MANNKIND CORP
Form 10-K
March 16, 2011

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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, 2010

or

o **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 o 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 o 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 o

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 o No o

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. o

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

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

As of June 30, 2010, 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 $414,517,434.

As of February 18, 2011, there were 130,654,250 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 2011 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.

MANNKIND CORPORATION
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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, our ultra rapid-acting insulin product, 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. 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 registered 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. Unless explicitly stated otherwise, AFREZZA refers to the combination of AFREZZA inhalation powder and the AFREZZA inhaler.

OVERVIEW

MannKind Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead 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.

AFREZZA utilizes our proprietary Technosphere formulation technology, which is based on a class of organic molecules that are designed to self-assemble into small particles onto which drug molecules can be loaded. With AFREZZA, we load recombinant human insulin onto the Technosphere particles; 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 have been shown to be absorbed very rapidly into the arterial circulation, essentially mimicking intra-arterial administration.

In addition to our Technosphere platform, we are evaluating an investigational cancer immunotherapy product, MKC1106-MT, in a Phase 2 clinical trial. We are also conducting preclinical studies of a drug candidate, MKC204, that may have the potential to treat certain malignancies and inflammatory diseases.

In February 2011, we implemented a restructuring to streamline our operations, reduce our operating expenses, extend our cash runway and focus our resources on securing the approval of the new drug application, or NDA, for AFREZZA by the United States Food and Drug Administration, or FDA. In connection with this restructuring, we reduced our total workforce by approximately 41 percent and halted activity in certain development programs,

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although we retained the key assets and intellectual property required to restart development activities if and when we are able to do so.

The following chart indicates the current stage of development and status of each of our product candidates.

	Preclinical	Clinical Studies		
		Phase	Phase	Phase
	Development	1	2	3
Technosphere Platform				
AFREZZA (insulin)				active
MKC253 (GLP-1)		halted		
MKC180 (obesity compound)	halted			
Cancer Immunotherapy				
MKC1106-MT			active	
MKC1106-PP		halted		
MKC1106-NS	halted			
Cancer Drugs				
MKC204 (IRE-1 inhibitor)	active			

We were incorporated in the State of Delaware in 1991. Our principal executive offices are located at 28903 North Avenue Paine, Valencia, California 91355, and our telephone number at that address is (661) 775-5300. Our website address is http://www.mannkindcorp.com. Our filings with the Securities and Exchange Commission, or SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. We regularly post copies of our press releases as well as additional information on our website. Interested persons can subscribe on the website to e-mail alerts that are sent automatically when we issue press releases, file reports with the SEC or post certain other information to the website.

AFREZZA

Our lead product candidate, AFREZZA (insulin human [rDNA origin]) Inhalation Powder, 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, 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 containing the powder 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 facilitate the delivery of Technosphere-formulated drugs to the deep lung, we developed an inhaler that utilizes single-use, disposable, plastic cartridges containing drug-loaded powder. Our first-generation inhaler, also known as the MedTone inhaler, is light and easy to use, and fits in the palm of the patient s hand. All of our pivotal safety and

efficacy clinical studies were conducted using the MedTone (model C) inhaler.

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To date, the AFREZZA clinical program has involved 56 different studies of AFREZZA and over 5,300 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. AFREZZA Inhalation Powder has a shorter duration of action than other insulin therapies, so its glucose-lowering effect better meets a patient s needs following a meal. 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 control than comparator insulin therapies. As we reported with external authors in a report of one of our earlier Phase 3 studies that was published in *The Lancet* in 2010, this observation might be the result of greater suppression of endogenous glucose production with AFREZZA combined with 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 FDA or otherwise included in final product labeling or advertising, if it is approved.

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.

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 an NDA for AFREZZA to the FDA. In this submission, we sought approval of the AFREZZA Inhalation Powder and the MedTone (model D) inhaler. The MedTone (model D) inhaler is a more rugged and less costly commercial version of the MedTone (model C) inhaler used in clinical trials. As part of our original NDA submission, we included the results of a study, known as study 138, that evaluated the bioequivalence

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of AFREZZA Inhalation Powder administered using the MedTone (model C) and the MedTone (model D) inhalers in 75 patients with type 1 diabetes.

At the time of our original NDA submission, we were also advancing the development of a next-generation inhaler, known internally as the Dreamboat inhaler, which is even smaller (thumb-sized), easier to use and lower in manufacturing cost than the MedTone inhaler and which allows for more efficient emptying of the cartridge. In August 2009, we submitted a request for a meeting with the FDA to review the path to transition from MedTone to the next-generation inhaler for AFREZZA. In November 2009, the FDA provided a letter with advice regarding this path which would include an assessment of the bioequivalence of insulin administered using the next-generation inhaler and the MedTone (model C) inhaler. We incorporated this advice into our development plan for the next-generation inhaler.

On March 12, 2010, we received a Complete Response letter from the FDA regarding the NDA for AFREZZA. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form. The March 2010 Complete Response letter requested several items, including:

- information and currently available clinical data that support the clinical utility of AFREZZA, a request that reflects a desire to understand the positioning of AFREZZA within the range of available therapies for patients with diabetes and a desire to know how, in whom and when in the course of therapy it should be used;
- information about the comparability of the commercial version of the inhaler, i.e., MedTone (model D), to the MedTone (model C) version of the device that was used in clinical trials;
- changes to the proposed labeling of the MedTone cartridges, foil pouches and cartons; and
- updated safety data related to AFREZZA.

We believe that the request about the comparability of the MedTone inhalers stemmed from a question raised by the FDA about the method utilized by our contract laboratory to analyze blood samples for insulin and glucose in study 138. Because blood samples degrade over time, it was not possible to re-analyze the material from study 138 using the analytical method preferred by the FDA. However, we were able to utilize this analytical method in our analysis of blood samples from a study, known as study 142, that assessed the bioequivalence of insulin administered using the next-generation inhaler and the MedTone (model C) inhaler in 66 healthy volunteers. The results of study 142 demonstrated that the MedTone (model C) and next-generation inhalers are bioequivalent that is, notwithstanding the fact that a cartridge used with the next-generation inhaler contains one-third less insulin powder than the corresponding MedTone (model C) cartridge, the same amount of the same insulin formulation passes quickly through the pulmonary membrane and reaches the bloodstream when either inhaler is used.

In June 2010, we held an End-of-Review meeting with the FDA to discuss our approach for addressing their questions. To address the agency s request related to the clinical utility of AFREZZA, we presented data from a newly completed study, known as study 117, that provided additional evidence of efficacy and further clarified the clinical utility of AFREZZA in 130 patients with type 1 diabetes. To address the agency s requests related to the comparability of the clinical and commercial devices, we discussed the bioequivalency results for the next-generation inhaler. Following the conclusion of this meeting, we determined that submitting our comparability data for the next-generation inhaler was the best approach for addressing the FDA s inhaler-related questions. Accordingly, in late June 2010, we submitted the results of studies 117 and 142 as part of our response to the March 2010 Complete Response letter.

On January 18, 2011, we received a second Complete Response letter from the FDA. The principal issue raised by the FDA in the January 2011 Compete Response letter was the usage of *in vitro* performance data and bioequivalence data to bridge our next-generation inhaler to the Phase 3 trials conducted using the MedTone (model C) inhaler. The FDA requested that we conduct two clinical studies with the next-generation inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one study including a treatment group using the MedTone (model C) inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for

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the two devices. The FDA also stated that after an adequate titration of study medication there should be at least 12 weeks of relatively stable insulin dosing during the treatment period. In addition to this request, the FDA requested additional information concerning the performance characteristics, usage, handling, shipment and storage of the next-generation inhaler, an update of safety information related to AFREZZA as well as information on proposed user training and changes to the proposed labeling of the device, blister pack, foil wrap and cartons.

We are scheduled to hold an End-of-Review meeting with the agency in mid-April to discuss the protocols for the two studies, known as study 171 in type 1 patients and study 172 in type 2 patients, that we expect will generate data to form the basis of our response to the January 2011 Complete Response letter. The protocol for an earlier version of study 172, then known as study 162, was submitted to the FDA in September 2010. Study 162 was initiated in October 2010 and, by the time we halted enrollment in February 2011, approximately 39 patients had been enrolled into the study. In February 2011, the FDA sent us a letter suggesting changes to the study 162 protocol in light of its January 2011 Complete Response letter. In advance of our End-of-Review meeting, we have incorporated the agency s advice into the protocols for new studies 171 and 172, which are designed to evaluate A1C levels after an adequate titration of AFREZZA followed by a relatively stable insulin dose for at least 12 weeks. We plan to continue working closely with the FDA in our effort to ensure that studies 171 and 172 address the agency s requests. However, there can be no assurance that we will be able to satisfy all of the FDA s requirements or that the FDA will find our proposed approach to these and other future clinical studies acceptable. The FDA could also request that we conduct additional clinical trials to provide sufficient data for approval of the NDA.

As part of our original NDA submission, we proposed a Risk Evaluation and Mitigation Strategy, or REMS, for ensuring that the benefits of AFREZZA outweighed its risks. Our proposed REMS included communication tools, such as the prescribing information, medication guide, educational materials and training materials, as well as evaluation tools, such as prescriber and patient surveys, and a pharmacovigilance program including special monitoring of targeted medical events. We have been informed by the FDA that a REMS will be necessary for AFREZZA, if it is approved, to ensure that the benefits of the drug outweigh:

- the risk of respiratory difficulty immediately post-inhalation, especially in patients with undiagnosed chronic lung disease;
- the risk of pulmonary function decline over time; and
- the potential risk of harm due to use by inappropriate patient populations, such as smokers and patients with chronic lung disease.

We expect to continue our discussions with the FDA regarding the REMS after we submit our response to the January 2011 Complete Response letter.

INVESTIGATIONAL CANCER THERAPIES

Our cancer immunotherapy program utilizes the body s immune system to help eradicate tumor cells. The immune system is a network of cells and organs that defends the body against infection and abnormal cells, such as tumor cells. A key element of the immune system is its ability to distinguish between healthy cells and foreign or diseased cells that do not belong in the body. The immune system accomplishes this task by recognizing distinctive molecules called epitopes on the surface of each cell as either normal or abnormal, and responding to them appropriately. Any substance capable of being recognized by the immune system is known as an antigen. An antigen can be all or part of a pathogenic organism or it can be a by-product of diseased cells. Certain specialized cells of the immune system (antigen-presenting cells or APC) sample antigens found in the body and present the epitopes associated with foreign antigens to other cells of the immune system, known as T cells, whose function is to destroy any cell that expresses the same epitope; this process is known as cell-mediated immunity. In this way, the immune system can launch a very specific response to infection or disease.

Our approach uses DNA- and peptide-based compounds that correspond to tumor-associated antigens that are expressed in a range of tumors. We select as target antigens molecules that either play a role in disease progression or that are very selectively expressed by tumor cells. A patient s immune system is first primed by DNA-based compounds, or plasmids, that are injected directly into the patient s lymph nodes. This is designed to sensitize the

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immune system to the tumor-associated antigens encoded by the plasmids. After a period of time, the patient s lymph nodes are then injected with synthetic peptides that are designed to boost or greatly amplify the immune response to the target antigens. The immune response is maintained by repeated immunization cycles. This prime-boost regimen is designed to provoke a potent cell-mediated immune response that destroys cancer cells along with the underlying blood supply to tumors.

The key features of our cancer immunotherapy program include the following:

- It is a targeted therapeutic approach that aims to redirect patients immune response to the tumor targets expressed by their cancer. The patients with a highest likelihood to benefit from this treatment can be identified by histological analysis of their tumors.
- It involves an innovative and potent vaccination approach comprising direct intra-lymphatic administration of the immunizing components using a prime-boost sequence that is designed to achieve optimal response.
- The selected target antigens are molecules that play a key role in tumor progression and migration and that display increased expression, or selective expression, in tumor cells. Moreover, they are expressed in a range of tumors.
- The immunizing components are off-the-shelf formulations of DNA and peptides containing excipients that are well recognized and generally regarded as safe. There is no need to harvest any material from patients tumors or cells in order to manufacture our immunotherapy products.

To date, we have evaluated two product candidates in clinical trials: MKC1106-PP and MKC1106-MT. MKC1106-PP consists of three components: a plasmid that encodes pharmacologically active elements from two tumor-associated antigens, known as PRAME and PSMA, and two synthetic peptides, one an analog of a PRAME epitope and the other an analog of a PSMA epitope. In addition to melanoma, PRAME is expressed in carcinomas such as prostate, lung, breast, ovarian, renal, pancreatic and colorectal. PSMA was originally isolated from prostate carcinoma cells and later shown to be expressed in the blood vessels that supply several types of carcinoma, including breast, lung, ovarian, pancreatic, renal and colorectal carcinoma and melanoma. MKC1106-MT consists of a plasmid that encodes portions of two antigens known as Melan-A and tyrosinase, and two synthetic peptides, one an analog of a Melan-A epitope and the other an analog of a tyrosinase epitope. Melan-A and tyrosinase are antigens commonly expressed by melanoma tumor cells.

In one study, MKC1106-PP was used to treat 26 advanced cancer patients with diverse tumor types, metastatic disease and/or progressive, refractory disease. Patients were evaluated after two therapeutic cycles of six weeks each and again after four therapeutic cycles, as applicable. Patients demonstrating a clinical response or no evidence of disease progression remained in the clinical trial and received up to six cycles of treatment over nine months. In all patients, the treatment was well tolerated with few and mild adverse events. The primary endpoint of this study was the determination of an immune response following the first or second cycle of treatment. Overall, 15 subjects had an immune response to the either the PRAME or PSMA antigens, or both. Ten subjects overall demonstrated no disease progression and continued treatment past the second treatment cycle. Of these ten subjects, five subjects had an immune response for at least two cycles of treatment, one subject had an immune response during the first treatment cycle only, and four subjects had no immune response. In connection with our restructuring in February 2011, clinical development activities for MKC1106-PP were halted to focus our resources on securing the approval of the NDA for AFREZZA, although we retained the key assets and intellectual property required to restart development activities for MKC1106-PP if and when we are able to do so.

In a separate study, 18 patients with advanced melanoma were treated with MKC1106-MT. Patients were evaluated after each therapeutic cycle of six weeks and those who demonstrated a clinical response or no evidence of disease progression remained in the clinical trial and received up to eight cycles of treatment over one year. Treatment with MKC1106-MT was well tolerated by all patients. An endpoint of this study was the determination of an immune response following the first or second cycle of treatment. Overall, nine subjects had an immunologic response to the either the Melan A or tyrosinase antigens. Of these subjects, two subjects showed objective tumor responses. Of the remaining nine subjects with no or undetermined immune response, four subjects achieved an objective tumor response.

