 3 clinical trial of AFREZZA, we determined that the use of AFREZZA in patients with diabetes was non-inferior to usual diabetes care with respect to a decline in FEV1, a measure of lung function that assesses the volume of air that can be forcibly expired within one second. Similar results were obtained for other measures of lung function.

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Our clinical trials for AFREZZA have not demonstrated an increased risk of pulmonary cancer. In addition, we conducted comprehensive nonclinical studies of AFREZZA and unloaded Technosphere particles, including a two-year rat carcinogenicity study and a six-month transgenic mouse study. These studies indicated that there was no increased risk of cancer, or any other pathological effects.

Regulatory Approval Status

In March 2009, we submitted a new drug application, or NDA, for AFREZZA, in which we sought approval of the product using MedTone, our first-generation inhaler. In March 2010, we received a Complete Response letter from the FDA that requested additional information and currently available clinical data to support the clinical utility of AFREZZA as well as information about the comparability of the commercial version of the MedTone inhaler to the earlier version of this device that was used in pivotal clinical trials. After meeting with the FDA in June 2010, we determined that the best way to address the agency s inhaler-related questions was to submit information regarding the bioequivalence of the MedTone inhaler and our next-generation inhaler, known as Dreamboat, which by that time had become our preferred device from a clinical and commercial perspective, given that it is smaller, easier to use and lower in cost than the MedTone inhaler. In June 2010, we submitted to the FDA the available bioequivalency data for the two devices along with additional evidence of efficacy of AFREZZA as part of our response to the 2010 Complete Response letter.

In January 2011, we received a second Complete Response letter in which the FDA requested that we conduct two clinical studies with the Dreamboat inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one trial including a treatment group using the MedTone inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices. Over the next eight months, we participated in a number of written and verbal exchanges with the FDA in order to clarify the agency s requirements for approval of AFREZZA, culminating in an in-person meeting in August 2011 in which we confirmed with the FDA the designs of the two requested studies.

The study in patients with type 1 diabetes, known as study 171, is an open-label study in which all patients are first optimized on their basal insulin regimen before being randomized to one of three arms: a control arm, in which patients utilize an injected insulin analog at mealtimes, or one of two AFREZZA arms, one each for our MedTone device and our Dreamboat device. After the mealtime insulin is titrated, there will be a 12-week observation period on relatively stable doses of the mealtime insulin to assess A1c levels. The primary endpoint is to show non-inferiority of the change in A1c levels in the Dreamboat group compared to the injected insulin analog group. The inclusion of two AFREZZA arms will permit us to perform a head-to-head comparison of the pulmonary safety data for the two devices, which we anticipate will provide a bridge to the extensive safety data that we collected in our earlier clinical studies of the MedTone inhaler. The basic design of this study (comparing different mealtime insulins in combination with a basal insulin regimen) is similar in design to a previous Phase 3 study that we conducted in patients with type 1 diabetes using our MedTone inhaler.

The other requested study, known as study 175, is a placebo-controlled study in patients with type 2 diabetes who are inadequately controlled on metformin with or without a second or third oral medication. Patients are assigned to treatment with AFREZZA or placebo powder in a randomized fashion. There is a titration period followed by a 12-week observation period to assess A1c levels. The primary objective of this study is to show superiority of the AFREZZA group over the placebo group in lowering A1c levels. We have previously compared AFREZZA to placebo powder in successful Phase 2 studies involving patients with type 2 diabetes using the MedTone inhaler.

Both studies are currently enrolling subjects. If enrollment continues as expected, we anticipate completing both of these studies by or near the end of 2012. We then would expect to submit the results to the FDA as an amendment to our NDA during the first half of 2013. However, the data collected from these clinical trials may not reach statistical significance or otherwise be sufficient to support an amendment to our NDA, or FDA approval. Moreover, there can be no assurance that we will satisfy all of the FDA s requirements with these two clinical studies or that the FDA will ultimately find our proposed approach to these clinical studies acceptable. The FDA could also request that we conduct additional clinical studies beyond the currently planned studies in order to provide sufficient data for approval of AFREZZA.

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Other Product Opportunities

AFREZZA utilizes our proprietary Technosphere formulation technology; however, this technology is not limited to insulin delivery. We believe it represents a versatile drug delivery platform that may allow pulmonary administration of certain drugs that currently require administration by injection. Beyond convenience, we believe the key advantage of drugs inhaled as Technosphere formulations is that they can be absorbed very rapidly into the arterial circulation, essentially mimicking intra-arterial administration. Currently, we are actively working with several parties to assess the feasibility of formulating different active ingredients on Technosphere particles. Additionally, our inhaler technology has been well received and has the potential to be utilized for the administration of dry powder formulations for various other applications.

In addition to our Technosphere platform, we have evaluated an investigational cancer immunotherapy product, MKC1106-MT, in a Phase 2 clinical trial. We have also conducted preclinical studies of a drug candidate, MKC204, that may have the potential to treat certain malignancies and inflammatory diseases. Due to resource constraints, we have halted most of our internal development activities in our non-AFREZZA programs.

OUR STRATEGY

The following are key elements of our strategy:

Complete the remaining clinical studies and gain FDA approval of AFREZZA. We have confirmed with the FDA the design of the two requested clinical studies to evaluate the efficacy and safety of AFREZZA and are actively recruiting patients into these studies. If enrollment continues at current levels, we expect to complete both of these studies by or near the end of 2012. We then would expect to submit the results to the FDA as an amendment to our NDA during the first half of 2013.

Seek a development and commercialization partner for AFREZZA. We intend to pursue potential collaboration opportunities with large pharmaceutical companies in the United States, Europe and elsewhere in order to provide the financial and operational resources to develop, commercialize, market and sell AFREZZA. We have not licensed or transferred any of our rights to this product or to our platform technology.

Capitalize on our proprietary Technosphere and inhaler technology for the delivery of active pharmaceutical ingredients. We are actively exploring opportunties to out-license our proprietary Technosphere formulation technology. We believe that Technosphere formulations of active pharmaceutical ingredients have the potential to demonstrate clinical advantages over existing therapeutic options in a variety of therapeutic areas. Additionally, our inhaler technology has been well received and has the potential to be utilized for the administration of dry powder formulations for various other applications.

SALES AND MARKETING

Our efforts to date have primarily been directed at developing pharmaceutical products for a number of different markets. We currently have no sales or distribution capabilities and have no experience as a company in marketing or selling pharmaceutical products. However, we have built a small marketing team and are engaged in the planning and market research activities that would normally be undertaken to support the late-stage development of a pharmaceutical product.

In order to commercially market any of our products, we need either to develop an internal sales team, continue to expand our marketing infrastructure or collaborate with third parties who have greater sales and marketing capabilities and have access to potentially large markets. Although we believe that establishing our own sales and marketing organizations in North America would have substantial advantages, we recognize that this may not be practical for some of our products and that collaborating with companies with established sales and marketing capabilities in a particular market or markets may be a more effective alternative for some products. To date, we have retained worldwide commercialization rights for all of our product candidates, including AFREZZA. We intend to pursue potential collaboration opportunities to assist us in the commercialization of AFREZZA in the United States and other major markets.

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MANUFACTURING AND SUPPLY

We formulate and fill the AFREZZA inhalation powder into plastic cartridges and blister package the cartridges in our Danbury facility. We believe that our Danbury facility has enough capacity to satisfy the initial commercial demand for AFREZZA, if approved, although the facility includes expansion space that can allow production capacity to be increased based on anticipated needs during the initial years of commercialization. The quality management systems of our facility were certified to be in conformance with the ISO 13485 and ISO 9001 standards. In addition, our facility underwent a successful pre-approval inspection by the FDA during the fall of 2009. A portion of this pre-approval inspection was related to our ability to fill and package cartridges for the MedTone inhaler. We anticipate that our facility may need to undergo another successful pre-approval inspection related to our ability to fill and package cartridges for the next-generation inhaler before the FDA will approve the NDA for AFREZZA using the Dreamboat inhaler.

Currently, our insulin inventory is from two sources. In June 2011, we entered into a letter agreement with N.V. Organon, a subsidiary of Merck, to settle a dispute that arose between us and Organon in connection with the termination by us of the insulin supply agreement between us and Organon dated November 2007. Under the terms of the letter agreement, we agreed to pay Organon an aggregate of $16.0 million in two installments, after we received certain quantities of recombinant human insulin manufactured and supplied by Organon. The letter agreement is in full and final settlement of, and we and Organon agreed to release each other from, any and all actions and claims that we and Organon had or may have against each other in connection with the dispute regarding the supply agreement and related matters. As of July 31, 2011, we had received both shipments of recombinant human insulin and had paid the full amount of $16.0 million.

In June 2009, we acquired a quantity of bulk insulin from Pfizer Manufacturing Frankfurt GmbH, a subsidiary of Pfizer Inc., or Pfizer, as well as Pfizer s rights under a license to manufacture insulin for pulmonary delivery. In addition, we acquired an option to purchase additional insulin inventory, in whole or in part, at a specified price, to the extent it remains available.

Once we have used our existing supply of insulin, we will need to secure additional insulin from market sources.

We are in the process of qualifying a manufacturer to supply us with our Dreamboat inhaler and the corresponding cartridges. We rely on our manufacturers to comply with relevant regulatory requirements, including compliance with Quality System Regulations, or QSRs.

Currently, we purchase the raw material from which we produce Technosphere particles from a major chemical manufacturer with facilities in Europe and North America. We also have the capability of manufacturing this chemical ourselves in our Danbury facility, which is treated as a back-up facility. Like us, our third-party manufacturers are subject to extensive governmental regulation.

INTELLECTUAL PROPERTY AND PROPRIETARY TECHNOLOGY

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

Our Technosphere drug delivery platform, including AFREZZA, enjoys patent protection relating to the particles, their manufacture, and their use for pulmonary delivery of drugs. We have additional patent coverage relating to the treatment of diabetes using AFREZZA. We have been granted patent coverage for our inhaler and cartridges in the form in which we expect our insulin product to be sold to the consumer, if and when approved by the FDA. We have additional pending patent applications, and expect to file further applications, relating to the drug delivery platform, methods of manufacture, the AFREZZA product and its use, and other Technosphere-

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based products, inhalers and inhaler cartridges. Overall, AFREZZA is protected by over 300 issued patents, and we also have over 300 pending applications in the United States and selected jurisdictions around the world related to our Technosphere platform. These include composition and method of treatment patents providing protection for AFREZZA that will remain in force into 2020. In addition, patents providing protection for our inhaler and cartridges will remain in force into 2023, and we have certain treatment claims that can be maintained in force variously into 2026 and 2029.

In addition, we own or have in-licensed intellectual property relating to several drug targets of interest in the treatment of cancer and other fields. Patents and patent applications in this area are drawn to drug screening methods, methods of treatment, and chemical structures of inhibitors of these targets. Our cancer immunotherapy program is built on proprietary methods for the selection, design and administration of epitopes, as well as the plasmids and peptides that are the active ingredients of our product candidates.

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

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

Although we own a number of domestic and foreign patents and patent applications relating to our Technosphere-based investigational products and our cancer products under development, we have identified certain third-party patents having claims relating to pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of AFREZZA. We have also identified third-party patents disclosing methods and compositions of matter related to cancer vaccines that also may trigger an allegation of infringement upon the commercial manufacture and sale of our cancer immunotherapy. We believe that we are not infringing any valid claims of any patent owned by a third party. However, if a court were to determine that our inhaled insulin product or cancer immunotherapies were infringing any of these patent rights, we would have to establish with the court that these patents were invalid in order to avoid legal liability for infringement of these patents. Proving patent invalidity can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in an infringement or invalidity action we will either have to acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase costs and therefore may materially affect product profitability. Furthermore, if the patent holder refuses to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents. In either event, our business would be harmed and our profitability could be materially adversely impacted. If third parties file patent applications, or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of invention. We may be required to participate in interference proceedings involving our issued patents and pending applications.

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We also rely on trade secrets and know-how, which are not protected by patents, to maintain our competitive position. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of our relationship must be kept confidential, except in specified circumstances. These agreements also provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information.

We also execute confidentiality agreements with outside collaborators. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators apply technological information to our projects that are developed independently by them or others, or apply our technology to outside projects, and there can be no assurance that any such disputes would be resolved in our favor. In addition, any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

COMPETITION

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

Diabetes Treatments

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

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

Rapid-acting (Injected) Insulin

Currently, there is no approved insulin product that is absorbed into the bloodstream as rapidly as AFREZZA, i.e., reaching peak levels within 12 to 14 minutes after administration. There are several formulations of rapid-acting insulin analogs that claim to reach peak insulin levels within 30 to 90 minutes after injection. The principal products in this category are Humalog®, which was developed by Eli Lilly & Company, or Lilly, NovoLog®, which was developed by Novo Nordisk A/S, or Novo Nordisk, and Apidra®, which was developed by sanofi-aventis.