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In October 2010, we initiated a Phase 2 study of MKC1106-MT involving up to 44 patients with advanced melanoma that is confined to the skin, subcutaneous tissue or lymph nodes. The primary end-point of this open-label, non-randomized study is to evaluate objective tumor response. Clinical efficacy will also be assessed using measures of time-to-progression, progression-free survival and overall survival. We do not expect to obtain results from this study until the second half of 2012.

Cancer Drug Discovery

Our drug discovery effort is directed at a biochemical signaling pathway known as the unfolded protein response, or UPR, which is a response to stress or changes in cellular conditions during which proteins cease to function correctly. The UPR is intended to restore the normal function of the cell and preserve its viability, by halting protein production while molecular chaperones remove the improperly folded proteins. When cellular stress continues for an extended period of time, the role of the UPR changes from restoring normal function to initiating programmed cell death or apoptosis. In this manner, the improperly functioning cell is removed from the body.

However, in myeloma cells and possibly other malignancies, the UPR is not properly regulated. In these cells, an enzyme known as inositol-requiring enzyme-1, or IRE-1 , activates the X-box binding protein-1 gene, or XBP-1, thus enhancing molecular chaperone activity and protein degradation. The result is that tumor cells escape apoptosis, proliferate and invade vital organs in cancer patients, and/or confer resistance to other therapeutic means that induce cellular stress, including chemotherapy, radiotherapy and anti-angiogenic drugs.

Multiple myeloma, the second most prevalent blood cancer after non-Hodgkin s lymphoma, is a key focus of our IRE-1 program. This disease results in excessive abnormal cells as a result of transformation of normal B-cells (B-lymphocytes) into malignant plasma cells.

Using our proprietary IRE-1 assay, we have identified novel compounds that selectively antagonize IRE-1 *in vitro* and consequently down-regulates XBP-1 activity in tumor cells and animal models. We are currently undertaking nonclinical studies in order to position a compound for clinical trials.

OUR STRATEGY

Our primary objective is to secure the approval of the NDA for AFREZZA by the FDA, and our resources are focused on the activities necessary to pursue this objective. In February 2011, we implemented a restructuring to streamline our operations, reduce our operating expenses and extend our cash runway. We expect that we will require additional financial resources in order to continue the development of AFREZZA and to support our other ongoing activities. In addition to traditional financing transactions, such as the sale of equity and/or debt securities, we intend to explore opportunities to generate additional financial resources through the entry into one or more strategic business collaborations. Specifically, we intend to:

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.

Out-license our proprietary Technosphere formulation technology for the delivery of active pharmaceutical ingredients. We believe that additional Technosphere formulations of active pharmaceutical ingredients have the potential to demonstrate clinical advantages over existing therapeutic options in a variety of therapeutic areas. We intend to pursue opportunities to out-license our technology to pharmaceutical companies that are in need of alternative formulations for their proprietary active pharmaceutical ingredients.

Pursue transactional opportunities for our investigational cancer therapies. We are currently conducting a Phase 2 clinical trial of one of our investigational cancer immunotherapy products. As this program and the

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cancer drug discovery program reach upcoming milestones that are expected to increase the perceived value of these programs, we intend to pursue opportunities to enter into transactions with potential partners or acquirers.

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.

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, although the facility includes expansion space that will 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 is able to approve the NDA for AFREZZA.

Currently, our insulin inventory is from two sources. In November 2007, we entered into a long-term supply agreement with N.V. Organon, or Organon, now a subsidiary of Merck & Co., Inc., pursuant to which Organon would manufacture and supply specified quantities of recombinant human insulin to us. Under the terms of this supply agreement, we had the right to terminate the agreement upon 30 days advance written notice to Organon if the FDA fails to approve AFREZZA. In connection with the January 2011 Complete Response letter that we received from the FDA, on February 8, 2011, we gave 30 days written notice to Organon to terminate the supply agreement effective March 10, 2011. As a result of the termination of the agreement. Organon is not entitled to make (and we are not obliged to accept) any deliveries of insulin for which a delivery date under a purchase order has not yet passed, which includes all purchase orders previously placed for 2011 shipments. However, pursuant to the terms of the supply agreement, we may be required to pay Organon a termination fee if Organon is unable to sell certain quantities of insulin to other parties under commercially viable terms within 12 months after termination. While we cannot determine at this time the amount of the termination fee, if any, that we may have to pay to Organon, we estimate that the maximum amount of the termination fee is approximately $40.1 million based on the applicable exchange rate and purchase price at the time the termination notice was sent. We must rely on our insulin supplier to maintain compliance with relevant regulatory requirements including current Good Manufacturing Practices, or cGMP.

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.

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We are in the process of qualifying a manufacturer to supply us with our next-generation 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 our insulin product will be sold to the consumer. 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-based products, inhalers and inhaler cartridges. Overall, we own 102 issued utility patents, 74 issued design patents and over 240 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, and patents on our inhaler and inhaler cartridges that will remain in force into 2023.

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. Overall, we own 55 issued patents and over 230 pending applications in the United States and selected jurisdictions around the world related to our immunotherapy program.

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 will be able to secure internationally. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In addition, patent applications in the United States filed before November 29, 2000 are currently maintained in secrecy until the patent issues, although in certain countries, including the United States, for applications filed on or after November 29, 2000, applications are generally published 18 months after the application s priority date. In any event, because

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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.

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.

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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. is conducting 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.

Biodel, Inc. submitted an NDA for Linjeta , its proprietary diluent that is combined with human insulin to create a rapid-acting insulin formulation. In October 2010, Biodel received a Complete Response letter from the FDA requesting that the company conduct two Phase 3 clinical trials, one in patients with type 1 diabetes and the other in patients with type 2 diabetes, to establish the efficacy and safety of Linjeta.

Novo Nordisk is conducting 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.

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.

In March 2008, Lilly announced that it too 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.

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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.

Cancer Treatments

For many types of cancer, chemotherapy remains a significant component of the treatment regimen. Increasingly, however, drugs and antibodies that specifically target the abnormal mechanisms of proliferation, differentiation and invasion of malignant cells are being used to treat cancer. One such cancer therapy is Rituxan® (rituximab), an antibody marketed in the United States by Biogen IDEC Inc. and Genentech, Inc., or Genentech, a wholly-owned member of the Roche Group, or Roche, and by Roche in the rest of the world. Genentech and Roche have also partnered to market two other successful antibodies: Avastin® (bevacizumab) and Herceptin® (trastuzumab). Erbitux® (cetuximab) is another antibody approved for use in metastatic colon cancer and squamous cell carcinoma of the head and neck. This antibody is marketed domestically by ImClone Systems Inc., a wholly-owned subsidiary of Lilly, and Bristol-Myers Squibb Company and elsewhere by Merck KGaA.

The armamentarium of cancer treatments has been strengthened in recent years by several drugs that target specific molecular aberrations in tumor cells. One such drug is Gleevec®, developed and marketed by Novartis AG, which was initially approved for use in chronic myeloid leukemia. The drug has subsequently been approved for use in additional types of cancer. Velcade®, developed by Millenium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, and Ortho Biotech Inc., now Centocor Ortho Biotech Inc., acts by inhibiting protein degradation, thereby inducing apoptosis. It was initially approved for use in multiple myeloma; its label now includes an indication for mantle cell lymphoma.

Our cancer products may face competition from the products described above as well as from other brands. In addition, our cancer immunotherapy products may face direct competition from one or more therapeutic cancer vaccines that may be approved in the coming years. Although there have been a number of notable failures recently among immunotherapy products in development, a few approaches continue to show potential:

Provenge®, developed by Dendreon Corporation, is a vaccine composed of autologous APC that are loaded with an antigen (prostate acid phosphatase) from prostate tumor cells then re-injected into patients. In April 2010, the FDA approved Provenge for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

MAGE-A3 is a tumor-specific antigen that is expressed in a large variety of cancers but not in normal cells. GlaxoSmithKline plc is evaluating a cancer vaccine that combines MAGE-A3, delivered as a purified recombinant protein, with certain immunostimulating compounds that are intended to increase the anti-tumor immune response. This investigational product is being evaluated in Phase 3 clinical trials for the treatment of non-small cell lung cancer and melanoma.

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Rindopepimut (CDX-110) is an immunotherapy being developed by Celldex, Inc. Rindopepimut targets a mutated form of epidermal growth factor receptor that is present in multiple cancer types and is currently being evaluated for the treatment of glioblastoma multiforme in a Phase 2 clinical trial.

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 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.

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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.

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 drug cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity, and potency of the final products. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Submission to the FDA of 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 and Allergy Products, both within the Center for Drug Evaluation and Research, as well as review within the Center for Devices and Radiological Health, the Center within the FDA that reviews Medical Devices. The Division of Metabolic and Endocrine 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

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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 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. For example, healthcare reform legislation currently being considered in Congress could provide the FDA and other federal agencies with greater authority to consider the comparative effectiveness of products and to control costs of public spending on prescription drugs and biologics. 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.

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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 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.

For additional information regarding the regulatory approval of AFREZZA, see discussion under the heading Regulatory Approval Status beginning on page 5 of this report.

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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.

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.

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EMPLOYEES

As of December 31, 2010, we had 436 full-time employees. 47 of these employees were engaged in research and development, 155 in manufacturing, 132 in clinical, regulatory affairs and quality assurance and 102 in administration, finance, management, information systems, marketing, corporate development and human resources. 55 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 $112.3 million in 2010, $156.3 million in 2009 and $250.4 million in 2008.

On February 10, 2011, we announced that we had implemented a restructuring to streamline our operations, reduce our operating expenses, extend our cash runway and focus our resources on securing the FDA s approval of the NDA for AFREZZA. In connection with the restructuring, we reduced our total workforce by approximately 41 percent to 257 employees.

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
Richard Bergenstal, MD	International Diabetes Center, Park Nicollet Institute
Geremia Bolli	University of Perugia
Alan D. Cherrington, PhD	Vanderbilt University Medical Center
David D Alessio, MD	University of Cincinnati
Steven Edelman, MD	University of California, San Diego
Alexander Fleming, MD	Kinexum Box LLC
Brian Frier, MD, FECP, BS	Edinburgh Royal Infirmary
Irl B. Hirsch, MD	University of Washington Medical Center
Lois Jovanovic, MD	Sansum Medical Research Institute
Daniel Lorber, MD	Diabetes Care & Information Center of New York
Sten Madsbad	Hvidovre University Hospital, Copenhagen
Chantal Mathieu, MD, PhD	Laboratorium voor Experimentele Geneeskunde en Endocrinologie
Mark Peyrot, MD	Loyola College Center
Daniel Porte, MD	University of California, San Diego
Julio Rosenstock, MD	Dallas Diabetes and Endocrinology Center

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Name	Primary Affiliation
Jesse Roth, MD, FACP	North Shore-Long Island Jewish Health System
Richard Rubin, PhD, CDE	Johns Hopkins University School of Medicine
Robert Sherwin, MD	Yale University School of Medicine
Jay Skyler, MD, MACP	University of Miami, Diabetes Research Institute

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

Name	Primary Affiliation
Kenneth Anderson, M.D.	Dana Farber Cancer Institute, Boston
James Berenson, M.D.	Institute for Myeloma and Bone Cancer Research
Philippe Bey, Ph.D.	Pharmaceutical consultant
Bernard Fox, Ph.D.	Earle A. Chiles Research Institute
W. Martin Kast, Ph.D.	University of Southern California
Antoni Ribas, M.D.	University of California, Los Angeles
Frank Sicheri, Ph.D.	University of Toronto

EXECUTIVE OFFICERS

The following table sets forth our current executive officers and their ages as of December 31, 2010:

Name	Age	Position(s)
Alfred E. Mann	85	Chairman of the Board of Directors and Chief Executive Officer
Hakan S. Edstrom	60	President, Chief Operating Officer and Director
Matthew J. Pfeffer	53	Corporate Vice President and Chief Financial Officer
Juergen A. Martens, Ph.D.	55	Corporate Vice President, Technical Operations and Chief Technical Officer
Diane M. Palumbo	57	Corporate Vice President, Human Resources
Dr. Peter C. Richardson	51	Corporate Vice President and Chief Scientific Officer
David Thomson, Ph.D., J.D.	44	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 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 is also non-executive Chairman of the Southern California Biomedical Council and a Director of the Nevada Cancer Institute. 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,

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

Dr. Peter C. Richardson has been our Corporate Vice President and Chief Scientific Officer since October 2005. From 1991 to October 2005, he was employed by Novartis Pharmaceuticals Corporation, which is the U.S. affiliate of Novartis AG, a world leader in healthcare, most recently as Senior Vice President, Global Head of Development Alliances. From 2003 until 2005, he was Senior Vice President and Head of Development of Novartis Pharmaceuticals KK Japan. He earlier practiced as an endocrinologist. Dr. Richardson holds a B.Med.Sci (Hons.) and a BM.BS (Hons.) from University of Nottingham Medical School; a MRCP (UK) from the Royal College of Physicians, UK; a Certificate in Pharmaceutical Medicine from Universities of Freibourg, Strasbourg and Basle; and a Diploma in Pharmaceutical Medicine from the Royal College of Physicians Faculty of Pharmaceutical Medicine.

David 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 the Toronto law firm of Davies Ward Phillips & Vineberg LLP. 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.

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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 a Complete Response letter received on January 18, 2011, the FDA requested that we conduct two clinical studies with the next-generation inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one study including a treatment group using the MedTone (model C) inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices. The FDA also stated that after an adequate titration of study medication there should be at least 12 weeks of relatively stable insulin dosing at the end of the treatment period. We are scheduled to hold an End-of-Review meeting with the agency in mid-April to discuss the protocols for the two requested studies. As part of our briefing to the FDA, we have submitted the protocols for two studies that are designed to evaluate A1C levels after an adequate titration of AFREZZA followed by a relative stable insulin dose for at least 12 weeks We expect that data from these two studies, known as study 171 in type 1 patients and study 172 in type 2 patients, will form the basis of our response to the January 2011 Complete Response letter. We plan to work closely with the FDA in our effort to ensure that these clinical studies address the agency s requests. There can be no assurance that we will be able to satisfy all of the FDA s requirements or that the FDA will find our proposed approach to these and other future clinical studies acceptable. The FDA could also request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. There can be no assurance that we will be able to satisfy all of the FDA s requirements or that the FDA will find our proposed approach to these and other future clinical studies acceptable. The FDA could also 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.

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

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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 become profitable.

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 and, as of December 31, 2010, we had incurred a cumulative net loss of $1.8 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, 2010, we had a stockholders deficit of $185.5 million. Our ability to achieve and sustain 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 be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will become profitable, if at all.

If we fail to raise additional capital our financial condition and business would suffer.

It is costly to develop therapeutic product candidates and conduct clinical trials for these product candidates. Although we are currently focusing on AFREZZA as our lead product candidate, we had begun to conduct clinical trials for additional product candidates. Our existing capital resources will not be sufficient to support the expense of fully developing and commercializing AFREZZA or fully developing any of our other product candidates.

Based upon our current expectations, we believe that our existing capital resources, including the loan arrangement with The Mann Group LLC, an entity controlled by our principal stockholder. but excluding any proceeds to us from the common stock purchase agreement that we entered into with Seaside 88, LP, or Seaside, will enable us to continue planned operations through the fourth quarter of 2011. 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. In any event, we plan 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, 2010, we had a stockholders deficit of $185.5 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:

- the 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;
- our success in establishing strategic business collaborations and the timing and amount of any payments we might receive from any collaboration we are able to establish;
- actions taken by the FDA and other regulatory authorities affecting our products and competitive products;

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our degree of success in commercializing AFREZZA;
the emergence of competing technologies and products and other adverse market developments;
the timing and amount of payments we might receive from potential licensees;
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 the restructuring that we implemented following receipt of the Complete Response letter from the FDA in January 2011;
the costs of discontinuing projects and technologies;
the costs of decommissioning existing facilities, if we undertake such activities; and
the costs of performing additional clinical trials requested by the FDA.

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. In August 2010, we entered into the Seaside purchase agreement and the Mann purchase agreement for the sale and issuance by us of up to 36,400,000 shares of our common stock over a period of approximately 50 weeks. To date, we have issued and sold a total of 7.0 million shares to Seaside and The Mann Group under these agreements, and could issue and sell an additional 18.2 million shares under both agreements if we are able to satisfy the conditions precedent for sales of shares under these agreements, including the minimum price requirement. 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 could impact the rights of the holders of our common stock and may dilute their ownership percentage. We anticipate that we will seek approval by our stockholders of an amendment to our certificate of incorporation to increase the authorized number of shares of our common stock to facilitate any future capital-raising transactions. Such a proposal would require approval by the holders of a majority of the outstanding shares of our common stock. If we were unable to obtain the requisite approval, our ability to raise additional capital by selling our equity securities would be constrained. 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, credit facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA commercialization, 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

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insolvent, investors in our stock may lose the entire value of their investment.

Deteriorating global economic conditions may have an adverse impact on the loan facility with an entity controlled by our principal stockholder, which we currently cannot predict.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing 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 the loan facility with The Mann Group. If we are unable to draw on this financial resource, our business and financial condition will 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 may 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

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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 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 unforeseen

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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 Affinity 1, Affinity 2 or other 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. In June 2009, we purchased from Pfizer, a portion of its inventory of bulk insulin and acquired an option to purchase the remainder of Pfizer s insulin inventory, in whole or in part, at a specified price to the extent that Pfizer has not otherwise disposed of or used the retained insulin.

We obtain FDKP, the precursor raw material for AFREZZA, from a major multinational chemical manufacturer. We have completed a successful validation campaign of FDKP at commercial scale. We can also utilize our in-house chemical manufacturing plant for supplemental capacity. We believe our contract manufacturer has the capacity to supply our current clinical and future commercial requirements. We obtain our intended commercial AFREZZA inhaler and cartridges from a plastic molding company located in the United States.

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.

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We use our Danbury facility to formulate AFREZZA, fill plastic cartridges with AFREZZA, blister package the cartridges, place the blister packs into foil bags and package three bags plus two inhalers and the package insert as units in 90-unit boxes (and single bag packs for trials). 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 the MedTone (model D) inhaler. We anticipate that our facility may need to undergo further inspection related to our ability to fill and package cartridges for the next-generation inhaler before we can be approved to manufacture commercially. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. 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.

Additionally, when we manufacture commercial material on a significantly larger production scale than the production scale for clinical trial materials, we are required by the FDA to establish that the results obtained from the clinical trials may reasonably be extrapolated to such commercial material. We have submitted documentation to the FDA to show correlation to the clinical-scale production materials but can provide no assurance that approval will be obtained.

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 recently initiated securities class actions and a derivative lawsuit that could result in substantial costs and divert management s attention.

We are aware of lawsuits in which 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 are also aware of a state derivative lawsuit that has 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. Even though we believe we carry commercially reasonable liability insurance and stage-appropriate business interruption insurance, and our contractors may carry liability insurance that protect us in certain events, 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

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

When we purchased the facilities located in Danbury, Connecticut in 2001, there was a soil cleanup plan in process. As part of the purchase, we obtained an indemnification from the seller related to the remediation of the soil for all known environmental conditions that existed at the time the seller acquired the property. The seller was, in turn, indemnified for these known environmental conditions by the previous owner. We also received an indemnification from the seller for environmental conditions created during its ownership of the property and for environmental problems unknown at the time that the seller acquired the property. These additional indemnities are limited to the purchase price that we paid for the Danbury facilities.

During the construction of our expanded manufacturing facility, we completed the final stages of the soil cleanup plan in the third quarter of 2008, at a cost of approximately $2.25 million. We reached an agreement with the party responsible for their contribution to past clean-up costs and were reimbursed $1.625 million in July 2010. The responsible party has agreed to pay for or indemnify us for any future costs and expenses 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 products 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, we plan 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 competitor s spending levels for pre-launch marketing preparation, including medical education. We cannot assure you that we will succeed in entering into acceptable collaborations,

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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 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 potential for profitability 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

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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 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 million. We believe these limits are reasonable to cover us from potential damages arising from current and previous clinical trials of AFREZZA. 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, clinical trials management, regulatory affairs, business development, and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel. We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all.

The loss of the services of any principal member of our management and scientific staff could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are at will and we currently do not have employment agreements with any of the principal members of our management or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experience required to develop, gain regulatory approval of and commercialize our product candidates successfully.

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

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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.

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

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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 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 has advised us that it will regulate 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 FDA indicated that the review of our NDA for AFREZZA will involve 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. Our product candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.

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

We will not be able to commercialize AFREZZA or any other product candidates until 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

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experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval.

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

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

Even if regulatory authorities approve any of our product candidates, they could approve less than the full scope of uses or labeling that we seek or otherwise require special warnings or other restrictions on use or marketing 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. Based on currently available clinical studies, we believe that AFREZZA may have certain advantages over currently approved insulin products including its approximation of the natural early insulin secretion normally seen in healthy individuals following the beginning of a meal. Nonetheless, there are no assurances that these or any other 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 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

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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 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 or difficulties in obtaining approval of AFREZZA. 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 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.

We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets, 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.

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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 U.S. Patent and Trademark Office 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 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

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

RISKS RELATED TO OUR COMMON STOCK

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:

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- 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;
- the issuance and sale of our common stock pursuant to the Seaside purchase agreement and the Mann purchase agreement over the terms of these agreements;
- 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 recently-completed 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, statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym may be difficult to verify 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 of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

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

Our 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, 2010, Mr. Mann beneficially owned approximately 39.2% 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 or the conversion of our senior convertible notes into common stock could negatively affect our stock price.

As of December 31, 2010, we had 127,793,178 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 could adversely affect the trading price of our common stock. In addition, the existence of these notes 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 of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

On August 10, 2010, we entered into the Seaside purchase agreement and the Mann purchase agreement, which together provide for the sale and issuance by us of up to 36,400,000 shares of our common stock over a period of approximately 50 weeks. As of December 31, 2010, we issued and sold a total of 4,200,000 shares under these agreements. The future issuance of shares of our common stock pursuant to these two agreements, or the expectation that these issuances will occur, may further depress the price of 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.

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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 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of December 31, 2010, we had a total of 72,206,822 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 and the Seaside purchase agreement and Mann purchase agreement. 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.

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.

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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 November 23, 2010, John Arditi, our former Senior Director GCP Regulatory Affairs, filed a Demand for Arbitration against us and three employees our Chief Scientific Officer, our Vice President World Wide Regulatory Affairs, and our Chief Financial Officer claiming that we terminated his employment in retaliation for his purported reporting of alleged unlawful practices in connection with our clinical trials. Mr. Arditi has asserted claims for violation of the New Jersey Conscientious Employee Protection Act, wrongful discharge, breach of contract, breach of the implied covenant of good faith and fair dealing, defamation and intentional infliction of emotional distress. Mr. Arditi is seeking, among other relief, compensatory and punitive damages and counsel fees, costs and interest. Before Mr. Arditi filed his arbitration demand, we had completed an internal investigation and retained an independent outside firm to conduct an independent investigation of Mr. Arditi s claims. Neither investigation found any basis for his claims. We believe the allegations made by Mr. Arditi are without merit and we intend to defend against them vigorously.

Following the receipt by us of the Complete Response letter from the FDA regarding the NDA for AFREZZA in January 2011 and the subsequent decline of the price of our common stock, several complaints were filed in the U.S. District Court for the Central District of California against us and certain of our officers and directors on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been brought as purported shareholder class actions. In general, the complaints allege that we and certain of our officers and directors 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. We expect the court to appoint a lead plaintiff and lead counsel and to order the lead plaintiff to file a consolidated complaint. We will vigorously defend against the claims advanced.

In February 2011, a shareholder derivative complaint was filed in the Superior Court of California for the County of Los Angeles against our directors and certain of our officers. The complaints in the shareholder derivative action allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaint alleges that our directors and certain of our officers 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. We will vigorously defend against the claims advanced.

Item 4. ***(Removed and Reserved)***

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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, 2009		
First quarter	$ 4.09	$2.00
Second quarter	$ 9.25	$3.35
Third quarter	$12.30	$6.62
Fourth quarter	$ 9.94	$5.02
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

The closing sales price of our common stock on the Nasdaq Global Market was $3.86 on February 18, 2011 and there were 192 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, 2005, 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, 2010 without registration under the Securities Act:

(1) On October 20, 2010, we issued 700,000 shares of our common stock to The Mann Group, an entity controlled by our principal stockholder.

(2) On December 15, 2010, we issued 700,000 shares of our common stock to The Mann Group.

(3) On December 29, 2010, we issued 700,000 shares of our common stock to The Mann Group.

The aggregate purchase price of the above transactions was approximately $16.7 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

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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.

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:	**2006**	**2007**	**2008**	**2009**	**2010**
	(In thousands, except per share amounts)				
Revenue	$ 100	$ 10	$ 20	$	$ 93
Operating expenses:					
Research and development	191,796	256,844	250,442	156,331	112,279
General and administrative	42,001	50,523	55,343	53,447	40,312
Total operating expenses	233,797	307,367	305,785	209,778	152,591
Loss from operations	(233,697)	(307,357)	(305,765)	(209,778)	(152,498)
Other income (expense)	208	(197)	(62)	51	(725)
Interest expense on note payable to principal stockholder	(1,511)		(12)	(5,679)	(10,249)
Interest expense on senior convertible notes	(222)	(3,408)	(2,327)	(4,768)	(7,128)
Interest income	4,679	17,775	5,129	70	40
Loss before provision for income taxes	(230,543)	(293,187)	(303,037)	(220,104)	(170,560)
Income taxes	(5)	(3)	(2)		
Net loss applicable to common stockholders	$ (230,548)	$ (293,190)	$ (303,039)	$ (220,104)	$ (170,560)
Basic and diluted net loss per share	$ (4.52)	$ (3.66)	$ (2.98)	$ (2.07)	$ (1.50)
Shares used to compute basic and diluted net loss per share	50,970	80,038	101,561	106,534	113,672

	December 31,				
Balance Sheet Data:	**2006**	**2007**	**2008**	**2009**	**2010**
	(In thousands)				
Cash, cash equivalents and marketable securities	$ 436,479	$ 368,285	$ 46,492	$ 32,494	$ 70,431
Working capital	404,588	311,154	503	8,813	55,820
Total assets	539,737	543,443	282,459	247,397	277,256
Other liabilities	24	24			

Senior convertible notes	111,267	111,761	112,253	112,765	209,335
Note payable to related party			30,000	165,000	235,319
Deficit accumulated during the development stage	(787,849)	(1,081,039)	(1,384,078)	(1,604,182)	(1,774,742)
Total stockholders equity (deficit)	383,487	364,100	86,734	(59,221)	(185,532)

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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.

OVERVIEW

We are 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 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, 2010, we have incurred a cumulative net loss of $1.8 billion and a stockholders deficit of $185.5 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 be substantial doubt about our ability to continue as a going concern.

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.

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 profitable even if we succeed in commercializing any of our product candidates. We expect to make substantial expenditures and to incur additional operating losses as we:

- continue the clinical development of AFREZZA for the treatment of diabetes;
- seek regulatory approval to sell AFREZZA in the United States and other markets; and
- pursue development and commercialization collaborations with other companies, if available on commercially reasonable terms.

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

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates 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, 2010 were purchases of insulin totaling $16.3 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.

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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 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.

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.

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 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.

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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, 2010, we have established a valuation allowance of $633.9 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.

RESULTS OF OPERATIONS

Years ended December 31, 2010 and 2009

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, 2010 and 2009 (dollars in thousands):

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	Year Ended December 31,			
	2010	2009	$ Change	% Change
Clinical	$ 23,558	$ 44,163	$ (20,605)	(47)%
Manufacturing	67,146	82,116	(14,970)	(18)%
Research	14,034	19,259	(5,225)	(27)%
Research and development tax credit	(385)	(1,322)	937	(71)%
Stock-based compensation expense	7,926	12,115	(4,189)	(35)%
Research and development expenses	$ 112,279	$ 156,331	$ (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, 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 costs associated with the clinical studies and other development activities in our effort to address the FDA s requests in the Complete Response letter received on January 18, 2011.

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, 2010 and 2009 (dollars in thousands):

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

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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.

Years ended December 31, 2009 and 2008

Revenues

During the year ended December 31, 2009 we recognized no revenue, and during the year ended December 31, 2008, we recognized $20,000 in revenue under a license agreement.