Several insulin products in development are reported to have a time-action profile that is more rapid than that of the currently available rapid-acting insulin analogs. Halozyme Therapeutics, Inc. has conducted Phase 2 clinical studies to evaluate the safety and efficacy of a formulation of human insulin or an insulin analog that is co-administered with human hyaluronidase enzyme. This enzyme temporarily degrades a naturally occurring, space-filling substance that is a major component of normal tissues throughout the body, thereby facilitating the penetration and diffusion of insulin that is injected under the skin.

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Novo Nordisk has conducted Phase 1 clinical studies of NN1218, an insulin analog that is intended to provide faster onset of action than the currently available rapid-acting insulin analogs.

Biodel, Inc. is developing ultra-rapid acting insulin formulations, one of which it has selected to study in a Phase 1 clinical trial that is scheduled to start in the first quarter of 2012.

Inhaled Insulin Delivery Systems

In January 2006, Exubera®, developed by Pfizer in collaboration with Nektar Therapeutics, was approved for the treatment of adults with type 1 and type 2 diabetes. Exubera® was slow to gain market acceptance and, in October 2007, Pfizer announced that it was discontinuing the product. In September 2008, we announced a collaboration agreement with Pfizer pursuant to which certain patients with a continuing medical need for inhaled insulin were transitioned to AFREZZA on a compassionate use basis. Pfizer subsequently withdrew the NDA for Exubera from the FDA.

In January 2008, Novo Nordisk announced that it was halting development of its inhaled insulin product, having reached the conclusion that the product did not have adequate commercial potential. Notwithstanding the termination of this program, Novo Nordisk stated that it intended to increase research and development activities targeted at inhalation systems for long-acting formulations of insulin and GLP-1 products.

In March 2008, Lilly announced that it was terminating the development of its AIR® inhaled insulin system. Lilly stated that this decision resulted from increasing uncertainties in the regulatory environment and after a thorough evaluation of the evolving commercial and clinical potential of its product compared to existing medical therapies.

In January 2011, Dance Pharma announced that it will develop an inhaled insulin product based on aerosol technology licensed to Dance Pharma by Aerogen Ltd.

Non-insulin Medications

We expect that AFREZZA will compete with currently available non-insulin medications for type 2 diabetes. These products include the following:

Sulfonylureas, also called oral hypoglycemic agents, prompt the pancreas to secrete insulin. This class of drugs is most effective in individuals whose pancreas still have some working pancreas cells.

Meglitinides are taken with meals and reduce the elevation in blood glucose that generally follows eating. If these drugs are not taken with meals, blood glucose will drop dramatically and inappropriately.

Biguanides lower blood glucose by improving the sensitivity of cells to insulin (*i.e.*, by diminishing insulin resistance).

Thiazolidinedione improves the uptake of glucose by cells in the body.

Alpha-glucosidase inhibitors lower the amount of glucose absorbed from the intestines, thereby reducing the rise in blood glucose that occurs after a meal.

Inhibitors of dipeptidyl peptidase IV are a class of drugs that work by blocking the degradation of GLP-1, which is a naturally occurring incretin.

Incretin mimetics work by several mechanisms including stimulating the pancreas to secrete insulin when blood glucose levels are high.

GOVERNMENT REGULATION AND PRODUCT APPROVAL

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of medical devices and new drug and biologic products. These agencies, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended, or FDCA, and other regulations, regulate research and development activities and the

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development, testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale and distribution of such products. In addition, if our products are marketed abroad, they also are subject to export requirements and to regulation by foreign governments. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including hold letters on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

The steps typically required before an unapproved new drug or biologic product for use in humans may be marketed in the United States include:

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

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

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

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

In Phase 1, the drug is initially introduced into a small number of individuals and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 1 clinical trials are often conducted in healthy human volunteers and such cases do not provide evidence of efficacy. In the case of severe or life-threatening diseases, the initial human testing is often conducted in patients rather than healthy volunteers. Because these patients already have the target disease, these studies may provide initial evidence of efficacy that would traditionally be obtained in Phase 2 clinical trials. Consequently, these types of trials are frequently referred to as Phase 1/2 clinical trials. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension or termination of clinical trials if it concludes that an unwarranted risk is presented to patients or healthy volunteers.

Phase 2 involves clinical trials in a limited patient population to further identify any possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3 clinical trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites. Phase 3 clinical trials usually include a broader patient population so that safety and efficacy can be substantially established. Phase 3 clinical trials cannot begin until Phase 2 evaluation demonstrates that a dosage range of the product may be effective and has an acceptable safety profile.

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Phase 4 clinical trials are performed if the FDA requires, or a company pursues, additional clinical trials after a product is approved. These clinical trials may be made a condition to be satisfied after a drug receives approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA s voluntary adverse drug reaction reporting system.

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

Submission to the FDA of an NDA, or Biologics License Application, or BLA, based on the clinical trials. The results of product development, preclinical studies, and clinical trials are submitted to the FDA in the form of an NDA or BLA for approval of the marketing and commercial shipment of the product. Under the Pediatric Research Equity Act of 2003, NDAs are required to include an assessment, generally based on clinical study data, of the safety and efficacy of drugs for all relevant pediatric populations. The statute provides for waivers or deferrals in certain situations but we can make no assurances that such situations will apply to us or our product candidates.

Medical products containing a combination of new drugs, biological products, or medical devices are regulated as combination products in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (*e.g.*, drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic, or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. The FDA considers AFREZZA to be a drug-device combination product, so the review of our NDA for AFREZZA involves reviews within the Division of Metabolism and Endocrinology Products and the Division of Pulmonary, Allergy and Rheumatology Products, both within the FDA s Center for Drug Evaluation and Research, or CDER, as well as review within the Center for Devices and Radiological Health, the Center within the FDA that reviews Medical Devices. CDER s Division of Metabolism and Endocrinology Products is the lead group and obtains consulting reviews from the other two FDA groups.

The testing and approval process requires substantial time, effort and financial resources. Data that we submit are subject to varying interpretations, and the FDA and comparable regulatory authorities in foreign jurisdictions may not agree that our product candidates have been shown to be safe and effective. We cannot be certain that any approval of our products will be granted on a timely basis, if at all. If any of our products are approved for marketing by the FDA, we will be subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with certain electronic records and signature requirements. Prior to and following approval, if granted, all manufacturing sites are subject to inspection by the FDA and other national regulatory bodies and must comply with cGMP, QSR and other requirements enforced by the FDA and other national regulatory bodies through their facilities inspection program. Foreign manufacturing establishments must comply with similar regulations. In addition, our drug-manufacturing facilities located in Danbury and the facilities of our insulin supplier, the supplier(s) of our Technosphere material and the supplier(s) of our inhaler and cartridges are subject to federal registration and listing requirements and, if applicable, to state licensing requirements. Failure, including those of our suppliers, to obtain and maintain applicable federal registrations or state licenses, or to meet the inspection criteria of the FDA or the other national regulatory bodies, would disrupt our

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manufacturing processes and would harm our business. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance. Currently, we believe we are operating under all of the necessary guidelines and permits.

As a drug-device combination, we currently expect that our inhaler will be approved, if at all, as part of the NDA for AFREZZA. However, numerous device regulatory requirements still apply to the device part of the drug-device combination. These include:

- product labeling regulations;
- general prohibition against promoting products for unapproved or off-label uses;
- corrections and removals (*e.g.*, recalls);
- establishment registration and device listing;
- general prohibitions against the manufacture and distribution of adulterated and misbranded devices; and
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Further, the company we contract with to manufacture our inhaler and cartridges will be subject to the QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process of medical devices, among other requirements.

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

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

Products manufactured in the United States and marketed outside the United States are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold. We also would be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are studied or marketed abroad. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries usually must be obtained prior to the marketing of the product in those countries. The approval process varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Product development and approval within this regulatory framework take a number of years, involve the expenditure of substantial resources and are uncertain. Many drug products ultimately do not reach the market

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

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

In addition to the foregoing, we are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, controlled drug substances, privacy of individually identifiable healthcare information, safe working conditions, manufacturing practices, environmental protection and fire hazard control. Further, if a drug product is reimbursed by Medicare, Medicaid or other federal or state health care programs, sales, marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, and similar state laws. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the PPACA establishes: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. In the future, there may continue to be additional proposals relating to the reform of the U.S. health care system, some of which could further limit the prices we are able to charge for our products, or the amounts of reimbursement available for our products. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. We may incur significant costs to comply with those laws and regulations now or in the future.

Patent Restoration and Marketing Exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, permits the FDA to approve abbreviated new drug applications, or ANDAs, for generic versions of innovator drugs and also provides certain patent restoration and market exclusivity protections to innovator drug manufacturers. The ANDA process permits competitor companies to obtain marketing approval for a new drug with the same active ingredient for the same uses, dosage form and strength as an innovator drug but does not require the conduct and submission of preclinical or clinical studies demonstrating safety and efficacy for that product. Instead of providing completely new safety and efficacy data, the ANDA applicant only needs to submit manufacturing information and clinical data demonstrating that the copy is bioequivalent to the innovator s product in order to gain marketing approval from the FDA.

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Another type of marketing application allowed by the Hatch-Waxman Amendments, a Section 505(b)(2) application, may be permitted where a company does not own or have a right to reference all the data required for approval. Section 505(b)(2) applications are often submitted for drug products that contain the same active ingredient as those in first approved drug products and where additional studies are required for approval, such as for changes in routes of administration or dosage forms.

Once an NDA is approved, the product covered thereby becomes a listed drug which can, in turn, be cited by potential competitors in support of approval of an ANDA or a 505(b)(2) application.

The Hatch-Waxman Amendments provide for a period of three years exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. During this period of exclusivity, the FDA cannot grant effective approval of an ANDA or a 505(b)(2) application based on that listed drug.

The Hatch-Waxman Amendments also provide a period of five years exclusivity following approval of a drug containing no previously approved active ingredients. During this period of exclusivity, ANDAs or 505(b)(2) applications based upon those drugs cannot be submitted unless the submission accompanies a challenge to a listed patent, in which case the submission may be made four years following the original product approval.

Additionally, in the event that the sponsor of the listed drug has informed the FDA of patents covering its listed drug and FDA lists those patents in the Orange Book, applicants submitting an ANDA or a 505(b)(2) application referencing that drug are required to certify whether they intend to market their generic products prior to expiration of those patents. If an ANDA applicant certifies that it believes one or more listed patents is invalid or not infringed, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If either party then initiates a suit for patent infringement against the ANDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA until either 30 months has passed or there has been a court decision holding that the patent in question is invalid or not infringed. If the ANDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then the FDA cannot grant effective approval of the ANDA until those patents expire. The first ANDA applicant submitting substantially complete applications certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days after a court decision of invalidity or non-infringement or after it begins marketing its product, whichever occurs first. During this 180 day period, subsequently submitted ANDAs cannot be granted effective approval.

Pediatric exclusivity, if granted, provides an additional six months of market exclusivity in the United States for new or currently marketed drugs if certain pediatric studies requested by the FDA are completed by the applicant and the applicant has other existing patent or exclusivity protection for the drug. To obtain this additional six months of exclusivity, it would be necessary for us to first receive a written request from the FDA to conduct pediatric studies and then to conduct the requested studies according to a previously agreed timeframe and submit the report of the study. There can be no assurances that we would receive a written request from the FDA and if so that we would complete the studies in accordance with the requirements for this six-month exclusivity. The current pediatric exclusivity provision is scheduled to end on October 1, 2012, and there can be no assurances that it will be reauthorized.

EMPLOYEES

As of December 31, 2011, we had 250 full-time employees. 12 of these employees were engaged in research and development, 91 in manufacturing, 81 in clinical, regulatory affairs and quality assurance and 65 in administration, finance, management, information systems, marketing, corporate development and human resources. 34 of these employees had a Ph.D. degree and/or M.D. degree and were engaged in activities relating to research and development, manufacturing, quality assurance and business development. A significant percentage of our operating expenses relates to research and development totaling $100.0 million in 2011, $112.3 million in 2010, and $156.3 million in 2009.

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None of our employees is subject to a collective bargaining agreement. We believe relations with our employees are good.