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 2008 (dollars in thousands):

	Year Ended December 31,			
	2009	2008	$ Change	% Change
Clinical	$ 44,163	$ 114,922	$ (70,759)	(62)%
Manufacturing	82,116	92,935	(10,819)	(12)%
Research	19,259	30,081	(10,822)	(36)%
Research and development tax credit	(1,322)	(1,846)	524	(28)%
Stock-based compensation expense	12,115	14,350	(2,235)	(16)%
Research and development expenses	$ 156,331	$ 250,442	$ (94,111)	(38)%

The decrease in research and development expenses for the year ended December 31, 2009, as compared to the year ended December 31, 2008, was primarily due to decreased costs associated with the clinical development of AFREZZA as we completed our pivotal AFREZZA trials during 2008, 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. The decrease in research expenses reflects reduced salary-related and other research costs as a result of a reduction in force that we implemented in April 2009.

The research and development tax credit recognized for the years ended December 31, 2009 and 2008 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, 2009 and 2008, research and development expenses were offset by $1.3 million and $1.8 million, respectively, in connection with Connecticut s income tax credit carryforward exchange program.

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 2008 (dollars in thousands):

	Year Ended December 31,			
	2009	2008	$ Change	% Change
Salaries, employee related and other general expenses	$ 45,343	$ 44,900	$ 443	1%
Stock-based compensation expense	8,104	10,443	(2,339)	(22)%
General and administrative expenses	$ 53,447	$ 55,343	$ (1,896)	(3)%

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The decrease in general and administrative expenses for the year ended December 31, 2009, as compared to the year ended December 31, 2008, was primarily due to decreased stock compensation expense and the purchase of patents from Emisphere Technologies, Inc. during the first quarter of 2008, offset by increased professional fees related to the transaction with Pfizer during the second quarter of 2009 and partnership efforts during the third quarter of 2009.

Interest Income and Expense

Interest income for the year ended December 31, 2009 decreased $5.1 million as compared to the year ended December 31, 2008 primarily due to lower cash and cash equivalent balances as we used cash to fund operating and capital expenditures. Interest expense for the year ended December 31, 2008 and 2009 related to the convertible notes issued in December 2006 and amortization of the debt issuance costs, partially offset by capitalized interest related to construction in progress. Interest expense for the year ended December 31, 2009 also included interest related to amounts borrowed under the loan agreement with our principal stockholder in December 2008.

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.

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. 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, 2010, the amount borrowed and outstanding under the arrangement was $235.3 million and we had $98.0 million of available borrowings under the arrangement.

In August 2010, Seaside and we entered into a common stock purchase agreement, or the Seaside purchase agreement. The Seaside purchase agreement requires us to issue and sell, and Seaside to buy, up to 18,200,000 shares of our common stock in installments of 700,000 shares once every 14 days, subject to the satisfaction of certain closing conditions at each closing, beginning on September 22, 2010 and ending approximately 50 weeks after the initial closing. The price of the shares that we sell to Seaside is at an 8% discount to the volume weighted average trading price for our common stock for the ten consecutive trading days immediately preceding each closing date. For a particular closing to take place, the ten-day volume weighted average trading price for our common stock immediately prior to such closing must be at least $6.50 per share. If the ten-day volume weighted average trading price for a particular closing is below $6.50 per share, then that closing will not occur and the aggregate number of shares to be purchased will be reduced by 700,000 shares. Seaside also has the right not to complete a purchase of shares at a closing if it would cause Seaside s beneficial ownership of our common stock, calculated in accordance with Rule 13d-3 under the Exchange Act to exceed 10% of our outstanding common stock immediately after such subsequent closing. Seaside has agreed not to engage in short sales of our common stock during the term of the Seaside purchase agreement and agreed that it will not sell more than 10% of the total number of shares of common

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stock traded on any trading day. In August 2010, we entered into an agreement with Omni Capital Corporation to pay that firm a finder s fee in an amount equal to 1% of the aggregate value of all cash invested by Seaside under the Seaside purchase agreement. As of December 31, 2010, a total of 2.1 million shares had been sold to Seaside under the Seaside purchase agreement.

In conjunction with the Seaside agreement, in August 2010, The Mann Group and we entered into a common stock purchase agreement, or the Mann purchase agreement. Under the Mann purchase agreement, we are required to issue and sell, and The Mann Group is obligated to purchase, the same number of shares of our common stock that Seaside purchases on each closing date under the Seaside purchase agreement. The price of the shares that we issue and sell to The Mann Group is equal to the greater of $7.15 per share (the closing bid price of our common stock on August 10, 2010) and the closing bid price of our common stock on the trading day immediately preceding the applicable closing date. The aggregate purchase price for the shares of common stock we issue and sell to The Mann Group is paid by cancelling an equal amount of the outstanding principal under the $350.0 million revolving loan arrangement provided by The Mann Group. To the extent that the outstanding principal amount owed under the loan arrangement is insufficient to pay the full purchase price for the shares of common stock to be acquired, The Mann Group will be obligated to pay cash for the balance of the shares of common stock it is obligated to purchase under the Mann purchase agreement. The Mann purchase agreement will terminate on the day following the final closing under the Seaside purchase agreement or upon termination of the Seaside purchase agreement. As of December 31, 2010, a total of 2.1 million shares had been issued to The Mann Group under the Mann purchase agreement, which were paid for by the cancellation of outstanding principal under the loan 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. We intend to use the net proceeds from the sale of the notes to fund the costs of our clinical trials programs and other research and development activities, to expand our manufacturing operations, both on-going and planned, and for general corporate purposes, including working capital.

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.

During the year ended December 31, 2010, we used $148.7 million of cash for our operations compared to using $184.1 million for our operations in the year ended December 31, 2009. We had a net loss of $170.6 million for the year ended December 31, 2010, of which $30.9 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

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We used $11.7 million of cash in investing activities during the year ended December 31, 2010, compared to $3.1 million for the year ended December 31, 2009. For the years ended December 31, 2010 and 2009, $9.5 million and $18.9 million, respectively, were used to purchase machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFREZZA.

Our financing activities generated $196.4 million of cash for the year ended December 31, 2010, compared to $189.5 million for the same period in 2009. For the year ended December 31, 2010, cash from financing activities was primarily from a senior convertible notes offering completed in August 2010, related party borrowings and the sale of common stock to Seaside during the fourth quarter of 2010 as well as the exercise of stock options.

As of December 31, 2010, we had $70.4 million in cash, cash equivalents and marketable securities (including $4.2 million of certificates of deposit held as collateral for foreign exchange hedging instruments). Although we believe our existing cash resources, including the $98.0 million remaining available under our loan arrangement with The Mann Group will be sufficient to fund our anticipated cash requirements through the fourth quarter of 2011, we will require significant additional financing in the future to fund our operations and if we are unable to do so, there will be substantial doubt about our ability to continue as a going concern. Accordingly, we expect that 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.

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 for the treatment of different types of cancers. 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.

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

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Off-Balance Sheet Arrangements

As of December 31, 2010, 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 May 2010 and November 2010), the senior convertible notes, and open purchase order and supply commitments consisted of the following at December 31, 2010 (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)	$ 42,202	$ 57,971	$ 1,281	$	$ 101,454
Senior convertible notes(2)	10,059	135,432	111,660		257,151
Note payable to principal stockholder(3)	10,607	248,600			259,207
Operating lease obligations	626	285			911
Total contractual obligations	$ 63,494	$ 442,288	$ 112,941	$	$ 618,723

(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 and the purchase of raw materials under long-term supply agreements (including the Organon arrangement prior to termination). On February 8, 2011, we gave written notice to Organon to terminate the supply agreement, effective March 10, 2011. Pursuant to the terms of the supply agreement, we will be required to pay Organon a termination fee if Organon is unable to sell certain quantities of insulin to other parties under commercially viable terms within 12 months after termination. While we cannot determine at this time the amount of the termination fee, if any, that we may have to pay to Organon, we estimate that the maximum amount of the termination fee is approximately $40.1 million based on the applicable exchange rate and purchase price as of February 9, 2011 which is not included in the obligations above.

(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 $235.3 million of borrowings as of December 31, 2010. 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 December 31, 2012.

RELATED PARTY TRANSACTIONS

For a description of our related party transactions see Note 16 Related Party Transactions in the notes to our financial statements.

RECENT ACCOUNTING PRONOUNCEMENTS

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, *Improving Disclosures About Fair Value Measurements*. ASU No. 2010-06 requires separate disclosure of the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and reasons for the transfers and separate presentation of information about purchases, sales, issuances, and settlements in the reconciliation for Level 3 fair value measurements. Additionally, ASU No. 2010-06 clarifies existing disclosures regarding level of disaggregation and inputs and valuation techniques. The new disclosures and clarifications of existing disclosures under ASU No. 2010-06 are effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value

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measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. We adopted the disclosure requirements of significant transfers in an out of Level 1 and Level 2 fair value measurements. We do not expect the adoption of the Level 3 disclosure requirements to have a material effect on our consolidated financial statements.

On April 29, 2010, the FASB issued ASU No. 2010-17, *Milestone Method of Revenue Recognition,* which establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, which requires an entity to record the milestone payment in its entirety in the period received if the milestone meets all the necessary criteria to be considered substantive. The scope of ASU No. 2010-17 is limited to research and development arrangements. The ASU is effective for fiscal years beginning on or after June 15, 2010, and interim periods within those years. Early adoption is permitted. Adoption of this guidance is expected to have a significant effect on the accounting for certain future revenue arrangements (principally research and development partnership arrangements) should we enter into such arrangements.

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, 2010 are comprised mainly of certificates of deposit and a common stock investment. We have entered into a foreign exchange hedging transaction as part of our risk management program. We continue to utilize our $350.0 million credit facility to fund operations. As of December 31, 2010, the amount borrowed and outstanding under the credit facility was $235.3 million. The interest rate is fixed at the time of the draw. If interest rates were to increase from levels at December 31, 2010 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.

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, 2010. Based on that evaluation, our chief executive officer and

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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, 2010. Deloitte & Touche LLP, the independent registered public accounting firm that audited the financial statements included in this 2010 Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2010, which is included herein.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three month period ended December 31, 2010 which have materially affected, or are reasonably likely to materially affect, our 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, 2010, 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, 2010, 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, 2010 of the Company and our report dated March 16, 2011 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP
Los Angeles, California
March 16, 2011

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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 2010 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

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limiting the foregoing, the information under the captions Report of the Audit Committee of the Board of Directors and Compensation Committee Report in the Proxy Statement is not incorporated by reference.

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 64:

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.
3.4(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.
10.1(15)	Promissory Note made by MannKind in favor of The Mann Group LLC dated February 26, 2009.
10.2(18)	Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated August 10, 2010.
10.3(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.
10.4(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*(5)	Description of 2006 executive officer salaries.
10.10*(5)	Description of 2006 non-employee director compensation.
10.11*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.12*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.13*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Peter Richardson.
10.14*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.15*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.16*(11)	Executive Severance Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.17*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.18*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.19*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Peter Richardson.
10.20*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.21*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.22*(11)	Change of Control Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.23*(13)	Agreement dated December 20, 2007, between MannKind and Richard L. Anderson.
10.24*(7)	2004 Equity Incentive Plan, as amended.
10.25*(1)	Form of Stock Option Agreement under the 2004 Equity Incentive Plan.
10.26*(6)	Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan.
10.27*(8)	2004 Non-Employee Directors Stock Option Plan and form of stock option agreement there under.
10.28*(1)	2004 Employee Stock Purchase Plan and form of offering document there under.
10.29*(1)	Pharmaceutical Discovery Corporation 1991 Stock Option Plan.

10.30*(1)	Pharmaceutical Discovery Corporation 1999 Stock Plan and form of stock option plan there under.
10.31*(1)	AlleCure Corp. 2000 Stock Option and Stock Plan.
10.32*(1)	CTL Immunotherapies Corp. 2000 Stock Option and Stock Plan.
10.33*(1)	2001 Stock Awards Plan.
10.34**(16)	Supply Agreement, dated November 16, 2007, between MannKind and N.V. Organon.
10.35**(14)	Insulin Maintenance and Call-Option Agreement, dated June 19, 2009, by and among Pfizer Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind.
10.36(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.

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Exhibit Number	Description of Document
10.37(19)	Share Lending Agreement, dated August 18, 2010, by and between MannKind and Bank of America, N.A.
10.38(18)	Common Stock Purchase Agreement, dated August 10, 2010, by and between MannKind and Seaside 88, LP.
10.39(18)	Letter Agreement, dated August 10, 2010, by and between MannKind and Omni Capital Corporation.
10.40(18)	Common Stock Purchase Agreement, dated August 10, 2010, by and between MannKind and The Mann Group LLC.
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)

* Indicates management contract or compensatory plan.

** 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 9, 2009.

(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.