SCIENTIFIC ADVISORS

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

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

Our diabetes program is supported by the following scientific advisors (and their primary affiliations):

Name	Primary Affiliation
Geremia Bolli	University of Perugia
Steven Edelman, MD	University of California, San Diego
Brian Frier, MD, FECP, BS	Edinburgh Royal Infirmary
Lois Jovanovic, MD	Sansum Medical Research Institute
Mark Peyrot, MD	Loyola College Center
Daniel Porte, MD	University of California, San Diego
Philip Raskin, MD, FACE, FACP	University of Texas
Julio Rosenstock, MD	Dallas Diabetes and Endocrinology Center
Richard Rubin, PhD, CDE	Johns Hopkins University School of Medicine
Jay Skyler, MD, MACP	University of Miami, Diabetes Research Institute

EXECUTIVE OFFICERS

The following table sets forth our current executive officers and their ages as of December 31, 2011:

Name	Age	Position(s)
Alfred E. Mann	86	Chairman of the Board of Directors and Chief Executive Officer
Hakan S. Edstrom	61	President, Chief Operating Officer and Director
Matthew J. Pfeffer	54	Corporate Vice President and Chief Financial Officer
Juergen A. Martens, Ph.D.	56	Corporate Vice President, Technical Operations and Chief Technical Officer
Diane M. Palumbo	58	Corporate Vice President, Human Resources
David B. Thomson, Ph.D., J.D. .	45	Corporate Vice President, General Counsel and Secretary

Alfred E. Mann has been one of our directors since April 1999, our Chairman of the Board since December 2001 and our Chief Executive Officer since October 2003. He founded and formerly served as Chairman and Chief Executive Officer of MiniMed, Inc., a publicly traded company focused on diabetes therapy and microinfusion drug delivery that was acquired by Medtronic, Inc. in August 2001. Mr. Mann also founded and, from 1972 through 1992, served as Chief Executive Officer of Pacesetter Systems, Inc. and its successor, Siemens Pacesetter, Inc., a manufacturer of cardiac pacemakers, now the Cardiac Rhythm Management Division of St. Jude Medical Corporation. Mr. Mann founded and since 1993, has served as Chairman and until January 2008, as Co-Chief Executive Officer of Advanced Bionics Corporation, a medical device manufacturer focused

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on neurostimulation to restore hearing to the deaf and to treat chronic pain and other neural deficits, that was acquired by Boston Scientific Corporation in June 2004. In January 2008, the former stockholders of Advanced Bionics Corporation repurchased certain segments from Boston Scientific Corporation and formed Advanced Bionics LLC for cochlear implants and Infusion Systems LLC for infusion pumps. Mr. Mann was non-executive Chairman of both entities. Advanced Bionics LLC was acquired by Sonova Holdings on December 30, 2009. Infusion Systems LLC was acquired by the Alfred E. Mann Foundation in February 2010. Mr. Mann has also founded and is non-executive Chairman of Second Sight Medical Products, Inc., which is developing a visual prosthesis for the blind; Bioness Inc., which is developing rehabilitation neurostimulation systems; Quallion LLC, which produces batteries for medical products and for the military and aerospace industries; and Stellar Microelectronics Inc., a supplier of electronic assemblies to the medical, military and aerospace industries. Mr. Mann also founded and is the managing member of PerQFlo, LLC, which is developing drug delivery systems. Mr. Mann is the managing member of the Alfred Mann Foundation and is also non-executive Chairman of Alfred Mann Institutes at the University of Southern California, AMI Purdue and AMI Technion, and the Alfred Mann Foundation for Biomedical Engineering, which is establishing additional institutes at other research universities. Mr. Mann holds bachelor s and master s degrees in Physics from the University of California at Los Angeles, honorary doctorates from Johns Hopkins University, the University of Southern California, Western University and the Technion-Israel Institute of Technology and is a member of the National Academy of Engineering.

Hakan S. Edstrom has been our President and Chief Operating Officer since April 2001 and has served as one of our directors since December 2001. Mr. Edstrom was with Bausch & Lomb, Inc., a health care product company, from January 1998 to April 2001, advancing to the position of Senior Corporate Vice President and President of Bausch & Lomb, Inc. Americas Region. From 1981 to 1997, Mr. Edstrom was with Pharmacia Corporation, where he held various executive positions, including President and Chief Executive Officer of Pharmacia Ophthalmics Inc. Mr. Edstrom was educated in Sweden and holds a master s degree in Business Administration from the Stockholm School of Economics.

Matthew J. Pfeffer has been our Corporate Vice President and Chief Financial Officer since April 2008. Previously, Mr. Pfeffer served as Chief Financial Officer and Senior Vice President of Finance and Administration of VaxGen, Inc. from March 2006 until April 2008, with responsibility for finance, tax, treasury, human resources, IT, purchasing and facilities functions. Prior to VaxGen, Mr. Pfeffer served as CFO of Cell Genesys, Inc. During his nine year tenure at Cell Genesys, Mr. Pfeffer served as Director of Finance before being named CFO in 1998. Prior to that, Mr. Pfeffer served in a variety of financial management positions at other companies, including roles as Corporate Controller, Manager of Internal Audit and Manager of Financial Reporting. Mr. Pfeffer began his career at Price Waterhouse. Mr. Pfeffer serves on boards and advisory committees of the Biotechnology Industry Organization and the American Institute of Certified Public Accountants. Mr. Pfeffer has a bachelor s degree in Accounting from the University of California, Berkeley and is a Certified Public Accountant.

Juergen A. Martens, Ph.D. has been our Corporate Vice President of Operations and Chief Technology Officer since September 2005. From 2000 to August 2005, he was employed by Nektar Therapeutics, Inc., most recently as Vice President of Pharmaceutical Technology Development. Previously, he held technical management positions at Aerojet Fine Chemicals from 1998 to 2000 and at FMC Corporation from 1996 to 1998. From 1987 to 1996, Dr. Martens held a variety of management positions with increased responsibility in R&D, plant management, and business process development at Lonza, in Switzerland and in the United States. Dr. Martens holds a bachelor s degree in chemical engineering from the Technical College Mannheim/Germany, a bachelor s and master s degree in Chemistry and a doctorate in Physical Chemistry from the University of Marburg/Germany.

Diane M. Palumbo has been our Corporate Vice President of Human Resources since November 2004. From July 2003 to November 2004, she was President of her own human resources consulting company. From June 1991 to July 2003, Ms. Palumbo held various positions with Amgen, Inc., a California-based biopharmaceutical company, including Senior Director, Human Resources. In addition, Ms. Palumbo has held Human Resources positions with Unisys and Mitsui Bank Ltd. of Tokyo. She holds a master s degree in Business Administration

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from St. John s University, New York and a bachelor s degree, magna cum laude, also from St. John s University.

David B. Thomson, Ph.D., J.D. has been our Corporate Vice President, General Counsel and Corporate Secretary since January 2002. Prior to joining us, he practiced corporate/commercial and securities law at a major Toronto law firm. Earlier in his career, Dr. Thomson was a post-doctoral fellow at the Rockefeller University. Dr. Thomson obtained his bachelor s degree, master s degree and Ph.D. degree from Queens University and obtained his J.D. degree from the University of Toronto.

Executive officers serve at the discretion of our Board of Directors. There are no family relationships between any of our directors and executive officers.

Item 1A. ***Risk Factors***

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this Annual Report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

RISKS RELATED TO OUR BUSINESS

We depend heavily on the successful development and commercialization of our lead product candidate, AFREZZA, which is not yet approved.

To date, we have not commercialized any product candidates. We have expended significant time, money and effort in the development of our lead product candidate, AFREZZA, which has not yet received regulatory approval and which may not be approved by the FDA in a timely manner, or at all. Our other product candidates are generally in early clinical 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 AFREZZA.

In January 2011, the FDA issued a Complete Response letter and requested that we conduct additional clinical studies of AFREZZA using our next-generation inhaler. In early May 2011, we held an End-of-Review meeting with the agency to discuss the protocols for the additional studies. In August 2011, we confirmed with the FDA the design of two clinical studies to evaluate the efficacy and safety of AFREZZA administered using our Dreamboat inhaler. We plan to continue working closely with the FDA in our effort to ensure that our clinical studies address the agency s requests for additional information about AFREZZA. There can be no assurance that we will satisfy all of the FDA s requirements or that the FDA will find our proposed approach to these clinical studies acceptable. The FDA could also again request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. There can be no assurance that we will obtain approval of the NDA in a timely manner or at all.

We must receive the necessary approvals from the FDA and similar foreign regulatory agencies before AFREZZA can be marketed and sold in the United States or elsewhere. Even if we were to receive regulatory approval, we ultimately may be unable to gain market acceptance of AFREZZA 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 AFREZZA, our business, financial condition and results of operations will be materially and adversely affected.

We have sought to develop our product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all.

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A significant portion of the research that we have conducted involves new and unproven compounds and technologies, including AFREZZA, Technosphere platform technology and immunotherapy product candidates. 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. 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 AFREZZA 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.

We have a history of operating losses, we expect to continue to incur losses and we may never generate positive cash flow from operations.

We are a development stage company with no commercial products. All of our product candidates are still being developed, and all but AFREZZA are still in the 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 cannot be certain when AFREZZA may be approved or if it will be approved.

We have never been profitable or generated positive cash flow from operations and, as of December 31, 2011, we had incurred a cumulative net loss of $1.9 billion. The cumulative net loss 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, including AFREZZA. This cumulative net loss may increase significantly as we continue development and clinical trial efforts.

Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders equity. As of December 31, 2011, we had a stockholders deficit of $313.7 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends upon obtaining regulatory approvals for and successfully commercializing AFREZZA, 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 generate positive cash flow from operations or be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

We will be required to raise additional capital to fund our operations, and our inability to do so could raise substantial doubt about our ability to continue as a going concern.

Based upon our current expectations, we believe that our existing capital resources, including the available borrowings under our loan arrangement with The Mann Group, as amended on January 16, 2012, as well as the net proceeds from the sale of 35,937,500 units, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock in February 2012, will enable us to continue planned operations into the fourth quarter of 2012. 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. We will need to raise additional funds, whether through the sale of equity or debt securities, the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, or an increase in the borrowings available under the loan arrangement with our related party, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. However, it may be difficult for us to raise additional funds through these planned measures. As of December 31, 2011, we had a stockholders deficit of $313.7 million which may raise concerns about our solvency and affect our ability to raise additional capital. The amount of additional funds we need will depend on a number of factors, including:

- rate of progress and costs of our clinical trials and research and development activities, including costs of procuring clinical materials and operating our manufacturing facilities;

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our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions we are able to establish;

actions taken by the FDA and other regulatory authorities affecting our products and competitive products;

our degree of success in commercializing AFREZZA assuming receipt of required regulatory approvals;

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;

the level of our legal expenses, including those expenses associated with the securities class actions and derivative lawsuits filed against us and certain of our executive officers and directors and any settlement or damages payments associated with litigation;

the costs of discontinuing projects and technologies; and

the costs of decommissioning existing facilities, if we undertake such activities.

We have raised capital in the past primarily through the sale of equity and debt securities. We may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities including asset based borrowings. There can be no assurances, however, that we will be able to raise additional capital through such an offering on acceptable terms, or at all. Issuances of additional debt or equity securities, or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and may dilute their ownership percentage. Moreover, the establishment of other funding facilities 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 or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses 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, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

Because we will not be able to generate operating cash flow before AFREZZA is commercialized, which we expect will require us to reach an agreement with a commercialization partner, we cannot provide assurances that changed or unexpected circumstances, including, among other things, delays in obtaining regulatory approval and in identifying and reaching agreements with a commercialization partner, will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we may be required to raise additional capital. There can be no assurances that we will be able to raise additional capital on acceptable terms, or at all. If planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financings or entering into a strategic business collaboration with a pharmaceutical or biotechnology company, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will be continued

substantial doubt about our ability to continue as a going concern.

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Deteriorating global economic conditions may have an adverse impact on our loan facility with The Mann Group.

As widely reported, financial markets in the United States, Europe and Asia have experienced a period of unprecedented turmoil and upheaval characterized by extreme volatility and declines in security prices, severely diminished liquidity and credit availability, inability to access capital markets, the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government and other governments. We cannot predict the impact of these events on our loan facility with The Mann Group. If we are unable to draw on The Mann Group loan facility, our business and financial condition may be adversely affected.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business would be harmed and the market price of our common stock could decline.

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

In addition, if we do not obtain sufficient additional funds through sales of securities, strategic collaborations or the license or sale of certain of our assets on a timely basis, we will be required to reduce expenses by delaying, reducing or curtailing our development of AFREZZA. 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 (or within the timeframes expected by analysts or investors), our business and results of operations will be harmed and the market price of our common stock will 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.

A number of established pharmaceutical companies have or are developing 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. In addition, gaining favorable reimbursement is critical to the

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success of AFREZZA. Many of our competitors have existing infrastructure and relationships with managed care organizations and reimbursement authorities which can be used to their advantage.

The rapid rate of scientific discoveries and technological changes could result in one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology and AFREZZA less competitive, uneconomical or obsolete. Our future success will depend not only on our ability to develop our product candidates but to improve them and 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 AFREZZA, we may not be able to execute on our business model.