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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 16, 2011

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 16, 2011
/s/ Hakan S. Edstrom Hakan S. Edstrom	President, Chief Operating Officer and Director	March 16, 2011
/s/ Matthew J. Pfeffer Matthew J. Pfeffer	Corporate Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 16, 2011
/s/ A. E. Cohen A. E. Cohen	Director	March 16, 2011
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	March 16, 2011
/s/ Michael Friedman	Director	March 16, 2011

Michael Friedman, M.D.		
/s/ Kent Kresa	Director	March 16, 2011
Kent Kresa		
/s/ David H. MacCallum	Director	March 16, 2011
David H. MacCallum		
/s/ Henry L. Nordhoff	Director	March 16, 2011
Henry L. Nordhoff		
/s/ James S. Shannon	Director	March 16, 2011
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, 2009 and 2010 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, 2010 and for the period from February 14, 1991 (date of inception) to December 31, 2010. 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, 2009 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 and for the period from February 14, 1991 (date of inception) to December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

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, 2010, 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 16, 2011 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP
Los Angeles, California
March 16, 2011

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	December 31, 2009	2010
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,019	$ 66,061
Marketable securities	2,475	4,370
State research and development credit exchange receivable current	1,500	674
Prepaid expenses and other current assets	3,672	2,849
Total current assets	37,666	73,954
Property and equipment net	208,229	202,356
State research and development credit exchange receivable net of current portion	918	629
Other assets	584	317
Total	$ 247,397	$ 277,256
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 6,519	$ 3,294
Accrued expenses and other current liabilities	22,334	14,840
Total current liabilities	28,853	18,134
Senior convertible notes	112,765	209,335
Note payable to related party	165,000	235,319
Total liabilities	306,618	462,788
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, 2009 and 2010		
Common stock, $0.01 par value 150,000,000 and 200,000,000 shares authorized at December 31, 2009 and 2010, respectively; 113,025,291 and 127,793,178 shares issued and outstanding at December 31, 2009 and 2010, respectively	1,130	1,278
Additional paid-in capital	1,544,112	1,587,858
Accumulated other comprehensive income (loss)	(281)	74
Deficit accumulated during the development stage	(1,604,182)	(1,774,742)
Total stockholders deficit	(59,221)	(185,532)

Total	$ 247,397	$ 277,256

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,
	2008	2009	2010	2010
	(In thousands, except per share data)			
Revenue	$ 20	$	$ 93	$ 3,081
Operating expenses:				
Research and development	250,442	156,331	112,279	1,266,092
General and administrative	55,343	53,447	40,312	339,601
In-process research and development costs				19,726
Goodwill impairment				151,428
Total operating expenses	305,785	209,778	152,591	1,776,847
Loss from operations	(305,765)	(209,778)	(152,498)	(1,773,766)
Other income (expense)	(62)	51	(725)	(2,617)
Interest expense on note payable to related party	(12)	(5,679)	(10,249)	(17,451)
Interest expense on senior convertible notes	(2,327)	(4,768)	(7,128)	(17,853)
Interest income	5,129	70	40	36,971
Loss before provision for income taxes	(303,037)	(220,104)	(170,560)	(1,774,716)
Income taxes	(2)			(26)
Net loss	(303,039)	(220,104)	(170,560)	(1,774,742)
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	$ (303,039)	$ (220,104)	$ (170,560)	$ (1,797,954)
Net loss per share applicable to common stockholders basic and diluted	$ (2.98)	$ (2.07)	$ (1.50)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	101,561	106,534	113,672	

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 Shares	Series B Convertible Preferred Stock Amount	Series C Convertible Preferred Stock Shares	Series C Convertible Preferred Stock Amount	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable Officer	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
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						36		1,805					1,805

for cash and services						
Collection of stock subscription				400		400
Net loss					(2,004)	(2,004)
BALANCE, DECEMBER 31, 1994	1,126	11	4,528		(5,246)	(707)
Issuance of common stock for services			8			8
Exercise of stock options	1		22			22
Stock compensation			384			384
Net loss					(2,815)	(2,815)
BALANCE, DECEMBER 31, 1995	1,127	11	4,942		(8,061)	(3,108)
Issuance of common stock for cash and services	1		59			59
Exercise of stock options	3		12			12
Stock compensation			126			126
Net loss					(2,570)	(2,570)
BALANCE, DECEMBER 31, 1996	1,131	11	5,139		(10,631)	(5,481)
Issuance of common stock for cash and services	548	6	190			196
Stock compensation			2			2
Exercise of stock options	27		135			135
Conversion of notes payable	12		60			60
Net loss					(2,280)	(2,280)

BALANCE, DECEMBER 31, 1997			1,718	17	5,526		(12,911)	(7,368)
Issuance of common stock for cash and services			2,253	23	12,703			12,726
Stock compensation					150			150
Exercise of stock options			68	1	24			25
Conversion of notes payable			215	2	1,200			1,202
Net loss							(3,331)	(3,331)
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)
					999			999

Amount in excess of redemption obligation	

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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 Officer	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
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
Issuance of common stock for cash			3,922	40	58,775			58,815
Issuance of common stock for cash already received			234	2	(2)			
Issuance of stock award to employee			3		84			84
Cash received for common stock issuable					98			98
Accrued interest on notes						(229)		(229)
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					(1,421)			(1,421)

feature of Series B convertible preferred stock										
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							225	(225)		

officers				
Accrued interest on notes		(102)	(3)	(105)
Beneficial conversion feature of Series B convertible preferred stock	1,017			1,017
Deemed dividend related to beneficial conversion feature of Series B convertible preferred stock	(1,017)			(1,017)
Accretion to redemption value on Series A redeemable convertible preferred stock	(253)			(253)
Stock-based compensation	4,501			4,501
Put shares sold to majority stockholder	623			623
Net loss			(65,879)	(65,879)

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock	Convertible Preferred Stock			Additional	Notes Receivable	Notes Receivable	Deficit Accumulated During the	
						Subscriptions	Common Stock		Paid-In	from	Other Comprehensive	Development	
ousands)	Shares	Amount	Shares	Amount	Issuable	Receivable	Shares	Amount	Capital	Stockholders	Officers	Income (Loss)	Stage	To
ANCE, EMBER 03	193	15,000			50,000	(18,153)	19,975	200	433,141	(1,412)	(228)		(366,971)	11
ce of C rtible red stock sh			356	18,153	(18,153)	18,153								18
ce of C rtible red stock sh y ed			624	31,847	(31,847)									
se of options							86		1,079					1
se of nts ed st on							4		46					
ment of able by holder to rs										(107)				
ment of note able									(225)		228			
ersion of A rtible							(90)	(1)	(1,518)	1,519				
							891	9	5,239					5

red stock mmon							
rsion of B rtible red stock mmon	(193)	(15,000)			811	8	14,992
rsion of C rtible red stock mmon			(980)	(50,000)	4,464	45	49,955
ce of on shares hange for nts					22		
ce of on shares oyee Purchase					36		430
oceeds nitial offering					6,557	66	83,110
icial rsion e of B rtible red stock ed nds l to cial rsion e of B and C rtible red stock							19,822
tion to ption on A mable rtible red stock							(19,822)
							(60)

-based ensation			6,810		6
ss				(75,992)	(75
ANCE, MBER 04	32,756	327	592,999	(442,963)	150
ce of on shares hange for nts	24		245		
ce of on shares					
oyee Purchase	58	1	494		
se of options	304	3	1,948		1
ce of awards to ltants	40	1	(146)		
ce of and nts for	17,132	171	170,063		170
-based ensation			(1,828)		(1
ss				(114,338)	(114
ANCE, MBER 05	50,314	503	763,775	(557,301)	206
se of nts	339	3	2,691		2
ce of on shares					
oyee Purchase	86	1	980		
se of options	263	3	2,309		2
llation of on shares ck notes able	(844)	(8)	8		
ce of for cash	23,000	230	384,440		384

ce of on shares he e of ted stock	102	1	(341)		
ce of on shares ant to ch ment	100	1	2,073		2
based ensation			14,667		14
ss				(230,548)	(230
ANCE, MBER 06	73,360	734	1,170,602	(787,849)	383
ce of on shares					
oyee Purchase	124	1	1,064		1
se of options	607	6	4,917		4
ce of awards to ltants	30		123		

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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 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
Issuance of stock for cash						27,014	270	249,480					249,750
Issuance of common shares from the release of restricted stock units						146	2	(526)					(524)
Issuance of common shares pursuant to research agreement						100	1	943					944
Stock-based compensation								17,522					17,522
Net loss												(293,190)	(293,190)
BALANCE, DECEMBER 31, 2007						101,381	1,014	1,444,125				(1,081,039)	364,100
Issuance of common shares under Employee Stock Purchase Plan						349	4	896					900
Issuance of stock awards to consultants						30		(18)					(18)
Issuance of common shares from the release of restricted stock units						248	2	(317)					(315)
								24,811					24,811

Stock-based compensation								
Comprehensive loss:								
Net loss							(303,039)	(303,039)
Unrealized gain on available-for-sale securities						295		295
Comprehensive loss								(302,744)
BALANCE, DECEMBER 31, 2008		102,008	1,020	1,469,497		295	(1,384,078)	86,734
Issuance of common shares under Employee Stock Purchase Plan		323	3	1,397				1,400
Issuance of stock for cash		8,360	84	59,640				59,724
Issuance of common shares from the release of restricted stock units		2,240	22	(7,023)				(7,001)
Exercise of stock options		94	1	382				383
Stock-based compensation				20,219				20,219
Comprehensive loss:								
Net loss							(220,104)	(220,104)
Unrealized loss on available-for-sale securities						(581)		(581)
Unrealized gain on foreign currency translation						5		5
Comprehensive loss								(220,680)
BALANCE, DECEMBER 31, 2009	$	$	113,025	$ 1,130	$ 1,544,112	$	$ $ (281)	$ (1,604,182)	$ (59,221)

Issuance of common shares under Employee Stock Purchase Plan			288	3	1,602				1,605
Issuance of stock for cash			2,100	21	14,314				14,335
Issuance of stock in exchange for cancelling an equal amount of note payable to related party			2,100	21	16,660				16,681
Issuance of stock under share lending agreement			9,000	90	71				161
Issuance of common shares from the release of restricted stock units			962	10	(3,402)				(3,392)
Exercise of stock options			318	3	921				924
Stock-based compensation					13,580				13,580
Comprehensive loss:									
Net loss								(170,560)	(170,560)
Unrealized gain on available-for-sale securities							361		361
Unrealized loss on foreign currency translation							(6)		(6)
Comprehensive loss									(170,205)
BALANCE, DECEMBER 31, 2010	$	$	127,793	$ 1,278	$ 1,587,858	$	$	$ 74	$ (1,774,742)	$ (185,532)

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,			Cumulative Period from February 14, 1991 (Date of Inception) to December 31,
	2008	2009	2010	2010
	(In thousands)			
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (303,039)	$ (220,104)	$ (170,560)	$ (1,774,742)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	12,287	18,725	17,324	96,463
Stock-based compensation expense	24,793	20,219	13,580	113,422
Stock expense for shares issued pursuant to research agreement				3,018
Loss on sale, abandonment/disposal or impairment of property and equipment	213	12,869		23,575
Accrued interest on investments, net of amortization of premiums (discounts)	(237)	(12)		(191)
In-process research and development				19,726
Goodwill impairment				151,428
Loss on available-for-sale securities			644	873
Other, net		5	(6)	1,104
Changes in assets and liabilities:				
State research and development credit exchange receivable	(669)	582	1,115	(1,303)
Prepaid expenses and other current assets	3,613	2,311	823	(1,249)
Other assets		(36)	267	(317)
Accounts payable	(14,620)	(6,371)	(4,287)	1,702
Accrued expenses and other current liabilities	6,395	(12,271)	(7,554)	13,929
Other liabilities	(24)			(2)
Net cash used in operating activities	(271,288)	(184,083)	(148,654)	(1,352,564)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of marketable securities	(63,651)	(2,000)	(4,178)	(796,779)
Sales and maturities of marketable securities	46,100	17,800	2,000	792,565
Purchase of property and equipment	(82,453)	(18,852)	(9,542)	(320,251)
Proceeds from sale of property and equipment	70			284
Net cash used in investing activities	(99,934)	(3,052)	(11,720)	(324,181)

CASH FLOWS FROM FINANCING ACTIVITIES:				
Issuance of common stock and warrants	902	61,507	17,025	1,219,080
Collection of Series C convertible preferred stock subscriptions receivable				50,000
Issuance of Series B convertible preferred stock for cash				15,000
Cash received for common stock to be issued				3,900
Repurchase of common stock				(1,028)
Put shares sold to majority stockholder				623
Borrowings under lines of credit				4,220
Proceeds from notes receivables				1,742
Borrowings on notes payable from related party	30,000	135,000	87,000	322,000
Principal payments on notes payable to principal stockholder				(70,000)
Borrowings on notes payable				3,460
Principal payments on notes payable				(1,667)
Proceeds from senior convertible notes			95,783	207,050
Payment of employment taxes related to vested restricted stock units	(317)	(7,001)	(3,392)	(11,574)
Net cash provided by financing activities	30,585	189,506	196,416	1,742,806
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (340,637)	$ 2,371	$ 36,042	$ 66,061
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	368,285	27,648	30,019	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 27,648	$ 30,019	$ 66,061	$ 66,061
SUPPLEMENTAL CASH FLOWS DISCLOSURES:				
Cash paid for income taxes	$ 2	$	$	$ 26
Interest paid in cash	4,313	8,131	13,662	32,149
Accretion on redeemable convertible preferred stock				(952)
Issuance of common stock upon conversion of notes payable				3,331
Increase in additional paid-in capital resulting from merger				171,154
Issuance of common stock for notes receivable				2,758
Issuance of put option by stockholder				(2,949)
Put option redemption by stockholder				1,921
Issuance of Series C convertible preferred stock subscriptions				50,000
Issuance of Series A redeemable convertible preferred stock				4,296
Conversion of Series A redeemable convertible preferred stock				(5,248)

Non-cash construction in progress and property and equipment	6,597	620	1,742	1,742
Cancellation of principal on note payable to related party			16,681	16,681

In connection with the Company s initial public offering, all shares of Series B and Series C convertible preferred stock, in the amount of $15.0 million and $50.0 million, respectively, automatically converted into common stock in August 2004.

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of business and basis of presentation

Business MannKind Corporation (the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. The Company s lead product candidate, AFREZZA, (insulin human [rDNA origin]) Inhalation Powder, is an ultra rapid-acting insulin therapy in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

AFREZZA consists of the Company s proprietary Technosphere particles onto which insulin molecules are loaded. These loaded particles are then aerosolized and inhaled deep into the lung using the Company s AFREZZA inhaler.

Basis of Presentation The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. Since its inception through December 31, 2010 the Company has reported accumulated net losses of $1.8 billion, which include a goodwill impairment charge of $151.4 million (see Note 2), and cumulative negative cash flow from operations of $1.4 billion. It is costly to develop therapeutic products and conduct clinical trials for these products. At December 31, 2010 the Company s capital resources consisted of cash, cash equivalents, and marketable securities of $70.4 million (including $4.2 million of certificates of deposit held as collateral for foreign exchange hedging instruments) and $98.0 million of available borrowings under the loan agreement with an entity controlled by the Company s principal stockholder (see Note 7). Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations through the fourth quarter of 2011. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. In any event, the Company expects that it will need to raise additional capital, whether through the sale of equity or debt securities, a strategic business collaboration with a pharmaceutical 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 its related party, in order to continue the development and commercialization of AFREZZA and other product candidates and to support its other ongoing activities.

On December 12, 2001, the stockholders of AlleCure Corp. (AlleCure) and CTL ImmunoTherapies Corp. (CTL) voted to exchange their shares for shares of Pharmaceutical Discovery Corporation (PDC). Upon approval of the merger, PDC then changed its name to MannKind Corporation. PDC was incorporated in the State of Delaware on February 14, 1991. The stockholders of PDC did not vote on the merger. At the date of the merger, Mr. Alfred Mann owned 76% of PDC, 59% of AlleCure and 69% of CTL. Accordingly, only the minority interest of AlleCure and CTL was stepped up to fair value using the purchase method of accounting. As a result of this purchase accounting, in-process research and development of $19.7 million and goodwill of $151.4 million were recorded at the entity level. The historical basis of PDC and the historical basis relating to the ownership interests of Mr. Mann in AlleCure and CTL have been reflected in the financial statements. For periods prior to December 12, 2001, the results of operations have been presented on a combined basis. All references in the accompanying financial statements and notes to the financial statements to number of shares, sales price and per share amounts of the Company s capital stock have been retroactively restated to reflect the share exchange ratios for each of the entities that participated in the merger.