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. To date we have not reached an agreement on a collaboration with any of these companies. We cannot predict when, if ever, we could conclude an agreement with a partner. There can be no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms. If we are not able to enter into a collaboration on terms that are favorable to us, we may be unable to undertake and fund product development, clinical trials, manufacturing and/or marketing activities at our own expense, which would delay or otherwise impede the commercialization of AFREZZA. We will face similar challenges as we seek to develop our other product candidates. Our current strategy for developing, manufacturing and commercializing our other 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. Failure to enter into a collaboration with respect to any other product candidate could substantially increase our requirements for capital and force us to substantially reduce our development effort.

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

We may enter into license agreements, partnerships or other collaborative arrangements to support the financing, development and marketing of AFREZZA. 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 AFREZZA and our other product candidates. We cannot offer assurances 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.

Continued testing of AFREZZA or our other product candidates may not yield successful results, and even if it does, we may still be unable to commercialize our product candidates.

Our research and development programs are designed to test the safety and efficacy of AFREZZA and our other product candidates through extensive nonclinical and clinical testing. We may experience numerous

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unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of AFREZZA or any of our other product candidates, including the following:

- safety and efficacy results for AFREZZA obtained in our nonclinical and previous clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical trials or following long-term use, and we may as a result be forced to stop developing AFREZZA;

- the data collected from clinical trials of AFREZZA or our other product candidates may not reach statistical significance or otherwise 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.

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical trials or in much larger populations may not be consistent with the clinical results. If use of AFREZZA results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell AFREZZA, 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, we, any collaborator, the FDA, or any other regulatory authorities, may suspend or terminate clinical trials or marketing of AFREZZA 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 our suppliers fail to deliver materials and services needed for the production of AFREZZA in a timely and sufficient manner, or they fail to comply with applicable regulations, our business and results of operations would be harmed and the market price of our common stock could decline .

For AFREZZA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA s current good manufacturing practices, or cGMP for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with Quality System Regulations, or QSR. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of 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, the development or manufacturing of AFREZZA may be delayed. Any such events could delay market introduction and subsequent sales of AFREZZA and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

We have never manufactured AFREZZA or any other 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 use our Danbury, Connecticut facility to formulate AFREZZA inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, place the two blister packs into foil pouches and package three pouches plus two inhalers and the package insert as units in 90-unit boxes (and single blister pouch packs for trials). Although this facility has been qualified and undergone an inspection by the FDA in connection with our original NDA submission that sought approval of AFREZZA using our MedTone inhaler, we anticipate that our facility will need to undergo further inspection related to our ability to fill and package cartridges for the next-generation Dreamboat inhaler before we can be approved to distribute the manufactured products commercially. The manufacture of pharmaceutical products requires significant expertise and capital investment,

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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. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, 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 or required approvals of our product candidates, could entail higher costs and may result in our being unable to effectively commercialize our products. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of any product on a timely basis, and at commercially reasonable prices and acceptable quality, 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 quality on a timely basis, we would likely be unable to meet demand for such products and we would lose potential revenues.

We and certain of our executive officers and directors have been named as defendants in ongoing securities class actions and derivative lawsuits that could result in substantial costs and divert management s attention.

We and certain of our executive officers, have been sued for alleged violations of federal securities laws related to alleged false and misleading statements regarding AFREZZA. We have also been named in state and federal derivative lawsuits that have been filed against certain of our directors and executive officers. We intend to engage in a vigorous defense of such litigation. If we are not successful in our defense of such litigation, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management s attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

We expect that at least for the foreseeable future, our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of AFREZZA. This facility and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in Europe. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, volcanic eruptions, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. We might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs and adversely affect, which may include stopping, our readiness for commercial production.

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 and biological materials. In addition, our manufacturing operations involve the use of a chemical that 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 (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated

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substances, and (iii) regulating workplace safety. 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 $1.0 million per occurrence and $2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further $4.0 million of coverage; however, our insurance policy excludes pollution liability 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 or have an adverse impact on our business, results of operations and financial condition.

When we purchased the facilities located in Danbury, Connecticut in 2001, there was a soil and groundwater investigation and remediation being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection, or CT DEP, which is continuing. As part of the purchase, we obtained an indemnification from the seller for all known environmental conditions that existed at the time the seller acquired the property. The seller was, in turn, indemnified for these known environmental conditions by the previous owner and its operator (responsible party). 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 have since expired and were limited to the purchase price we paid for the Danbury facilities.

During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location, at a cost of approximately $2.25 million. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of $1.625 million in July 2010. The responsible party has further agreed to conduct at its expense all work and make all filings necessary to achieve closure for the environmental investigation and remediation being conducted at the site and agreed to pay for or indemnify us for any future costs and expenses we may incur that are directly related to the final closure of the environmental remediation. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business and results of operations may be harmed.

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

Our product candidates are intended to be used by a large number of healthcare professionals who will require substantial education and support. For example, a broad base of physicians, including primary care physicians and endocrinologists, treat patients with diabetes. A large sales force will be required in order to educate these physicians about the benefits and advantages of AFREZZA and to provide adequate support for them. Therefore, our primary strategy is to enter into collaborations with one or more pharmaceutical companies to market, distribute and sell AFREZZA, if it is approved. If we fail to enter into collaborations, we would be required to establish our own direct sales, marketing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and would delay our ability to commercialize AFREZZA. Because we lack experience in selling pharmaceutical products to the diabetes market, we would be at a disadvantage compared to our potential competitors, all of whom have substantially more resources and experience than we do. For example, several other companies selling products to treat diabetes have existing sales forces in excess of 1,500 sales representatives. We, acting alone, would not initially be able to field a sales force as large as our competitors or provide the same degree of marketing support. Also, we would not be able to match our competitors spending levels for pre-launch marketing preparation, including medical education. 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 any product that we may develop does not become widely accepted by physicians, patients, third-party payers and the healthcare community, we may be unable to generate significant revenue, if any.

AFREZZA and our other product candidates are new and unproven. Even if any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, third-party payers

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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 AFREZZA and our other product candidates will depend on many factors, including the:

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

Because of these and other factors, any product that we may develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

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

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payers to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing 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 payers for healthcare goods and services may take in response to any drug pricing reform proposals or legislation. Such reforms may make it difficult to complete the development and testing of AFREZZA and our other 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 payers, such as governmental and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. In addition, because each third-party payer individually approves reimbursement, obtaining these approvals is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be considered cost-effective or that reimbursement to the consumer would be

available, in which case our business and results of operations would be harmed and the market price of our common stock could decline.

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 AFREZZA and our other product candidates 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

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product, injury to our reputation, withdrawal of clinical trial volunteers and loss of revenues. We currently carry worldwide liability insurance in the amount of $10.0 million. In addition, we carry local policies per trial in each country in which we conduct clinical trials that require us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales in the future if AFREZZA is approved. 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 our business and results of operations would be harmed and the market price of our common stock may decline.

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 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.

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

If our Chairman and 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 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. 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.

If our internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, our internal controls over financial reporting.

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Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

RISKS RELATED TO REGULATORY APPROVALS

Our product candidates must undergo rigorous nonclinical 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 AFREZZA, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulations of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

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

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot be certain if or when the FDA might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. 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 AFREZZA. 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 AFREZZA, 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 essentially all of the risks

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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. We are not aware of any precedent for the successful commercialization of products based on our technology. In January 2006, the FDA approved the first pulmonary insulin product, Exubera. This approval has had an impact on, and notwithstanding the voluntary withdrawal of the product from the market by its manufacturer could still impact, the development and registration of AFREZZA in different ways. For example, Exubera may be used as a reference for safety and efficacy evaluations of AFREZZA, and the approval standards set for Exubera may be applied to other products that follow, including AFREZZA.

The FDA is regulating AFREZZA as a combination product because of the complex nature of the system that includes the combination of a new drug (AFREZZA) and a new medical device (the inhaler used to administer the insulin). The review of our NDA for AFREZZA involves several separate review groups of the FDA including: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health, which reviews medical devices. The Metabolic and Endocrine Drug Products Division is the lead group and obtains consulting reviews from the other two FDA groups. We can make no assurances at this time about what impact FDA review by multiple groups will have on the approvability of our product or that we will obtain approval of the NDA in a timely manner or at all.

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

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

We will not be able to commercialize AFREZZA or any other product candidates unless we have obtained regulatory approval. Until we prepared and submitted our NDA for AFREZZA, we had 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.

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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 or could require potentially costly post-marketing follow-up clinical trials. Regulatory authorities may limit the segments of the diabetes population to which we or others may market AFREZZA or limit the target population for our other product candidates. There are no assurances that any advantages of AFREZZA will be agreed to by the FDA or otherwise included in product labeling or advertising and, as a result, AFREZZA may not have our expected competitive advantages when compared to other insulin products.

The manufacture, marketing and sale of any of our product candidates will be subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning the safety or efficacy of a product appear following approval. We cannot be sure that FDA and United States Congressional initiatives or actions by foreign regulatory bodies 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 suppliers will be subject to FDA inspection before the agency approves an NDA for AFREZZA.

When we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier s ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of AFREZZA. We also depend on suppliers for other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements including QSR, and is subject to inspection by the FDA. There can be no assurance, in the conduct of an inspection of any of our suppliers, that the agency would find that the supplier substantially complies 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.

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 AFREZZA is associated with a significantly increased

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frequency of adverse events, or if other pharmaceutical companies announce that they observed frequent adverse events in their trials involving insulin therapies, we could encounter delays in the timing of our clinical trials, difficulties in obtaining approval of AFREZZA or be subject to class warnings in the label for AFREZZA, if approved. As well, the public perception of AFREZZA 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 products or product candidates.

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 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 alternative technologies.

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, although some patents providing protection for our AFREZZA inhalation powder expire in 2012, other patents providing similar protection will remain in force into 2020. In addition, patents providing protection for our inhaler and cartridges will remain in force into 2023, and we have broad method of treatment claims that can be maintained in force into 2020 as well as narrower treatment claims that can be maintained in force variously into 2026 and 2029. As and when these different patents expire, AFREZZA could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

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. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations in the United States. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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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, know-how 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. A court may also decide to award us a royalty from an infringing party instead of issuing an injunction against the infringing activity. 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 United States Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

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

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

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

A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner s patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry.

Patent 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

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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.

Moreover, certain components of AFREZZA and/or our cancer vaccines may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B), or a 337 action, with the International Trade Commission, or the ITC. A 337 action can be expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party s patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100% of the value of the patented products. 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, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. 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 AFREZZA and cancer vaccine products under development, we have identified certain third-party patents having claims relating to pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of AFREZZA, as well as third-party patents disclosing methods of use and compositions of matter related to cancer vaccines that also may trigger an allegation of infringement upon the commercial manufacture and sale of our cancer immunotherapy. 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 a non-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.

In addition, patent 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. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business and results of operations and cause the market price of our common stock to decline.

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

We have not selected trade names for some of our product candidates; therefore, we have not filed trademark registrations for all of our potential trade names for our product candidates in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. 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

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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

Our stock price is volatile.

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

- the progress and results of our clinical trials;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us or our competitors concerning clinical trial results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing AFREZZA or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- announcements by us concerning our financial condition or operating performance;
- changes in securities analysts estimates of our financial condition or operating performance;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- the status of litigation against us and certain of our executive officers and directors;

the existence of, and the issuance of shares of our common stock pursuant to, the share lending agreement and the short sales of our common stock effected in connection with the sale of our 5.75% convertible notes due 2015; and

discussion of AFREZZA, 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. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.

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 Global Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities

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

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

Our Chairman and 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.

At December 31, 2011, Mr. Mann beneficially owned approximately 39.4% of our outstanding shares of capital stock, after giving effect to the issuance of shares of our common stock in February 2012, excluding the 21,562,500 shares of common stock that may be issued from time to time upon exercise of the warrants issued in the offering. If further effect is given to the issuance of 31,250,000 restricted shares of our common stock in the concurrent private placement issuable upon receipt of stockholder approval to increase the number of our authorized shares, as of March 2, 2012, Mr. Mann would have beneficially owned approximately 41.8% of our outstanding shares of capital stock. By virtue of his holdings, Mr. Mann may be able to continue 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 United States 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 Institutes at the University of Southern California, the Technion-Israel Institute of Technology, and Purdue University, 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, his wife, three of his children and Dr. Joseph Schulman, the chief scientist of the AEMFBE. The AEMFBE is a membership foundation consisting of five members, including Mr. Mann, his wife, and the same three 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, the conversion of our senior convertible notes into common stock or the exercise of our warrants for common stock could negatively affect our stock price.

As of December 31, 2011, we had 131,522,945 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. Likewise the issuance of additional shares of our common stock upon the conversion of some or all of our senior convertible notes, or upon the exercise of some or all of the warrants we issued in February 2012, could adversely affect the trading price of our common stock. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registration rights, the sale

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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 or additional convertible debt, the market price of our common stock may decline and our existing stockholders may experience significant dilution.