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

Segment Information In accordance with Accounting Standards Codification (ASC) 280-10-50 *Segment Reporting* previously Financial Accounting Standards Board (FASB) Statement No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making

decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating primarily in the United States of America.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of significant accounting policies

Financial Statement Estimates The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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

Concentration of Credit Risk Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and marketable securities. Cash and cash equivalents consist primarily of interest-bearing accounts and are regularly monitored by management and held in high credit quality institutions. Marketable securities consist of $4.2 million of certificates of deposit held as collateral for foreign exchange hedging instruments, and a common stock investment.

Marketable Securities The Company accounts for marketable securities as available-for-sale, in accordance with ASC 320-10 *Investments- Debt and Equity Securities,* previously FASB Statement No. 115, *Accounting for Certain Debt and Equity Securities.* Unrealized holding gains and losses for available-for-sale securities are reported as a separate component of stockholders equity until realized. The Company reviews the portfolio for other than temporary impairment in accordance with ASC 320-10-35 *Investment- Debt and Equity Securities*, previously Emerging Issues Task Force (EITF) Issue No. 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* and FASB Staff Position No. 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.* Investments in marketable securities are recorded at fair value.

State Research and Development Credit Exchange Receivable The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for foregoing the carryforward of the research and development credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses.

Fair Value of Financial Instruments The Company utilizes fair value measurement guidance prescribed by GAAP to value its financial instruments. The guidance includes a definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and expands disclosures about the use of fair value measurements. The valuation techniques utilized are based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect internal market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Significant inputs to the valuation model are unobservable.

Goodwill and Identifiable Intangibles As a result of the merger with AlleCure and CTL on December 12, 2001, as described in Note 1, goodwill of $151.4 million was recorded at the entity level in 2001. Upon adoption of FASB Statement No. 142, *Goodwill and Other Intangible Assets*, now codified as ASC 350-10 *Intangibles-*

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Goodwill and Other, the Company adopted a policy of testing goodwill and intangible assets with indefinite lives for impairment at least annually, as of December 31, with any related impairment losses being recognized in earnings when identified. In December 2002 the Company concluded that the major AlleCure product development program should be terminated and that the clinical trials of the CTL product should be halted and returned to the research stage. As a result of this determination, the Company closed the CTL facility and reduced headcount for AlleCure and CTL by approximately 50%. In connection with the annual test for impairment of goodwill as of December 31, 2002, the Company determined that on the basis of the internal study, the goodwill recorded for the AlleCure and CTL units was potentially impaired. The Company performed the second step of the annual impairment test as of December 31, 2002 for each of the potentially impaired reporting units and estimated the fair value of the AlleCure and CTL programs using the expected present value of future cash flows which were expected to be negligible. Accordingly, the goodwill balance of $151.4 million was determined to be fully impaired and an impairment loss was recorded in 2002. Subsequent to December 31, 2002, the Company had no goodwill or intangibles with indefinite lives included on its balance sheet.

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

Impairment of Long-Lived Assets The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable in accordance with ASC 360-10-35 *Property Plant and Equipment*, previously FASB Statement No. 144, *Accounting for the Impairment or Disposal of Long Lived-Assets.* Assets are considered to be impaired if the carrying value may not be recoverable based upon management s assessment of the following events or changes in circumstances:

significant changes in the Company s strategic business objectives and utilization of the assets;

a determination that the carrying value of such assets can not be recovered through undiscounted cash flows;

loss of legal ownership or title to the assets;

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 the Company believes an asset to be impaired, the impairment recognized 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. No asset impairment was recognized during the years ended December 31, 2009 and 2010, respectively. During the year ended December 31, 2008 asset impairments of approximately $0.5 million were recognized as described in Note 5.

Accounts Payable and Accrued Expenses All liabilities, including accounts payable and accrued expenses, are recorded consistent with the definition of liabilities and accrual accounting.

Income Taxes Provisions for federal, foreign, state, and local income taxes are calculated on pre-tax income based on current tax law and include the cumulative effect of any changes in tax rates from those used previously in determining deferred tax assets and liabilities. Deferred income tax assets and liabilities are recorded for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized (see Note 16). If a tax position does not meet the minimum

statutory threshold to avoid payment of penalties, the Company recognizes an expense for the amount of the penalty in the period the tax position is claimed in the tax return of the company. The Company recognizes interest accrued related to unrecognized tax benefits in income tax expense. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income tax positions are considered for uncertainty in accordance with ASC 740-10-25 *Income Taxes,* previously FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48). The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. Due to uncertainties related to deferred tax assets as a result of the history of operating losses, a valuation allowance has been established against the gross deferred tax asset balance. The valuation allowance is based on management s estimates of taxable income by jurisdiction in which the Company operates and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company s financial position and results of operations.

Contingencies Contingencies are recorded in accordance with ASC 450 *Contingencies*, previously FASB Statement No. 5, *Accounting for Contingencies.* Accordingly, the Company records a loss contingency for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

Stock-Based Compensation As of December 31, 2010, the Company had three active stock-based compensation plans, which are described more fully in Note 10. The Company accounts for all share-based payments to employees, including grants of stock awards and the compensatory elements of the employee stock purchase plan in accordance with ASC 718 *Compensation- Stock Compensation* (ASC 718), previously FASB Statement No. 123R *Share-based Payment.* 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. The Company uses 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. The Company evaluates 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.

Warrants The Company has issued warrants to purchase shares of its common stock. Warrants have been accounted for as equity in accordance with the provisions of ASC 815-40 *Derivatives and Hedging, Contracts in an Entity s Own Stock*, previously EITF Issue No. 00-19: *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.*

Comprehensive Income (Loss) Other comprehensive income (loss) (OCI) is recorded in accordance with ASC 220-10-45 *Comprehensive Income,* previously FASB Statement No. 130, *Reporting Comprehensive Income,* which requires that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. OCI includes certain changes in stockholders equity that are excluded from net income. Specifically, the Company includes in OCI unrealized gains and losses on its available-for-sale securities and cumulative translation gains and losses.

Research and Development Expenses Research and development expenses consist primarily of costs associated with the clinical trials of the Company s product candidates, manufacturing supplies and other development materials, including raw material purchases of insulin, compensation and other expenses for research and development personnel, costs for consultants and related contract research, facility costs, and depreciation. Research and development costs, which are net of any tax credit exchange recognized for the Connecticut state research and development credit exchange program, are expensed as incurred consistent with ASC 730-10 *Research and Development*, previously FASB Statement No. 2, *Accounting for Research and Development Costs.*

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MANNKIND CORPORATION AND SUBSIDIARIES
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Clinical Trial Expenses Clinical trial expenses, which are reflected in research and development expenses in the accompanying statements of operations, result from obligations under contracts 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 the Company under such contracts. The appropriate level of trial expenses are reflected in the Company s financial statements by matching period expenses with period services and efforts expended. These expenses are recorded according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Clinical trial accrual estimates are determined 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 contractually obligated fee to be paid for such services. During the course of a clinical trial, the Company may adjust the rate of clinical expense recognized if actual results differ from management s estimates. 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.

Interest Expense Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest expense, net of interest capitalized, for the years ended December 31, 2008, 2009 and 2010 was $2.3 million, $10.4 million and $17.4 million, respectively. Interest costs capitalized for the year ended December 31, 2008 were $2.5 million and were not significant for the years ended December 31, 2009 and 2010.

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

Potentially dilutive securities outstanding are summarized as follows:

	December 31,		
	2008	**2009**	**2010**
Exercise of common stock options	5,591,101	6,403,498	7,760,833
Conversion of senior convertible notes into common stock	5,117,523	5,117,523	19,826,113
Exercise of common stock warrants	2,882,873	2,882,873	
Vesting of restricted stock units	5,947,408	3,419,533	3,271,644

Exit or Disposal Activities The obligations related to exit or disposal obligations, including reductions in force, are accounted for in accordance with ASC 420-10-30 *Exit or Disposal Cost Obligations,* (ASC 420-10-30), previously FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* and EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Costs to Exit and Disposal Activity (Including Certain Costs Incurred in a Restructuring).* In accordance with ASC 420-10-30, a liability for costs associated with an exit or disposal activity is recognized when the liability is incurred and establishes that fair value is the objective for initial measurements of the liability.

Recently Issued Accounting Standards In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, *Improving Disclosures About Fair Value Measurements*. ASU No. 2010-06 requires separate disclosure of the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and reasons for the transfers and separate presentation of information about purchases, sales, issuances, and settlements in the reconciliation for Level 3 fair value measurements. Additionally, ASU No. 2010-06 clarifies existing disclosures

regarding level of disaggregation and inputs and valuation techniques. The new disclosures and clarifications of existing disclosures under ASU No. 2010-06 are effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. The Company adopted the disclosure requirements of significant transfers in and out of Level 1 and Level 2 fair value measurements. The

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MANNKIND CORPORATION AND SUBSIDIARIES
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Company does not expect the adoption of the Level 3 disclosure requirements to have a material effect on its consolidated financial statements.

On April 29, 2010, the FASB issued ASU No. 2010-17, *Milestone Method of Revenue Recognition,* which establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, which requires an entity to record the milestone payment in its entirety in the period received if the milestone meets all the necessary criteria to be considered substantive. The scope of ASU No. 2010-17 is limited to research and development arrangements. The ASU is effective for fiscal years beginning on or after June 15, 2010, and interim periods within those years. Early adoption is permitted. Adoption of this guidance is expected to have a significant effect on the accounting for certain future revenue arrangements (principally research and development partnership arrangements) should the Company enter into such arrangements.

3. Investment in securities

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

	December 31, 2009			December 31, 2010		
	Cost Basis	Gross Unrealized Loss	Fair Value	Cost Basis	Gross Unrealized Gain	Fair Value
Available-for-sale securities	$2,761	$(286)	$2,475	$4,295	$ 75	$4,370

The Company s available-for-sale securities at December 31, 2009 consist principally of a $2.0 million certificate of deposit with a maturity greater than 90 days, held as collateral for foreign exchange hedging instruments, and a common stock investment. The Company s available-for-sale securities at December 31, 2010 consist principally of $4.2 million of certificates of deposit with a maturity greater than 90 days, held as collateral primarily for foreign exchange hedging instruments, and a common stock investment. During the year ended December 31, 2010, the Company recognized a $0.6 million other-than-temporary impairment loss on its 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. The Company s policy is to maintain a highly liquid short-term investment portfolio. Proceeds from the sales and maturities of available-for-sale securities amounted to approximately $46.1 million, $17.8 million and $2.0 million for the years ended December 31, 2008, 2009 and 2010, respectively. Gross realized gains and losses for available-for-sale securities were insignificant for the years ended December 31, 2008, 2009 and 2010. Gross realized gains and losses for available-for-sale securities are recorded as other income (expense). The cost of securities sold is based on the specific identification method. Unrealized gains and losses for available-for-sale securities were a loss of $581,000 and a gain of $361,000 for the years ended December 31, 2009 and 2010, respectively. Unrealized gains and losses are included in other comprehensive income (loss).

4. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. During the years ended December 31, 2008, 2009 and 2010, research and development expenses were offset by $1.8 million, $1.3 million and $0.4 million, respectively, in connection with the program.

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5. Property and equipment

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

	Estimated Useful Life (Years)	December 31, 2009	December 31, 2010
Land		$ 5,273	$ 5,273
Buildings	39-40	54,966	54,948
Building improvements	5-40	113,188	113,489
Machinery and equipment	3-15	72,958	73,812
Furniture, fixtures and office equipment	5-10	5,312	5,369
Computer equipment and software	3	15,840	16,306
Leasehold improvements		172	53
Construction in progress		6,261	14,496
		273,970	283,746
Less accumulated depreciation and amortization		(65,741)	(81,390)
Property and equipment net		$ 208,229	$ 202,356

Leasehold improvements are amortized over four years which is the shorter of the term of the lease or the service lives of the improvements. Depreciation and amortization expense related to property and equipment for the years ended December 31, 2008, 2009 and 2010, and the cumulative period from February 14, 1991 (date of inception) to December 31, 2010 was $11.8 million, $18.2 million, $16.5 million and $94.2 million, respectively.

In December 2008, the Company determined that software previously purchased would no longer be utilized, resulting in an impairment charge of $459,000.

In December 2009, the Company recognized a loss on disposal of approximately $12.8 million in research and development expense related to the abandonment of first-generation inhaler specific assets which would no longer be used as the Company pursued the commercialization of the next-generation device.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities are comprised of the following (in thousands):

	December 31, 2009	December 31, 2010
Salary and related expenses	$ 13,362	$ 5,624
Research and clinical trial costs	3,169	668
Accrued interest	2,065	4,993
Construction in progress	203	149
Other	3,535	3,406
Accrued expenses and other current liabilities	$ 22,334	$ 14,840

7. Related-party loan arrangement

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. Under the arrangement, the Company can borrow up to a total of $350.0 million. On February 26, 2009, the

promissory note underlying the loan arrangement was revised as a result of the principal stockholder being licensed as a finance lender under the California Finance Lenders Law. Accordingly, the lender was revised to The Mann Group LLC, an entity controlled by the Company s 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 will be payable quarterly in arrears. In August 2010, the Company 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. Under the amended and restated promissory note, The Mann Group can require the Company 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, the Company 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, the Company entered into a letter agreement confirming a previous commitment by The Mann Group to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the

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prepayment would require the Company to use its working capital resources, including the proceeds from the sale of its 5.75% Senior Convertible Notes due 2015 (see Note 8). In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group 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.

On August 10, 2010, the Company entered into a common stock purchase agreement with The Mann Group. Under this common stock purchase agreement, the Company is required to issue and sell, and The Mann Group is obligated to purchase, the same number of shares of the Company s common stock that Seaside 88, LP (Seaside) purchases on each closing date under its agreement with the Company. The price of the shares that the Company sells to The Mann Group under the agreement will be equal to the greater of $7.15 per share (the closing bid price of the Company s common stock on August 10, 2010) and the closing bid price of the Company s common stock on the trading day immediately preceding the applicable closing date. The aggregate purchase price for the shares of common stock the Company issues and sells to The Mann Group will be paid by cancelling an equal amount of the outstanding principal under the $350.0 million loan arrangement provided by The Mann Group. The August 2010 amendment and restatement of the Company s promissory note issued to The Mann Group in connection with the loan arrangement also provided for the cancellation of indebtedness under the note as described above and the elimination of the Company s ability to reborrow under the note the amount of any indebtedness that is cancelled. To the extent that the outstanding principal amount owed under the loan arrangement is insufficient to pay the full purchase price for the shares of common stock to be acquired, The Mann Group will be obligated to pay cash for the balance of the shares of common stock it is obligated to purchase under the common stock purchase agreement. The common stock purchase agreement with The Mann Group will terminate on the day following the final closing under the Company s common stock purchase agreement with Seaside or upon termination of the Seaside agreement.