We have reserved for future issuance substantially all of our authorized but unissued shares of common stock, which may impair our ability to conduct future financing and other transactions.

Our certificate of incorporation currently authorizes us to issue up to 250,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of December 31, 2011, we had a total of 118,477,055 shares of common stock that were authorized but unissued. We have reserved substantially all of our authorized but unissued shares for future issuance pursuant to outstanding equity awards, our equity plans, our 3.75% senior convertible notes due 2013, our 5.75% senior convertible notes due 2015, warrants with a term of 4 years expiring on February 8, 2016 and the Common Stock Purchase Agreement we entered into with The Mann Group LLC concurrently with our February 2012 offering of common stock and warrants. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

If we are unable to enter into new arrangements to issue shares of our common stock or securities convertible or exercisable into shares of our common stock, our ability to complete equity-based financings or other transactions that involve the potential issuance of our common stock or securities convertible or exercisable into our common stock, will be limited. In lieu of issuing common stock or securities convertible into our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which may require us to grant security interests in our assets and property and/or impose covenants upon us that restrict our business. If we are unable to issue additional shares of common stock or securities convertible or exercisable into our common stock, our ability to enter into strategic transactions such as acquisitions of companies or technologies, may also be limited. If we propose to amend our certificate of incorporation to increase our authorized shares of common stock, such a proposal would require the approval by the holders of a majority of our outstanding shares of common stock, and we cannot assure you that such a proposal would be adopted. If we are unable to complete financing, strategic or other transactions due to our inability to issue additional shares of common stock or securities convertible or exercisable into our common stock, our financial condition and business prospects may be materially harmed.

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.

We are incorporated in Delaware. Certain anti-takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our anti-takeover provisions include 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, 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, 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.

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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 or maintain its current price. You could lose the entire value of your investment in our common stock.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

In 2001, we acquired a facility in Danbury, Connecticut that included two buildings comprising approximately 190,000 square feet encompassing 17.5 acres. In September 2008, we completed the construction of approximately 140,000 square feet of new manufacturing space providing us with two buildings totaling approximately 328,000 square feet, housing our research and development, administrative and manufacturing functions, primarily for AFREZZA, filling and packaging. We believe the Danbury facility will have sufficient space to satisfy potential commercial demand for the launch of AFREZZA and, with the expansion completed, the first few years thereafter for AFREZZA and other AFREZZA-related products.

We own and occupy approximately 142,000 square feet of laboratory, office and warehouse space in Valencia, California. The facility contains our principal executive offices and houses our research and development laboratories for our cancer and other programs. We also use this facility to provide support for the development of our AFREZZA programs.

We lease approximately 23,000 square feet of office space in Paramus, New Jersey pursuant to a lease that expires in May 2012.

Item 3. ***Legal Proceedings***

On December 13, 2011, we announced that we reached a final resolution of the arbitration proceedings initiated by John Arditi, our former Senior Director GCP Regulatory Affairs. In connection with the resolution of the matter, Mr. Arditi withdrew his wrongful discharge and related claims against us. In return, we withdrew our claims against Mr. Arditi. Neither party paid any monetary consideration to the other party in connection with the resolution of the arbitration proceedings.

Beginning January 31, 2011, several complaints were filed in the U.S. District Court for the Central District of California against us and four of our officers Alfred E. Mann, Hakan S. Edstrom, Dr. Peter C. Richardson and Matthew J. Pfeffer on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and have been brought as purported shareholder class actions. In general, the complaints allege that the defendants violated federal securities laws by making materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. The complaints have been transferred to a single court and consolidated for all purposes. The court appointed a lead plaintiff and lead counsel and a consolidated complaint was filed on June 27, 2011. On August 12, 2011, we filed a motion to dismiss the complaint and a motion to strike the expert report attached to that complaint. On December 16, 2011, the court denied both motions. On January 27, 2012, defendants filed a motion to stay the action and certify the court s December 16 order for interlocutory appeal, or in the alternative to reconsider. On March 2, 2012, the court denied both motions. Discovery has commenced, and we will vigorously defend against the claims advanced. The parties have also agreed to mediation, which is set for April 30, 2012.

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In February 2011, shareholder derivative complaints were filed in the Superior Court of California for the County of Los Angeles and in the U.S. District Court for the Central District of California against all of our directors and certain of our officers. The complaints in the shareholder derivative actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that the defendants caused or allowed for the dissemination of materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief, including reforms to our corporate governance and internal procedures.

The Superior Court of California for the County of Los Angeles has consolidated the actions pending before it and appointed lead counsel. The Superior Court of California for the County of Los Angeles has stayed the litigation until September 5, 2012, consistent with the parties stipulation. A status conference is set for September 5, 2012.

Likewise, the U.S. District Court for the Central District of California has consolidated the derivative actions pending before it. The U.S. District Court for the Central District of California has also appointed lead plaintiffs and lead counsel and a consolidated complaint was filed on August 12, 2011. We filed a motion to dismiss this complaint on September 26, 2011 and the parties subsequently stipulated to stay the litigation. That stay expired on January 10, 2012, and on January 20, 2012, the Court issued a minute order setting a briefing schedule regarding defendants motion to dismiss. Plaintiff opposed the motion on February 6, and defendants filed a reply on February 13. On February 14, 2012, the Court granted defendants motion to dismiss without prejudice. Plaintiff filed an amended complaint on March 5, 2012. The Court has stayed the litigation pending the outcome of mediation, consistent with the parties stipulation.

Item 4. ***Mine Safety Disclosures***

Not applicable.

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PART II

Item 5. ***Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Common Stock Market Price

Our common stock has been traded on the NASDAQ Global Market under the symbol MNKD since July 28, 2004. The following table sets forth for the quarterly periods indicated, the high and low sales prices for our common stock as reported by the NASDAQ Global Market.

	High	Low
Year ended December 31, 2010		
First quarter	$ 11.12	$ 6.35
Second quarter	$ 7.33	$ 4.76
Third quarter	$ 7.36	$ 5.50
Fourth quarter	$ 9.23	$ 5.07
Year ended December 31, 2011		
First quarter	$ 10.05	$ 3.40
Second quarter	$ 4.75	$ 3.48
Third quarter	$ 3.99	$ 2.20
Fourth quarter	$ 3.87	$ 2.45

The closing sales price of our common stock on the NASDAQ Global Market was $2.28 on March 2, 2012 and there were 193 registered holders of record as of that date.

Performance Measurement Comparison

The material in this section is not soliciting material, is not deemed filed with the SEC and shall not be incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any of our filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act of 1934, as amended, or the Exchange Act, except to the extent we specifically incorporate this section by reference.

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Performance Measurement Comparison

The following graph illustrates a comparison of the cumulative total stockholder return (change in stock price plus reinvested dividends) of our common stock with (i) the NASDAQ Composite Index and (ii) the NASDAQ Biotechnology Index. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

Assumes a $100 investment, on December 31, 2006, in (i) our common stock, (ii) the securities comprising the NASDAQ Composite Index and (iii) the securities comprising the NASDAQ Biotechnology Index.

Dividend Policy

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

Recent Sales of Unregistered Securities

The following list sets forth information regarding all securities sold by us during the fiscal year ended December 31, 2011 without registration under the Securities Act:

(1) On January 12, 2011, we issued 700,000 shares of our common stock to The Mann Group.

(2) On January 26, 2011, we issued 700,000 shares of our common stock to The Mann Group.

The aggregate purchase price of the above transactions was approximately $11.1 million, which was paid by cancelling an equal amount of the outstanding principal under an existing $350.0 million revolving loan arrangement provided by The Mann Group. The offers, sales, and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act and/or Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The Mann Group was an accredited investor under Rule 501 of Regulation D. The Mann Group acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

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Item 6. ***Selected Financial Data***

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes thereto and with Management s Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
Statement of Operations Data:	**2007**	**2008**	**2009**	**2010**	**2011**
	(In thousands, except per share amounts)				
Revenue	$ 10	$ 20	$	$ 93	$ 50
Operating expenses:					
Research and development	256,844	250,442	156,331	112,279	99,959
General and administrative	50,523	55,343	53,447	40,312	40,630
Total operating expenses	307,367	305,785	209,778	152,591	140,589
Loss from operations	(307,357)	(305,765)	(209,778)	(152,498)	(140,539)
Other income (expense)	(197)	(62)	51	(725)	1,541
Interest expense on note payable to principal stockholder		(12)	(5,679)	(10,249)	(10,883)
Interest expense on senior convertible notes	(3,408)	(2,327)	(4,768)	(7,128)	(10,941)
Interest income	17,775	5,129	70	40	18
Loss before provision for income taxes	(293,187)	(303,037)	(220,104)	(170,560)	(160,804)
Income taxes	(3)	(2)			
Net loss applicable to common stockholders	$ (293,190)	$ (303,039)	$ (220,104)	$ (170,560)	$ (160,804)
Basic and diluted net loss per share	$ (3.66)	$ (2.98)	$ (2.07)	$ (1.50)	$ (1.32)
Shares used to compute basic and diluted net loss per share	80,038	101,561	106,534	113,672	121,817

	December 31,				
Balance Sheet Data:	**2007**	**2008**	**2009**	**2010**	**2011**
	(In thousands)				
Cash, cash equivalents and marketable securities	$ 368,285	$ 46,492	$ 32,494	$ 70,431	$ 3,196
Working capital	311,154	503	8,813	55,820	(19,539)
Total assets	543,443	282,459	247,397	277,256	199,553
Other liabilities	24				
Senior convertible notes	111,761	112,253	112,765	209,335	210,642
Note payable to related party		30,000	165,000	235,319	277,203
Deficit accumulated during the development stage	(1,081,039)	(1,384,078)	(1,604,182)	(1,774,742)	(1,935,546)
Total stockholders equity (deficit)	364,100	86,734	(59,221)	(185,532)	(313,652)

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and notes thereto included in this Annual Report on Form 10-K.

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OVERVIEW

We are a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes and cancer. Our lead product candidate, AFREZZA, is an ultra rapid-acting insulin therapy that is in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of December 31, 2011, we have incurred a cumulative net loss of $1.9 billion and a stockholders deficit of $313.7 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under a loan arrangement provided by our principal stockholder. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding in the future, there will continue to be substantial doubt about our ability to continue as a going concern.

We do not expect to record sales of any product prior to regulatory approval and commercialization of AFREZZA. We currently do not have the required approvals to market any of our product candidates, and we may not receive such approvals. We may not be able to achieve positive cash flow from operations even if we succeed in commercializing any of our product candidates. We expect to make substantial expenditures and to incur additional operating losses for at least the next several years as we:

- continue the clinical development of AFREZZA and new inhalation systems for the treatment of diabetes;
- seek regulatory approval to sell AFREZZA in the United States and other markets;
- seek development and commercialization collaborations for AFREZZA; and
- develop additional applications of our proprietary Technosphere formulation technology for the pulmonary delivery of other drugs.

Our business is subject to significant risks, including but not limited to the risks inherent in our ongoing clinical trials and the regulatory approval process, our potential inability to enter into sales and marketing collaborations or to commercialize AFREZZA in a timely manner, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of laboratory equipment. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash. Included in research and development expenses for the year ended December 31, 2011 were purchases of insulin totaling $8.4 million.

Our research and development staff conducts our internal research and development activities, which include research, product development, clinical development, manufacturing and related activities. This staff is located in our facilities in Valencia, California; Paramus, New Jersey; and Danbury, Connecticut. We expense research and development costs as we incur them.

Clinical development timelines, likelihood of success and total costs vary widely. We are focused primarily on advancing AFREZZA through regulatory filings.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates other than AFREZZA, we are unable to estimate with any certainty the costs that we will

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incur in the continued development of our product candidates for commercialization. The costs required to complete the development of AFREZZA will be largely dependent on the cost and efficiency of our clinical trial operations and discussions with the FDA regarding its requirements.

During the first quarter of 2011, we implemented a restructuring to streamline operations, reduce operating expenses, extend our cash runway and focus our resources on securing FDA approval of the NDA for AFREZZA. In connection with the restructuring, we recorded charges to research and development expenses of approximately $4.7 million for employee severance and other related termination benefits. The restructuring resulted in research and development operating cost savings of approximately $9.5 million in 2011. These savings were partially offset by increased costs associated with the additional trials required by the FDA.

GENERAL AND ADMINISTRATIVE EXPENSES

Our general and administrative expenses consist primarily of salaries, benefits and stock-based compensation for administrative, finance, business development, human resources, legal and information systems support personnel. In addition, general and administrative expenses include professional service fees and business insurance costs.

In connection with the restructuring, we recorded charges to general and administrative expenses of approximately $1.6 million for employee severance and other related termination benefits. The restructuring resulted in general and administrative operating cost savings of approximately $2.8 million in 2011. These savings were offset primarily by increased professional fees.

CRITICAL ACCOUNTING POLICIES

We have based our discussion and analysis of our financial condition and results of operations on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making estimates of expenses such as stock option expenses and judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. The significant accounting policies that are critical to the judgments and estimates used in the preparation of our financial statements are described in more detail below.

Impairment of long-lived assets

Assessing long-lived assets for impairment requires us to make assumptions and judgments regarding the carrying value of these assets. We evaluate long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

- significant changes in our strategic business objectives and utilization of the assets;
- a determination that the carrying value of such assets cannot be recovered through undiscounted cash flows;
- loss of legal ownership or title to the assets;
- a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset (asset group), including an adverse action or assessment by a regulator; or
- the impact of significant negative industry or economic trends.

If we believe our assets to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. In addition, we base

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the useful lives and related amortization or depreciation expense on our estimate of the useful lives of the assets. If a change were to occur in any of the above-mentioned factors or estimates, our reported results could materially change.

To date, we have had recurring operating losses, and the recoverability of our long-lived assets is contingent upon executing our business plan. If we are unable to execute our business plan, we may be required to write down the value of our long-lived assets in future periods.

Clinical trial expenses

Our clinical trial accrual process seeks to account for expenses resulting from our obligations under contract with vendors, consultants, and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate trial expenses in our financial statements by matching period expenses with period services and efforts expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through discussions with internal clinical personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Service provider status is then compared to the contractual obligated fee to be paid for such services. During the course of a clinical trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. In the event that we do not identify certain costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our reported expenses for a period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of the services are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-based compensation

We account for stock-based compensation in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718 (ASC 718) *Compensation- Stock Compensation*, previously FASB Statement No. 123R, *Accounting for Stock-Based Compensation*. ASC 718 requires all share-based payments to employees, including grants of stock options, restricted stock units, performance-based awards and the compensatory elements of employee stock purchase plans, to be recognized in the income statement based upon the fair value of the awards at the grant date. We use the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Restricted stock units are valued based on the market price on the grant date. We evaluate stock awards with performance conditions as to the probability that the performance conditions will be met and estimate the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

Accounting for income taxes

We must make management judgments when determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. At December 31, 2011, we have established a valuation allowance of $689.4 million against all of our net deferred tax asset balance, due to uncertainties related to our deferred tax assets as a result of our history of operating losses. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to change the valuation allowance, which could materially impact our financial position and results of operations.

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RESULTS OF OPERATIONS

Years ended December 31, 2010 and 2011

Revenues

During the year ended December 31, 2011 we recognized $50,000 in revenue, and during the year ended December 31, 2010, we recognized $93,000 under a license agreement. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFREZZA.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the years ended December 31, 2010 and 2011 (dollars in thousands):

	Year Ended December 31,			
	2010	2011	$ Change	% Change
Clinical	$ 23,558	$ 25,280	$ 1,722	7%
Manufacturing	67,146	58,523	(8,623)	(13)%
Research	14,034	11,399	(2,635)	(19)%
Research and development tax credit	(385)	(609)	(224)	58%
Stock-based compensation expense	7,926	5,366	(2,560)	(32)%
Research and development expenses	$ 112,279	$ 99,959	$ (12,320)	(11)%

The decrease in research and development expenses for the year ended December 31, 2011, as compared to the year ended December 31, 2010, was primarily due to lower purchases of raw materials as a result of the termination of our insulin supply agreement with Organon. We purchased $8.4 million of insulin in 2011 compared to $16.3 million in 2010. In connection with the termination of our insulin supply agreement, we recorded $7.6 million for a contract cancellation fee. Restructuring costs of $4.7 million incurred for the February 2011 reduction in force were offset by reduced salary and other compensation expenses of $2.8 million, including reduced stock-based compensation expense of $2.6 million. These decreases were partially offset by an increase in clinical spending related to the initiation of clinical trials related to AFREZZA. We anticipate that our research and development expenses will increase in 2012 as a result of our ongoing clinical trials to be completed during the year as part of our amended NDA for AFREZZA to be filed with the FDA.

The research and development tax credit recognized for the years ended December 31, 2011 and 2010 partially offsets our research and development expenses. The State of Connecticut provides an opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development credits. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. During the years ended December 31, 2011 and 2010, research and development expenses were offset by $0.6 million and $0.4 million, respectively, in connection with the program.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2010 and 2011 (dollars in thousands):

	Year Ended December 31,			
	2010	2011	$ Change	% Change
Salaries, employee related and other general expenses	$ 34,658	$ 34,792	$ 134	0%
Stock-based compensation expense	5,654	5,838	184	3%
General and administrative expenses	$ 40,312	$ 40,630	$ 318	1%

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The increase in general and administrative expenses for the year ended December 31, 2011, as compared to the year ended December 31, 2010, was primarily due to an increase of $2.1 million in legal fees incurred in defense of the Company in various legal proceedings and other matters. Restructuring costs of $1.6 million incurred for the February 2011 reduction in force were offset by $2.0 million in savings in salary related costs. Overall salary and employee related expenses increased in 2011 by $0.8 million compared to the prior year as we did not record a bonus accrual for 2010. These increases were offset by the non-recurrence in 2011 of projects conducted in 2010, including market research studies. Stock-based compensation expense increased in 2011 over the prior year due to retention grants awarded in the first quarter of 2011. We expect general and administrative expenses to be lower in 2012 as a result of the reduction of force implemented in 2011.

Other Income (Expense)

Other income for the year ended December 31, 2011 was $1.5 million, which was primarily due to realized gains of $1.3 million on the termination of foreign exchange hedging contracts related to our supply agreement with Organon. We terminated these contracts during the quarter ended March 31, 2011. For the year ended December 31, 2010, we recorded $0.7 million of other expense, as we recognized a $0.6 million other-than-temporary impairment loss on our common stock investment due to the length of time and the extent to which the fair value has been less than the amortized cost basis. In addition, we recorded a loss of $1.6 million on the execution of quarterly foreign exchange hedging contracts, offset by a reimbursement of $1.6 million received in connection with a soil cleanup plan.

Interest Income and Expense

Interest expense for the year ended December 31, 2011 increased compared to the year ended December 31, 2010, due to a full year of interest expense recorded on the convertible notes issued in August 2010 and related amortization of the debt issuance costs. Interest expense for the year ended December 31, 2011 also included interest related to additional amounts borrowed under the loan agreement with our principal stockholder.

Years ended December 31, 2009 and 2010

Revenues

During the year ended December 31, 2010 we recognized $93,000 in revenue, and during the year ended December 31, 2009, we recognized no revenue under a license agreement. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFREZZA.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the years ended December 31, 2009 and 2010 (dollars in thousands):

	Year Ended December 31,			
	2009	2010	$ Change	% Change
Clinical	$ 44,163	$ 23,558	$ (20,605)	(47)%
Manufacturing	82,116	67,146	(14,970)	(18)%
Research	19,259	14,034	(5,225)	(27)%
Research and development tax credit	(1,322)	(385)	937	(71)%
Stock-based compensation expense	12,115	7,926	(4,189)	(35)%
Research and development expenses	$ 156,331	$ 112,279	$ (44,052)	(28)%

The decrease in research and development expenses for the year ended December 31, 2010, as compared to the year ended December 31, 2009, was primarily due to decreased costs associated with the clinical development of AFREZZA, including decreased raw material purchases and clinical supplies costs, offset by a loss on disposal of approximately $12.8 million in manufacturing expense related to the abandonment of MedTone specific assets,

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which would no longer be used as we pursue the commercialization of the next-generation device in 2010, reduced salary-related and other research costs as a result of a reduction in force that we implemented in April 2009 and decreased stock-based compensation expense related to reduced number of restricted stock units vesting in 2010 as compared to 2009. We anticipate that our research and development expenses will increase in 2011 as a result of our obligation to purchase an increased amount of insulin as well as increased costs associated with the development of our commercial inhaler.

The research and development tax credit recognized for the years ended December 31, 2010 and 2009 partially offsets our research and development expenses. The State of Connecticut provides an opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development credits. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. During the years ended December 31, 2010 and 2009, research and development expenses were offset by $0.4 million and $1.3 million, respectively, in connection with the program. The decrease in the offset of research and development expenses resulted from reduced spending in Connecticut.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2009 and 2010 (dollars in thousands):

	Year Ended December 31,			
	2009	2010	$ Change	% Change
Salaries, employee related and other general expenses	$ 45,343	$ 34,658	$ (10,685)	(24)%
Stock-based compensation expense	8,104	5,654	(2,450)	(30)%
General and administrative expenses	$ 53,447	$ 40,312	$ (13,135)	(25)%

The decrease in general and administrative expenses for the year ended December 31, 2010, as compared to the year ended December 31, 2009, was primarily due to decreased salary related costs resulting from the April 2009 reduction in force as well as non-recurrence of costs related to the Pfizer transaction during the first half of 2009 and decreased professional fees related to market studies conducted in 2009. Additionally, stock-based compensation expense decreased as a result of reduced number of restricted stock units vesting in 2010 as compared to 2009. We expect general and administrative expenses to decrease in 2011 as a result of the reduction of force implemented in February 2011.

Other Income (Expense)

Other expense for the year ended December 31, 2010 increased, as compared to the year ended December 31, 2009, as we recognized a $0.6 million other-than-temporary impairment loss on our common stock investment due to the length of time and the extent to which the fair value has been less than the amortized cost basis. In addition, we recorded a loss of $1.6 million on the execution of quarterly window forward contracts, offset by a reimbursement of $1.6 million received in connection with a soil cleanup plan.

Interest Income and Expense

Interest expense for the year ended December 31, 2010 increased due to the convertible notes issued in August 2010 and related amortization of the debt issuance costs. Interest expense for the year ended December 31, 2010 also included interest related to additional amounts borrowed under the loan agreement with our principal stockholder.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under our loan arrangement with our principal stockholder.

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In October 2007, we entered into a loan arrangement with our principal stockholder allowing us to borrow up to a total of $350.0 million. In February 2009, as a result of our principal stockholder being licensed as a finance lender under the California Finance Lenders Law, the promissory note underlying the loan arrangement was revised to reflect the lender as The Mann Group LLC, an entity controlled by our principal stockholder. Interest will accrue on each outstanding advance at a fixed rate equal to the one-year LIBOR rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum and is payable quarterly in arrears. In August 2010, we amended and restated the existing promissory note evidencing the loan arrangement with The Mann Group to extend the maturity date from December 31, 2011 to December 31, 2012. In January, 2012, we amended the note with The Mann Group to extend the maturity date of the $350.0 million loan arrangement from December 31, 2012 to March 31, 2013. We can continue to borrow under the amended terms of the note until June 30, 2012. Under the amended and restated promissory note, The Mann Group can require us to prepay up to $200.0 million in advances that have been outstanding for at least 12 months. If The Mann Group exercises this right, we will have 90 days after The Mann Group provides written notice (or the number of days to maturity of the note if less than 90 days) to prepay such advances. In August 2010, we entered into a letter agreement confirming a previous commitment by The Mann Group to not require us to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require us to use our working capital resources, including the proceeds from the sale of our 5.75% Senior Convertible Notes due 2015. In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at the lender s option, and the interest rate will increase to the one-year LIBOR rate calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under the loan arrangement are unsecured. The loan arrangement contains no financial covenants. As of December 31, 2011, the amount borrowed and outstanding under the arrangement was $277.2 million and we had $45.0 million of available borrowings under the arrangement.

In August 2010, we completed a Rule 144A offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015. The net proceeds to us from the sale of the notes were approximately $95.8 million, after deducting the discount to the initial purchasers of $3.3 million and the offering expenses paid by us.

In connection with the offering of the notes, in August 2010, we entered into a share lending agreement with Bank of America, pursuant to which we lent 9,000,000 shares of our common stock to Bank of America, which is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to us on or about the 45th business day following the date as of which the entire principal amount of the notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America s option.

Also in August 2010, we entered into an underwriting agreement with Merrill Lynch and Bank of America, pursuant to which the borrowed shares were offered and sold to the public at a fixed price of $5.55 per share. We did not receive any proceeds from the sale of the borrowed shares to the public, but received a lending fee of $90,000 pursuant to the share lending agreement for the use by Bank of America of the borrowed shares. Bank of America received all of the net proceeds from the sale of the borrowed shares to the public.

On February 8, 2012, we sold $86.3 million worth of units in an underwritten public offering, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock, and reflects the full exercise of an over-allotment option granted to the underwriters. Net proceeds from this offering were approximately $80.6 million, excluding any warrant exercises. Concurrent with this public offering, The Mann Group LLC agreed to purchase $77.2 million worth of restricted shares of common stock which will be paid by cancellation of principal indebtedness under the amended loan arrangement, subject to stockholder approval to increase the number of our authorized shares.