In the fourth quarter of 2010, the Company issued and sold a total of 2.1 million shares of common stock to Seaside for net proceeds of $14.3 million in accordance with the Company s common stock purchase agreement with Seaside. Concurrently, with the sales to Seaside, the Company issued and sold a total of 2.1 million shares of common stock to The Mann Group, an entity controlled by the Company s principal stockholder, for a total purchase price of $16.7 million, which was paid by the cancellation of outstanding principal under the Company s amended and restated promissory note with The Mann Group.

The amount outstanding under the arrangement was $165.0 million and $235.3 million at December 31, 2009 and 2010, respectively. As of December 31, 2010, the Company had accrued interest of $2.8 million related to the amount outstanding and had $98.0 million of available borrowings under the loan agreement. Interest expense on the Company s note payable to a related party for the years ended December 31, 2008, 2009 and 2010 was $12,000, $5.7 million and $10.2 million, respectively.

8. Senior convertible notes

Senior convertible notes consist of the following (in thousands):

	December 31,	
	2009	**2010**
Notes due 2013		
Principal amount	$ 115,000	$ 115,000
Unamortized debt issuance expense	(2,235)	(1,699)
Net carrying amount	112,765	113,301

Notes due 2015		
Principal amount	$	$ 100,000
Unamortized debt issuance expense		(3,966)
Net carrying amount		96,034
Senior convertible notes	$ 112,765	$ 209,335

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On August 18, 2010, the Company completed a Rule 144A offering of $100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015. The Notes due 2015 are governed by the terms of an indenture dated as of August 24, 2010. The Notes due 2015 bear interest at the rate of 5.75% per year on the principal amount, payable in cash semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2011. As of December 31, 2010, the Company had accrued interest of $2.0 million related to the Notes due 2015. The Notes due 2015 are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company s secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other liabilities of the Company s subsidiaries. The maturity date of the Notes due 2015 is August 15, 2015 and payment is due in full on that date for unconverted securities. Holders of the Notes due 2015 may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding principal into shares of the Company s common stock at an initial conversion rate of 147.0859 shares per $1,000 principal amount, which is equal to a conversion price of approximately $6.80 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the Notes due 2015 converted in connection with a fundamental change by increasing the conversion rate on such Notes, which amount, if any, will be based on the Company s common stock price and the effective date of the fundamental change, and (2) each holder of Notes due 2015 will have the option to require the Company to repurchase all or any portion of such holder s Notes at a repurchase price of 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any. The Company may elect to redeem some or all of the Notes due 2015 if the closing stock price has equaled 150% of the conversion price for at least 20 of the 30 consecutive trading days ending on the trading day before the Company s redemption notice. The redemption price will equal 100% of the principal amount of the Notes due 2015 to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, plus a make-whole payment equal to the sum of the present values of the remaining scheduled interest payments through and including August 15, 2015 (other than interest accrued up to, but excluding, the redemption date). The Company will be obligated to make the make-whole payment on all the Notes due 2015 called for redemption and converted during the period from the date the Company mailed the notice of redemption to and including the redemption date. The Company may elect to make the make-whole payment in cash or shares of its common stock, subject to certain limitations.

The Company incurred approximately $4.2 million in issuance costs which are recorded as an offset to the Notes due 2015 in the accompanying condensed consolidated balance sheets. These costs are being amortized to interest expense using the effective interest method over the term of the Notes due 2015.

On December 12, 2006, the Company completed an offering of $115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013, including $15.0 million aggregate principal amount of the Notes due 2013 sold pursuant to the underwriters over-allotment option that was exercised in full. The Notes due 2013 are governed by the terms of an indenture dated as of November 1, 2006 and a First Supplemental Indenture, dated as of December 12, 2006. The Notes due 2013 bear interest at the rate of 3.75% per year on the principal amount, payable in cash semi-annually in arrears on June 15 and December 15 of each year, beginning June 15, 2007. The Company had accrued interest of $192,000 and $192,000 related to the Notes due 2013 for the years ended December 31, 2009 and 2010, respectively. The Notes due 2013 are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company s secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other liabilities of the Company. The maturity date of the Notes due 2013 is December 15, 2013 and payment is due in full on that date for unconverted securities. Holders may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding Notes due 2013 into shares of the Company s common stock at an initial conversion rate of 44.5002 shares per $1,000 principal amount of Notes due 2013, which is equal to a conversion price of approximately $22.47 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the Notes due 2013 converted in connection with a fundamental change by

increasing the conversion rate on such Notes due 2013, which amount, if any, will be based on the Company s common stock price and the effective date of the fundamental change, and (2) each holder of the Notes due 2013 will have the option to require the Company to repurchase all or any portion of such holder s Notes

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due 2013 at a repurchase price of 100% of the principal amount of the Notes due 2013 to be repurchased plus accrued and unpaid interest, if any.

The Company incurred approximately $3.7 million in debt issuance costs which are recorded as an offset to the debt in the accompanying balance sheet. These costs are being amortized to interest expense using the effective interest method over the term of the Notes due 2013.

Amortization of debt issuance expense in connection with the Notes offerings during the years ended December 31, 2008, 2009 and 2010 were $491,000, $513,000 and $787,000, respectively.

9. Fair Value of Financial Instruments

The carrying amounts of financial instruments, which include cash equivalents, marketable securities and accounts payable, approximate their fair values due to their relatively short maturities. The fair value of the note payable to related party cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment.

Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase that are readily convertible into cash. As of December 31, 2010, the Company held $52.8 million of cash equivalents, consisting of money market funds, U.S. Treasury notes, and commercial paper. The fair value of these investments was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

The Company s marketable securities consist principally of certificates of deposit with a maturity greater than 90 days, held as collateral primarily for foreign exchange hedging instruments, and a common stock investment that are classified as available-for-sale securities. The certificates of deposit are stated at fair value based on quoted prices for similar instruments in an active market (Level 2 in the fair value hierarchy) and the common stock investment is stated at fair value based on quoted prices in an active market (Level 1 in the fair value hierarchy). As of December 31, 2010, and 2009, there were marketable securities of $4.4 million and $2.5 million, respectively.

The senior convertible notes due 2013 had a carrying value of $112.8 million and $113.3 million, as of December 31, 2009 and 2010, respectively. The senior convertible notes due 2013 had an estimated fair value of $80.3 million and $69.1 million as of December 31, 2009, and 2010, respectively, calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy). The senior convertible notes due 2015 had a carrying value of $96.0 million as of December 31, 2010. The senior convertible notes due 2015 had an estimated fair value of $134.1 million as of December 31, 2010, calculated based on model-derived valuations whose inputs are observable (Level 2 in the fair value hierarchy).

Derivative financial instruments are recognized as other assets or other current liabilities in the financial statements and measured at fair value. The fair value of foreign exchange hedging contracts equals the carrying value at each balance sheet date. The fair value of these contracts are determined using methodologies based on market observable inputs (Level 2 in the fair value hierarchy), including foreign currency spot rates. The Company used derivative financial instruments to manage its exposure to foreign currency exchange risks related to past purchases of insulin. The Company does not use derivative financial instruments for trading or speculative purposes, nor does it use leveraged financial instruments. Credit risk related to derivative financial instruments is considered minimal and is managed by requiring high credit standards for counterparties and through periodic settlements of positions.

The Company s derivative financial instruments are not designated as hedging instruments, and gains or losses resulting from changes in the fair value are reported in other income (expense), in the consolidated statements of operations. The Company entered into foreign exchange hedging contracts with notional amounts totaling $14.5 million and $25.5 million at December 31, 2009 and 2010, respectively. The Company recorded an unrealized loss on the foreign exchange hedging contracts of $0.3 million at December 31, 2009 and $0.6 million at December 31, 2010. The Company recorded a realized gain of $52,000 and a realized loss of $1.6 million for the years ended December 31, 2009 and 2010, respectively, on the execution of quarterly window forward contracts.

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10. Common and preferred stock

Private Placements On August 5, 2005, the Company closed a $175.0 million private placement of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock to accredited investors including the Company s principal stockholder who purchased $87.3 million of the private placement. The Company sold 17,132,000 shares of common stock in the private placement, together with warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share which became exercisable on February 1, 2006 and expired on August 5, 2010. In connection with this private placement, the Company paid $4.5 million in commissions to the placement agents and incurred $300,000 in other offering expenses which resulted in net proceeds of approximately $170.2 million.

Public Equity Offering On August 5, 2009, the Company sold 8,360,000 shares of its common stock, including 960,000 shares sold pursuant to the full exercise of an over-allotment option granted to the underwriters of the offering, at a public offering price of $7.35 per share. The Company s principal stockholder purchased 1,000,000 of these shares from the underwriters at a price per share of $8.11. The sale of common stock resulted in aggregate net proceeds to the Company of approximately $59.7 million after deducting offering expenses.

Common Stock In June 2010, the Company s stockholders approved an increase in the Company s authorized shares of common stock from 150,000,000 to 200,000,000. As of December 31, 2010, 127,793,178 shares of common stock were issued and outstanding.

Included in the common stock outstanding as of December 31, 2010 are 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of the $100 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 (see Note 8). Bank of America is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company 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. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of $0.01 per share from Bank of America for the use of borrowed shares.

On August 10, 2010, the Company entered into an agreement with Seaside for the sale of up to 18,200,000 shares of common stock in increments of 700,000 shares on a bi-weekly basis with the first closing date scheduled for September 22, 2010 provided that certain conditions are met, including for a particular closing to take place, the ten-day volume weighted average trading price for the Company s common stock immediately prior to such closing must be at least $6.50 per share. If the ten-day volume weighted average trading price for a particular closing is below $6.50 per share, then that closing will not occur and the aggregate number of shares to be purchased will be reduced by 700,000 shares. The purchase price per share at each closing will be equal to 92% of that 10-day volume weighted average price. The agreement with Seaside will terminate on the day following the final closing under the agreement, or the Company may terminate the Seaside agreement at any time upon written notice. As of December 31, 2010, the Company issued and sold a total of 2.1 million shares of common stock to Seaside for net proceeds of $14.3 million in accordance with the agreement.

In conjunction with the Seaside agreement, on August 10, 2010, the Company entered into a common stock purchase agreement with The Mann Group. Under this common stock purchase agreement, the Company is required to issue and sell, and The Mann Group is obligated to purchase at a price equal to the greater of $7.15 per share (the closing bid price of the Company s common stock on August 10, 2010) and the closing bid price of common stock on the trading day immediately preceding the applicable closing date, the same number of shares of the Company s common stock that Seaside purchases on each closing date under its agreement with the Company (see Note 7). Concurrently with the Seaside closing, the Company issued and sold 2.1 million shares to The Mann Group as of December 31, 2010 for a total purchase price of $16.7 million, which was paid by the cancellation of outstanding principal under the Company s loan agreement with The Mann Group.

The Company had reserved shares of common stock for issuance as follows:

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	December 31, 2009	December 31, 2010
Exercise of common stock options	6,403,498	7,760,833
Conversion of senior convertible notes into common stock	5,117,523	19,826,113
Exercise of common stock warrants	2,882,873	
Vesting of restricted stock units	3,419,533	3,271,644
	17,823,427	30,858,590

Preferred Stock The Company is authorized to issue 10,000,000 shares of preferred stock. As of December 31, 2010, no shares of preferred stock were issued and outstanding.

11. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned under the share lending arrangement (see Note 10). As of December 31, 2010, 9,000,000 shares of the Company s common stock, which were loaned to a share borrower pursuant to the terms of a share lending agreement, as described in Note 10, were issued and are outstanding, and holders of the borrowed shares have all the rights of a holder of the Company s common stock. However, because the share borrower must return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof), the borrowed shares are not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 17,823,427 shares and 30,858,590 shares of the Company s common stock as of December 31 2009 and 2010, respectively, and exclude the 9,000,000 shares of the Company s common stock loaned under the share lending arrangement as of December 31, 2010.

12. Stock award plans

As of December 31, 2010, the Company has three active stock-based compensation plans the 2004 Equity Incentive Plan (the Plan), the 2004 Non-Employee Directors Stock Option Plan (the NED Plan), and the 2004 Employee Stock Purchase Plan (the ESPP). The Plan provides for the granting of stock awards including stock options and restricted stock units, to employees, directors and consultants. The NED Plan provides for the automatic, non-discretionary grant of options to the Company s non-employee directors. There are also options outstanding to the Company s principal stockholder at December 31, 2010 that were not granted under any plan; these options were granted during the year ended December 31, 2002, vested over four years, and have an exercise price of $25.23 per share. The following table summarizes information about the Company s stock-based award plans as of December 31, 2010:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance

2004 Equity Incentive Plan	6,922,362	3,271,644	3,613,146
2004 Non-Employee Directors Stock Option Plan	597,500		194,500
Options outside of any plan granted to principal stockholder	240,971		
Total	7,760,833	3,271,644	3,807,646

The Company s board of directors determines eligibility, vesting schedules and exercise prices for stock awards granted under the Plan. The NED Plan provides for automatic, non-discretionary grant of options to the Company s

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non-employee directors. Options and other stock awards under the Plan and the NED Plan expire not more than ten years from the date of the grant and are exercisable upon vesting. Stock options generally vest over four years. Current stock option grants vest and become exercisable at the rate of 25% after one year and ratably on a monthly basis over a period of 36 months thereafter. Restricted stock units generally vest at a rate of 25% per year over four years with consideration satisfied by service to the Company. Certain performance-based awards vest upon achieving either two or three pre-determined performance milestones which are expected to occur over periods ranging from 32 months to 66 months from the date of grant. The Plan provides for full acceleration of vesting if an employee is terminated within thirteen months of a change in control, as defined in the Plan.

On February 6, 2008, the Compensation Committee approved a management proposal designed to encourage employee retention. The proposal involved the issuance of restricted stock units to the majority of employees and executive officers of the Company. A total of 1,678,674 restricted stock units were granted under the Plan. These units fully vested on June 30, 2009. Stock compensation expense associated with these grants was recorded on a straight line basis from February 6, 2008 through June 30, 2009 and was approximately $11.0 million.

On May 22, 2008 and May 21, 2009, the Company s stockholders approved amendments to the Plan to increase the number of shares of common stock available for issuance under the plan by 5,000,000 shares each time.