During the year ended December 31, 2011, we used $123.9 million of cash for our operations and had a net loss of $160.8 million for the year ended December 31, 2011, of which $27.1 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. By comparison, during the year ended December 31, 2010, we used $148.7 million of cash for our operations and had a net loss of $170.6 million, of which $30.9 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. Cash used for our operations for the year ended December 31, 2011 decreased by $24.8

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million compared to cash used for our operations for the year ended December 31, 2010 due primarily to reduced salary-related costs and the positive impact of cost cutting measures on operating costs as a result of our February 2011 restructuring. Additionally, the change in accounts payable and accrued expenses and other current liabilities increased over the prior year due to an increase in current liabilities primarily related to clinical trial activities. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

We used $2.9 million of cash for investing activities during the year ended December 31, 2011, compared to $11.7 million of cash used for the year ended December 31, 2010. For the year ended December 31, 2011 and 2010, $6.9 million and $9.5 million, respectively, were used to purchase machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFREZZA. Cash used in investing activities for the year ended December 31, 2011 decreased $8.8 million compared to the same period in prior year due to the purchase of $4.2 million of marketable securities during the year ended December 31, 2010 compared to none in the current year. We received an increase of $1.8 million in proceeds received from sales and maturities of marketable securities compared to the same period in the prior year. We received cash of $3.8 million for the year ended December 31, 2011 related to the early termination of certificates of deposit that were previously held as collateral for foreign exchange hedging instruments compared to $2.0 million received in the same period in prior year as a certificate of deposit matured. Cash used to purchase machinery and equipment decreased $2.8 million compared to the same period in the prior year.

Our financing activities generated $63.4 million of cash for the year ended December 31, 2011, compared to $196.4 million for the same period in 2010. For the year ended December 31, 2011, cash from financing activities was primarily from $53.0 million of related party borrowings and $10.9 million related to the sale of common stock to Seaside during the first quarter of 2011 as well as the vesting of restricted stock units, exercise of stock options, and shares purchased through the employee stock purchase plan. For the year ended December 31, 2010, cash from financing activities was primarily from the issuance of $95.8 million of 5.75% Senior Convertible Notes due 2015 in August 2010, $87.0 million of related party borrowings, $14.1 million related to the sale of common stock to Seaside during the fourth quarter of 2010 and $2.9 million related to the sale of common stock as well as the vesting of restricted stock units, exercise of stock options, and shares purchased through the employee stock purchase plan. Cash from financing activities for the year ended December 31, 2011 decreased by $133.0 million compared to cash from financing for the same period in the prior year due to proceeds from the issuance of the 5.75% Senior Convertible Notes due 2015 in August 2010 as well as decreased related party borrowings, and decreased sales of common stock primarily to Seaside.

As of December 31, 2011, we had $3.2 million in cash, cash equivalents and marketable securities (including $0.4 million of certificate of deposit held as collateral for commercial credit card program). On February 8, 2012, we sold $86.3 million worth of units in an underwritten public offering, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock, and reflects the full exercise of an over-allotment option granted to the underwriters. Net proceeds from this offering were approximately $80.6 million, excluding any warrant exercises.

We believe our existing cash resources, including the $45.0 million remaining available under our loan arrangement with The Mann Group, will be sufficient to fund our anticipated cash requirements into the fourth quarter of 2012. Accordingly, we will need to raise additional capital, either through the sale of equity or debt securities, the entry into a strategic business collaboration with a pharmaceutical or biotechnology company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, or an increase in the borrowings available under the loan arrangement with our related party, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. This raises substantial doubt about our ability to continue as a going concern.

We intend to use our capital resources to continue the development and commercialization of AFREZZA, if approved. In addition, portions of our capital resources will be devoted to expanding our other product development programs. We are expending a portion of our capital to scale up our manufacturing capabilities in our Danbury facilities. We also intend to use our capital resources for general corporate purposes.

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We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. We cannot predict when, if ever, we could conclude an agreement with a partner. There can be no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms, if at all.

If we enter into a strategic business collaboration with a pharmaceutical or biotechnology company, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

However, we cannot provide assurances 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. If planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financing or entering a business collaboration, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of December 31, 2011, we did not have any off-balance sheet arrangements.

COMMITMENTS AND CONTINGENCIES

Our contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payments. Accordingly, the table below excludes contractual obligations relating to milestone and royalty payments due to third parties, all of which are contingent upon certain future events. The expected timing of payment of the obligations presented below is estimated based on current information. Future payments relate to operating lease obligations (including facility leases executed in November 2010), the senior convertible notes, and open purchase order and supply commitments consisted of the following at December 31, 2011 (in thousands):

	Payments Due in				
Contractual Obligations	**Less Than One Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**	**Total**
Open purchase order and supply commitments(1)	$ 17,796	$ 12,471	$ 90	$	$ 30,357
Senior convertible notes(2)	10,230	131,032	105,830		247,092
Note payable to principal stockholder(3)	14,936	288,999			303,935
Operating lease obligations	269	16			285
Total contractual obligations	$ 43,231	$ 432,518	$ 105,920	$	$ 581,669

(1) The amounts included in open purchase order and supply commitments are subject to performance under the purchase order or contract by the supplier of the goods or services and do not become our obligation until such performance is rendered. The amount shown is principally for the purchase of materials for our clinical trials, the acquisition of manufacturing equipment, and commitments related to the expansion of our manufacturing plant.

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(2) The senior convertible notes obligations include the Senior Notes due 2013 and the Senior Notes due 2015. The amounts include future interest payments at fixed rates of 3.75% and 5.75%, respectively, and payment of the notes in full upon maturity in 2013 and 2015, respectively.

(3) The obligation for the note payable to the principal stockholder includes future principal and interest payments related to the $277.2 million of borrowings as of December 31, 2011. Interest is paid based on a fixed rate equal to the one-year LIBOR rate on the date of advance plus 3% and the principal payment is due on March 31, 2013.

RELATED PARTY TRANSACTIONS

For a description of our related party transactions see Note 17 Related Party Transactions in the notes to our financial statements.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 2011, the FASB issued Accounting Standards Update No. 2011-05 for Comprehensive Income (Topic 220): Presentation of Comprehensive Income . This update improves the comparability, consistency and transparency of financial reporting and increases the prominence of items reported in other comprehensive income. This update is effective for interim and annual periods beginning after December 15, 2011. The adoption of this update will have an impact on the disclosure of comprehensive income on the Company s consolidated financial statements.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04 for Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs . This update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this update are effective for interim and annual periods beginning after December 15, 2011. The Company is currently evaluating the impact the adoption of this update will have on its consolidated financial statements.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

We are exposed to market risk related to changes in interest rates impacting our short-term investment portfolio as well as the interest rate on our credit facility with an entity controlled by our principal stockholder. The interest rate on our credit facility with our principal stockholder is a fixed rate equal to the one-year LIBOR rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum. Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds and investment-grade corporate, government and municipal debt. None of these investments is entered into for trading purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our short-term investments at December 31, 2011 are comprised mainly of a certificate of deposit and a common stock investment. We continue to utilize our $350.0 million credit facility to fund operations. As of December 31, 2011, the amount borrowed and outstanding under the credit facility was $277.2 million. The interest rate is fixed at the time of the draw. If interest rates were to increase from levels at December 31, 2011 we could experience a higher level of interest expense than assumed in our current operating plan.

Item 8. ***Financial Statements and Supplementary Data***

The information required by this Item is included in Items 15(a)(1) and (2) of Part IV of this Annual Report on Form 10-K.

Item 9. ***Changes in and Disagreements With Accountants on Accounting and Financial Disclosure***

None.

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Item 9A. ***Controls and Procedures***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our chief executive officer and chief financial officer performed an evaluation under the supervision and with the participation of our management, of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2011. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework set forth in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2011. Deloitte & Touche LLP, the independent registered public accounting firm that audited the financial statements included in this 2011 Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2011, which is included herein.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company s internal control over financial reporting during the three month period ended December 31, 2011 which have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Valencia, California

We have audited the internal control over financial reporting of MannKind Corporation and subsidiaries (the Company) as of December 31, 2011, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2011 of the Company and our report dated March 15, 2012 expressed an unqualified opinion on those financial statements and includes an explanatory paragraph relating to the Company s ability to continue as a going concern.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 15, 2012

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Item 9B. ***Other Information.***
None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file our Proxy Statement within 120 days after the end of our fiscal year pursuant to Regulations 14A for our 2012 Annual Meeting of Stockholders, and the information included in the Proxy Statement is incorporated herein by reference.

Item 10. ***Directors, Executive Officers and Corporate Governance.***
(a) *Executive Officers* For information regarding the identification and business experience of our executive officers, see Executive Officers in Part I, Item 1 of this Annual Report on Form 10-K.

(b) *Directors* The information required by this Item regarding the identification and business experience of our directors and corporate governance matters is contained in the section entitled Proposal 1- Election of Directors and Corporate Governance Principles and Board and Committee Matters in the Proxy Statement, and is incorporated herein by reference.

Additional information required by this Item is incorporated herein by reference to the section entitled Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement.

We have adopted a Code of Business Conduct and Ethics Policy that applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer and controller), and have posted the text of the policy on our website (*www.mannkindcorp.com*) in connection with Investors materials. In addition, we intend to promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

Item 11. ***Executive Compensation***
The information under the caption Executive Compensation, Compensation of Directors, Compensation Committee Interlocks and Insider Participation and Compensation Committee Report in the Proxy Statement is incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information under the captions Security Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance under Equity Compensation Plans in the Proxy Statement is incorporated herein by this reference.

Item 13. ***Certain Relationships, Related Transactions and Director Independence***
The information under the caption Certain Transactions and Corporate Governance Principles and Board and Committee Matters in the Proxy Statement is incorporated herein by reference.

Item 14. ***Principal Accounting Fees and Services***
The information under the caption Principal Accounting Fees and Services and Pre-Approval Policies and Procedures in the Proxy Statement is incorporated herein by reference.

With the exception of the information specifically incorporated by reference from the Proxy Statement in this Annual Report on Form 10-K, the Proxy Statement shall not be deemed to be filed as part of this report. Without limiting the foregoing, the information under the captions Report

of the Audit Committee of the Board of Directors in the Proxy Statement is not incorporated by reference.

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PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

(1)(2) Financial Statements and Financial Statement Schedules. The following Financial Statements of MannKind Corporation, Financial Statement Schedules and Report of Independent Registered Public Accounting Firm are included in a separate section of this report beginning on page 62:

All financial statement schedules have been omitted because the required information is not applicable or not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

(3) Exhibits. The exhibits listed under Item 15(b) hereof are filed or furnished with, or incorporated by reference into, this Annual Report on Form 10-K. Each management contract or compensatory plan or arrangement is identified separately in Item 15(b) hereof.

(b) Exhibits. The following exhibits are filed or furnished as part of, or incorporated by reference into, this Annual Report on Form 10-K:

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Exhibit Index

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(12)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(17)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(20)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.4(9)	Amended and Restated Bylaws.
4.1(10)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated November 1, 2006.
4.2(3)	First Supplemental Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated December 12, 2006.
4.3(3)	Form of 3.75% Senior Convertible Note due 2013.
4.4(1)	Form of common stock certificate.
4.5(1)	Registration Rights Agreement, dated October 15, 1998 by and among CTL ImmunoTherapies Corp., Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended.
4.6(19)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010.
4.7(19)	Form of 5.75% Senior Convertible Note due 2015.
4.8(22)	Form of Warrant to Purchase Common Stock issued February 8, 2012.
10.1(18)	Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated August 10, 2010.
10.2(19)	Letter Agreement, dated August 18, 2010, related to Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated August 10, 2010.
10.3(21)	Amendment, dated January 16, 2012 to Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated August 10, 2010.
10.4(12)	Agreement, dated September 13, 2006, between MannKind and Torcon, Inc.
10.5(2)	Securities Purchase Agreement, dated August 2, 2005 by and among MannKind and the purchasers listed on Exhibit A thereto.
10.6**(4)	Supply Agreement, dated December 31, 2004, between MannKind and Vaupell, Inc.
10.7*(1)	Form of Indemnity Agreement entered into between MannKind and each of its directors and officers.
10.8*(8)	Description of Officers Incentive Program.
10.9*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.10*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.11*(20)	Employment Agreement, dated June 27, 2011, between MannKind and Peter Richardson.
10.12*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.13*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.14*(11)	Executive Severance Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.

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Exhibit Number	Description of Document
10.15*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.16*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.17*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Peter Richardson.
10.18*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.19*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.20*(11)	Change of Control Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.21*(13)	Agreement dated December 20, 2007, between MannKind and Richard L. Anderson.
10.22*(7)	2004 Equity Incentive Plan, as amended.
10.23*(1)	Form of Stock Option Agreement under the 2004 Equity Incentive Plan.
10.24*(6)	Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan.
10.25*(8)	2004 Non-Employee Directors Stock Option Plan and form of stock option agreement there under.
10.26*(1)	2004 Employee Stock Purchase Plan and form of offering document there under.
10.27*(1)	Pharmaceutical Discovery Corporation 1991 Stock Option Plan.
10.28*(1)	Pharmaceutical Discovery Corporation 1999 Stock Plan and form of stock option plan there under.
10.29*(1)	AlleCure Corp. 2000 Stock Option and Stock Plan.
10.30*(1)	CTL Immunotherapies Corp. 2000 Stock Option and Stock Plan.
10.31*(1)	2001 Stock Awards Plan.
10.32**(20)	Letter Agreement, dated June 4, 2011, between MannKind and N.V. Organon.
10.33**(14)	Insulin Maintenance and Call-Option Agreement, dated June 19, 2009, by and among Pfizer Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind.
10.34(19)	Purchase Agreement, dated August 18, 2010, by and between MannKind and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representative for the initial purchasers named therein.
10.35(19)	Share Lending Agreement, dated August 18, 2010, by and between MannKind and Bank of America, N.A.
10.36(18)	Letter Agreement, dated August 10, 2010, by and between MannKind and Omni Capital Corporation.
10.37(22)	Common Stock Purchase Agreement by and between MannKind and The Mann Group LLC, dated February 2, 2012.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

* Indicates management contract or compensatory plan.

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** Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

(1) Incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020) filed with the SEC on April 30, 2004, as amended.

(2) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on August 5, 2005.

(3) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on December 12, 2006.

(4) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on February 23, 2005.

(5) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on February 22, 2006.

(6) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on December 14, 2005.

(7) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on June 8, 2011.

(8) Incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865) filed with the SEC on March 16, 2006.

(9) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on November 19, 2007.

(10) Incorporated by reference to MannKind s Registration Statement on Form S-3 (File No. 333-138373) filed with the SEC on November 2, 2006.

(11) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), as amended, filed with the SEC on October 16, 2007.

(12) Incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865) filed with the SEC on August 9, 2007.

(13) Incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865) filed with the SEC on December 20, 2007.

(14) Incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865) filed with the SEC on May 4, 2009.

(15) Incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865) filed with the SEC on February 27, 2009.

(16) Incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865) filed with the SEC on March 14, 2008.

(17) Incorporated by reference to MannKind s Quarterly report on Form 10-Q (File No. 000-50865), filed with the SEC on August 2, 2010.

(18) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on August 11, 2010.

(19) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on August 24, 2010.

(20) Incorporated by reference to MannKind s Quarterly report on Form 10-Q (File No. 000-50865), filed with the SEC on August 4, 2011.

(21) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on January 20, 2011.

(22) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on February 6, 2011.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MannKind Corporation

By: /s/ Alfred E. Mann
Alfred E. Mann
Chief Executive Officer

Dated: March 15, 2012

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hakan S. Edstrom, Matthew Pfeffer 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 amendments to this Report, 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 Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and 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)*	March 15, 2012
/s/ Hakan S. Edstrom Hakan S. Edstrom	President, Chief Operating Officer and Director	March 15, 2012
/s/ Matthew J. Pfeffer Matthew J. Pfeffer	Corporate Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 15, 2012
/s/ A. E. Cohen A. E. Cohen	Director	March 15, 2012
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	March 15, 2012
/s/ Michael Friedman	Director	March 15, 2012

Michael Friedman, M.D.		
/s/ Kent Kresa	Director	March 15, 2012
Kent Kresa		

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Signature	Title	Date
/s/ David H. MacCallum	Director	March 15, 2012
David H. MacCallum		
/s/ Henry L. Nordhoff	Director	March 15, 2012
Henry L. Nordhoff		
/s/ James S. Shannon	Director	March 15, 2012
James S. Shannon, M.D., MRCP(UK)		

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Valencia, California

We have audited the accompanying consolidated balance sheets of MannKind Corporation and subsidiaries (a development stage company) (the Company) as of December 31, 2010 and 2011 and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011 and for the period from February 14, 1991 (date of inception) to December 31, 2011. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements based on our audits.

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

In our opinion, such financial statements present fairly, in all material respects, the financial position of MannKind Corporation and subsidiaries as of December 31, 2010 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011 and for the period from February 14, 1991 (date of inception) to December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements for the year ended December 31, 2011 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company s existing cash resources and its operating losses since inception raise substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2012 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 15, 2012

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2010	2011
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,061	$ 2,681
Marketable securities	4,370	515
State research and development credit exchange receivable current	674	
Prepaid expenses and other current assets	2,849	2,625
Total current assets	73,954	5,821
Property and equipment net	202,356	193,029
State research and development credit exchange receivable net of current portion	629	473
Other assets	317	230
Total	$ 277,256	$ 199,553
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 3,294	$ 4,624
Accrued expenses and other current liabilities	14,840	20,736
Total current liabilities	18,134	25,360
Senior convertible notes	209,335	210,642
Note payable to related party	235,319	277,203
Total liabilities	462,788	513,205
Commitments and contingencies		
Stockholders deficit:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2010 and 2011		
Common stock, $0.01 par value 200,000,000 and 250,000,000 shares authorized at December 31, 2010 and 2011, respectively; 127,793,178 and 131,522,945 shares issued and outstanding at December 31, 2010 and 2011, respectively	1,278	1,315
Additional paid-in capital	1,587,858	1,620,535
Accumulated other comprehensive income (loss)	74	44
Deficit accumulated during the development stage	(1,774,742)	(1,935,546)
Total stockholders deficit	(185,532)	(313,652)
Total	$ 277,256	$ 199,553

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,			Cumulative Period from February 14, 1991 (Date of Inception) to December 31, 2011
	2009	2010	2011	
	(In thousands, except per share data)			
Revenue	$	$ 93	$ 50	$ 3,131
Operating expenses:				
Research and development	156,331	112,279	99,959	1,366,051
General and administrative	53,447	40,312	40,630	380,231
In-process research and development costs				19,726
Goodwill impairment				151,428
Total operating expenses	209,778	152,591	140,589	1,917,436
Loss from operations	(209,778)	(152,498)	(140,539)	(1,914,305)
Other income (expense)	51	(725)	1,541	(1,076)
Interest expense on note payable to related party	(5,679)	(10,249)	(10,883)	(28,334)
Interest expense on senior convertible notes	(4,768)	(7,128)	(10,941)	(28,794)
Interest income	70	40	18	36,989
Loss before provision for income taxes	(220,104)	(170,560)	(160,804)	(1,935,520)
Income taxes				(26)
Net loss	(220,104)	(170,560)	(160,804)	(1,935,546)
Deemed dividend related to beneficial conversion feature of convertible preferred stock				(22,260)
Accretion on redeemable preferred stock				(952)
Net loss applicable to common stockholders	$ (220,104)	$ (170,560)	$ (160,804)	$ (1,958,758)
Net loss per share applicable to common stockholders basic and diluted	$ (2.07)	$ (1.50)	$ (1.32)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	106,534	113,672	121,817	

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
Issuance of common stock for cash		$		$	$	$	998	$ 10	$ 890	$	$	$	$	$ 900
Net loss													(911)	(911)
BALANCE, FEBRUARY 29, 1992							998	10	890				(911)	(11)
Issuance of common stock for cash and services							73	1	887					888
Capital contribution									20					20
Net loss													(1,175)	(1,175)
BALANCE, FEBRUARY 28, 1993							1,071	11	1,797				(2,086)	(278)
Issuance of common stock for cash							11		526					526
Issuance of stock for notes receivable							8		400	(400)				
Net loss													(1,156)	(1,156)
BALANCE, FEBRUARY 28, 1994							1,090	11	2,723	(400)			(3,242)	(908)
Issuance of common stock for cash and services							36		1,805					1,805
Collection of stock subscription										400				400
Net loss													(2,004)	(2,004)
BALANCE, DECEMBER 31, 1994							1,126	11	4,528				(5,246)	(707)
Issuance of common stock for services									8					8
Exercise of stock options							1		22					22
Stock compensation									384					384
Net loss													(2,815)	(2,815)
BALANCE, DECEMBER 31, 1995							1,127	11	4,942				(8,061)	(3,108)
Issuance of common stock for cash and services							1		59					59
Exercise of stock options							3		12					12
Stock compensation									126					126
Net loss													(2,570)	(2,570)
							1,131	11	5,139				(10,631)	(5,481)

BALANCE, DECEMBER 31, 1996							
Issuance of common stock for cash and services			548	6	190		196
Stock compensation					2		2
Exercise of stock options			27		135		135
Conversion of notes payable			12		60		60
Net loss						(2,280)	(2,280)
BALANCE, DECEMBER 31, 1997			1,718	17	5,526	(12,911)	(7,368)
Issuance of common stock for cash and services			2,253	23	12,703		12,726
Stock compensation					150		150
Exercise of stock options			68	1	24		25
Conversion of notes payable			215	2	1,200		1,202
Net loss						(3,331)	(3,331)
BALANCE, DECEMBER 31, 1998			4,254	43	19,603	(16,242)	3,404
Issuance of common stock			162	2	532		534
Conversion of notes payable			80	1	994		995
Net loss						(5,679)	(5,679)
BALANCE, DECEMBER 31, 1999			4,496	46	21,129	(21,921)	(746)
Conversion of notes payable			63	1	1,073		1,074
Issuance of Series B preferred stock for cash	193	15,000					15,000
Issuance of common stock for cash, services and notes			4,690	46	33,945	(2,358)	31,633
Discount on notes below market rate						241	241
Accrued interest on notes						(117)	(117)
Purchase of Series A redeemable convertible preferred stock					(993)		(993)
Amount in excess of redemption obligation					999		999

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
Accretion to redemption value on Series A redeemable convertible preferred stock									(149)					(149)
Stock-based compensation									9,609					9,609
Net loss													(24,661)	(24,661)
BALANCE, DECEMBER 31, 2000	193	15,000					9,249	93	65,613	(2,234)			(46,582)	31,890
Issuance of common stock for cash							3,052	30	78,000					78,030
Cash received for common stock to be issued									3,900					3,900
Issuance of common stock for services							3		60					60
Exercise of stock options							1		13					13
Accrued interest on notes										(189)				(189)
Payments on notes receivable										28				28
Accretion to redemption value on Series A redeemable convertible preferred stock									(239)					(239)
Stock-based compensation									1,565					1,565
Issuance of put option by stockholder									(2,949)					(2,949)
Record merger of entities									171,154					171,154
Net loss													(48,245)	(48,245)
BALANCE, DECEMBER 31, 2001	193	15,000					12,305	123	317,117	(2,395)			(94,827)	235,018
							3,922	40	58,775					58,815

Issuance of common stock for cash										
Issuance of common stock for cash already received					234	2	(2)			
Issuance of stock award to employee					3		84			84
Cash received for common stock issuable							98			98
Accrued interest on notes								(229)		(229)
Payments on notes receivable								1,314		1,314
Beneficial conversion feature of Series B convertible preferred stock							1,421			1,421
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock							(1,421)			(1,421)
Accretion to redemption value on Series A redeemable convertible preferred stock							(251)			(251)
Stock-based compensation							268			268
Put option redemption by stockholder							1,921			1,921
Net loss									(206,265)	(206,265)
BALANCE, DECEMBER 31, 2002	193	15,000			16,464	165	378,010	(1,310)	(301,092)	90,773
Issuance of Series C convertible preferred stock subscriptions			50,000	(50,000)						
Cash collected on Series C convertible preferred stock subscriptions				31,847						31,847
Issuance of common stock for cash					3,494	35	49,965			50,000
Non-cash compensation expense of officer resulting from stockholder contribution							70			70
Issuance of common stock for cash already received					17					
Notes receivable by stockholder issued to officers							225		(225)	
								(102)	(3)	(105)

Accrued interest on notes			
Beneficial conversion feature of Series B convertible preferred stock	1,017		1,017
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock	(1,017)		(1,017)
Accretion to redemption value on Series A redeemable convertible preferred stock	(253)		(253)
Stock-based compensation	4,501		4,501
Put shares sold to majority stockholder	623		623
Net loss		(65,879)	(65,879)

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock Shares	Series B Convertible Preferred Stock Amount	Series C Convertible Preferred Stock Shares	Series C Convertible Preferred Stock Amount	Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
BALANCE, DECEMBER 31, 2003	193	15,000			50,000	(18,153)	19,975	200	433,141	(1,412)	(228)		(366,971)	111,577
Issuance of Series C convertible preferred stock for cash			356	18,153	(18,153)	18,153								