On July 9, 2008, the Company announced an Offer to Exchange Outstanding Options to Purchase Common Stock (the Offer) under which the Company offered eligible employees the opportunity to exchange out-of-the money stock options covering up to an aggregate of 5,417,840 shares on a grant by grant basis for a reduced number of restricted stock units. The Offer expired on August 6, 2008. Pursuant to the Offer, the Company accepted for exchange options to purchase an aggregate of 4,493,509 shares of the Company s common stock and issued restricted stock units covering an aggregate of 2,246,781 shares of the Company s common stock. For the restricted stock units issued pursuant to the offer, both the remaining estimated unamortized stock compensation expense related to the exchanged options of approximately $13.9 million and the estimated incremental stock compensation expense resulting from the exchange of approximately $3.7 million was amortized over the vesting period ending on August 1, 2010.

In March 2004, the Company s board of directors approved the ESPP, which became effective upon the closing of the Company s initial public offering. Initially, the aggregate number of shares that could be sold under the plan was 2,000,000 shares of common stock. On January 1 of each year, for a period of ten years beginning January 1, 2005, the share reserve automatically increases by the lesser of: 700,000 shares, 1% of the total number of shares of common stock outstanding on that date, or an amount as may be determined by the board of directors. However, under no event can the annual increase cause the total number of shares reserved under the ESPP to exceed 10% of the total number of shares of capital stock outstanding on December 31 of the prior year. On January 1, 2008, 2009 and 2010 the ESPP share reserve was increased by 700,000, 700,000 and 700,000 shares, respectively. In November 2006, the Company s board of directors approved a temporary decrease of 2.6 million shares to the reserve in order to make additional shares available for the Company s December 2006 offerings. In May 2007, the reserve was reinstated after a decrease of 2.6 million shares. As of December 31, 2010, 1,767,373 shares were available for issuance under the ESPP. For the years ended December 31, 2008, 2009 and 2010 the Company sold 349,317, 322,518 and 287,597 shares, respectively, of its common stock to employees participating in the ESPP.

In accordance with ASC 718, share-based payment transactions are recognized as compensation cost based on the fair value of the instrument on the date of grant. The Company accounts for non-employee stock-based compensation expense based on the estimated fair value of the options, determined using the Black-Scholes option valuation model and amortizes such expense on a straight-line basis over the service period for the entire award. These awards are subject to remeasurement until service is complete. As of December 31, 2010, there were options to purchase 143,033 shares of common stock outstanding to consultants.

During the years ended December 31, 2008, 2009 and 2010 the Company recorded stock-based compensation expense related to its stock award plans and the ESPP of $24.8 million, $20.2 million and $13.6 million respectively.

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Total stock-based compensation expense recognized in the accompanying statements of operations is as follows (in thousands):

	Year Ended December 31,		
	2008	2009	2010
Employee-related	$ 24,716	$ 19,653	$ 13,478
Consultant-related	77	566	102
Total	$ 24,793	$ 20,219	$ 13,580

Total stock-based compensation expense recognized in the accompanying statements of operations is included in the following categories (in thousands):

	Year Ended December 31,		
	2008	2009	2010
Research and development	$ 14,350	$ 12,115	$ 7,926
General and administrative	10,443	8,104	5,654
Total	$ 24,793	$ 20,219	$ 13,580

The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options. The expected life of the option is estimated using the simplified method as provided in ASC 718, previously SEC Staff Accounting Bulletin No. 107. Under this method, the expected life equals the arithmetic average of the vesting term and the original contractual term of the options. The Company has used the simplified method and will continue to use the simplified method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate an expected term as the Company is in the development stage. The Company estimates volatility using the historical volatility of its stock. The Company has selected risk-free interest rates based on U.S. Treasury securities with an equivalent expected term in effect on the date the options were granted. Additionally, the Company uses historical data and management judgment to estimate stock option exercise behavior and employee turnover rates to estimate the number of stock option awards that will eventually vest. The Company calculated the fair value of employee stock options for the years ended December 31, 2009 and 2010 using the following assumptions:

	Year Ended December 31,	
	2009	2010
Risk-free interest rate	2.16% 3.07%	0.74% 3.14%
Expected lives	5.8 6.1 years	2.6 6.1 years
Volatility	78% 80%	78% 102%
Dividends		

The following table summarizes information about stock options outstanding:

	Number of	Weighted Average Exercise Price	Weighted Average Grant Date	Aggregate Intrinsic

	Shares	Weighted Average Exercise Price per Share	Weighted Average Fair Value per Share	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2010	6,403,498	7.20		$20,422
Granted	2,051,300	6.03	$4.06	
Exercised	(317,787)	2.91		
Forfeit	(167,337)	4.67		
Expired	(208,841)	10.97		
Outstanding at December 31, 2010	7,760,833	6.91		$19,229
Vested or expected to vest at December 31, 2010	7,123,858	7.04		$17,515
Exercisable at December 31, 2010	3,622,421	8.57		$ 8,289

The total intrinsic value of options exercised during the years ended December 31, 2008, 2009 and 2010 was zero, $389,000 and $1.6 million, respectively. Intrinsic value is measured using the fair market value at the date of exercise (for options exercised) or at December 31 (for outstanding options), less the applicable exercise price.

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Cash received from the exercise of options during the years ended December 31, 2009 and 2010 was approximately $383,000 and $924,000, respectively. There were no stock options exercised during the year ended December 31, 2008. The weighted-average remaining contractual terms for options outstanding, vested or expected to vest, and exercisable at December 31, 2010 was 8.7 years, 7.5 years and 6.3 years, respectively.

A summary of restricted stock unit activity for the year ended December 31, 2010 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2010	3,419,533	$ 7.50
Granted	1,412,852	$ 5.98
Vested	(1,418,938)	$ 5.48
Forfeited	(141,803)	$ 6.46
Outstanding at December 31, 2010	3,271,644	$ 6.28

The total restricted stock units expected to vest as of December 31, 2010 was 2,929,060 with a weighted average grant date fair value of $6.28. The total intrinsic value of restricted stock units expected to vest as of December 31, 2010 was $23.6 million. Intrinsic value of restricted stock units expected to vest is measured using the closing share price at December 31, 2010.

Total intrinsic value of restricted stock units vested during the years ended December 31, 2008, 2009 and 2010 was $1.2 million, $23.6 million and $10.5 million, respectively. Intrinsic value of restricted stock units vested is measured using the closing share price on the day prior to the vest date. The total grant date fair value of restricted stock units vested during the years ended December 31, 2008, 2009 and 2010 was $4.2 million, $23.8 million and $7.8 million, respectively.

As of December 31, 2010, there was $14.0 million and $18.7 million of unrecognized compensation expense related to options and restricted stock units, respectively, which is expected to be recognized over the weighted average vesting period of 2.6 years.

13. Warrants

In connection with the sale of common stock in the private placement which closed on August 5, 2005, the Company concurrently issued warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share (see Note 10). These warrants became exercisable on February 1, 2006 and expired on August 5, 2010. For the years ended December 31, 2008, 2009 and 2010, no warrants were exercised.

14. Commitments and contingencies

Operating Leases The Company leases certain facilities and equipment under various operating leases, which expire at various dates through 2013. Future minimum rental payments required under operating leases are as follows at December 31, 2010 (in thousands):

Year Ending December 31,	
2011	$ 626
2012	269
2013	16
After 2013	0

Total minimum lease payments	$ 911

Rent expense under all operating leases for the years ended December 31, 2008, 2009 and 2010 was approximately $1.7 million, $2.1 million and $1.2 million, respectively.

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Capital Leases The Company s capital leases were not material for the years ended December 31, 2008, 2009 and 2010.

Supply Agreement In November 2007, the Company entered into a long-term supply agreement with Organon N.V. (Organon) pursuant to which Organon agreed to manufacture and supply specified quantities of recombinant human insulin. The initial term of this supply agreement was to end on December 31, 2012 and was subject to automatic extensions for consecutive two-year terms under specified circumstances. As of December 31, 2010, the Company has annual purchase commitments through the remaining initial term aggregating to approximately $78 million. On February 8, 2011, the Company gave written notice to Organon to terminate the supply agreement, effective March 10, 2011 (see Note 19).

Guarantees and Indemnifications In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company s request in such capacity. The term of the indemnification period is for the officer s or director s lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. The Company has not recorded any liability for these indemnities in the accompanying consolidated balance sheets. However, the Company accrues for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable. No such losses have been recorded to date.

Litigation The Company is involved in various legal proceedings and other matters. In accordance with ASC 450 *Contingencies*, previously FASB Statement No. 5, *Accounting for Contingencies*, the Company would record a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

On November 23, 2010, John Arditi, a former Senior Director GCP Regulatory Affairs of the Company, filed a Demand for Arbitration against the Company and three of its employees the Chief Scientific Officer, the Vice President World Wide Regulatory Affairs, and the Chief Financial Officer claiming that the Company terminated his employment in retaliation for his purported reporting of alleged unlawful practices in connection with the Company s clinical trials. Mr. Arditi has asserted claims for violation of the New Jersey Conscientious Employee Protection Act, wrongful discharge, breach of contract, breach of the implied covenant of good faith and fair dealing, defamation and intentional infliction of emotional distress. Mr. Arditi is seeking, among other relief, compensatory and punitive damages and counsel fees, costs and interest. Before Mr. Arditi filed his arbitration demand, the Company completed an internal investigation and retained an independent outside firm to conduct an independent investigation of Mr. Arditi s claims. Neither investigation found any basis for his claims. The Company believes the allegations made by Mr. Arditi are without merit and intend to defend against them vigorously.

Following the receipt of the Complete Response letter from the FDA regarding the NDA for AFREZZA in January 2011 and the subsequent decline of the price of the Company s common stock, several complaints were filed in the U.S. District Court for the Central District of California against the Company and certain of its officers and directors on behalf of certain purchasers of the Company s common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been brought as purported shareholder class actions. In general, the complaints allege that the Company and certain of its officers and directors violated federal securities laws by making materially false and misleading statements regarding the Company s business and prospects for AFREZZA, thereby artificially inflating the price of its 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 Company expects the court to appoint a lead plaintiff and a lead counsel and to order the lead plaintiff to file a consolidated complaint. The Company plans to vigorously defend against the claims advanced.

In February 2011, a shareholder derivative complaint was filed in the Superior Court of California for the County of Los Angeles against the Company s directors and certain of its officers. The complaints in the

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shareholder derivative action allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaint alleges that the Company s directors and certain of its officers caused or allowed for the dissemination of materially false and misleading statements regarding the Company s business and prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking unspecified monetary damages and other relief, including reforms to the Company s corporate governance and internal procedures. The Company plans to vigorously defend against the claims advanced.

Licensing Arrangement On October 12, 2006, the Company entered into an agreement with The Technion Research and Development Foundation Ltd. (TRDF), an Israeli corporation affiliated with the Technion-Israel Institute of Technology (the Technion) to license certain technology from TRDF and to collaborate with TRDF in the further research in and the development and commercialization of such technology. In exchange for the rights that the Company obtained under this agreement, the Company agreed to pay to TRDF aggregate license fees of $3.0 million and to issue to TRDF a total of 300,000 shares of the Company s common stock. The license fees were to be paid and the shares issued in three equal installments. The first installment occurred on October 18, 2006. The second installment was paid on December 3, 2007. The third installment was scheduled to occur, subject to the accomplishment of certain milestones, on October 12, 2008. The Company had also agreed to pay a total of $2.0 million to TRDF in three nearly equal installments to fund sponsored research to be conducted at TRDF by a team led by a faculty member at Technion. The initial sponsored research payment was made upon signing of the agreement. The second sponsored research payment occurred on December 3, 2007 and the third sponsored research payment was scheduled to occur, subject to the accomplishment of certain milestones, on October 12, 2008. The Company had also agreed to retain the services of the Technion faculty member as a consultant, for which the Company agreed to pay the consultant $60,000 per year and granted the individual an option to purchase 60,000 shares of the Company s common stock. Under the terms of the agreement, the Company issued 100,000 shares of common stock to TRDF on October 12, 2006 and November 29, 2007, respectively. Additionally, $1.6 million in license fees were paid on October 18, 2006 and December 3, 2007, respectively. In August 2008, the Company ended its agreement with TRDF and made no further payments for licensing fees in 2008.

15. Employee benefit plans

The Company administers a 401(k) Savings Retirement Plan (the MannKind Retirement Plan) for its employees. For the years ended December 31, 2008, 2009 and 2010, the Company contributed $914,000, $824,000 and $752,000 respectively, to the MannKind Retirement Plan.

16. Income taxes

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. A valuation allowance is established when uncertainty exists as to whether all or a portion of the net deferred tax assets will be realized. Components of the net deferred tax asset as of December 31, 2009 and 2010 are approximately as follows (in thousands):

	December 31,	
	2009	**2010**
Deferred tax assets:		
Net operating loss carryforwards	$ 462,913	$ 508,272
Research and development credits	44,597	54,949
Capitalized research	40,754	33,597
Accrued expenses	1,389	1,600
Non-qualified stock option expense	20,024	24,435
Depreciation	6,047	9,333
Total net deferred tax assets	575,724	632,186

Valuation allowance	(575,724)	(632,186)
Net deferred tax assets	$	$

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The Company s net deferred tax assets as of December 31, 2009, consist of $594.7 million of gross deferred tax assets and $19.0 million of gross deferred tax liabilities. The Company s net deferred tax assets as of December 31, 2010, consist of $655.0 million of gross deferred tax assets and $22.8 million of gross deferred tax liabilities.

The Company s effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2008, 2009 and 2010:

	December 31,		
	2008	**2009**	**2010**
Federal tax benefit rate	35.0%	35.0%	35.0%
State tax benefit, net of federal benefit			
Permanent items			
Intercompany transfer of intellectual property		(18.0)	(5.0)
Valuation allowance	(35.0)	(17.0)	(30.0)
Effective income tax rate	0.0%	0.0%	0.0%

As required by ASC 740 *Income Taxes* (ASC 740), formerly FASB Statement No. 109 *Accounting for Income Taxes,* management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, the net deferred tax assets have been fully reserved. Management reevaluates the positive and negative evidence on an annual basis. During the years ended December 31, 2008, 2009 and 2010, the change in the valuation allowance was $138.1 million, $50.2 million and $56.5 million, respectively, for income taxes.

At December 31, 2010, the Company had federal and state net operating loss carryforwards of approximately $1.3 billion and $840.3 million available, respectively, to reduce future taxable income and which will expire at various dates beginning in 2010 and 2012, respectively. As a result of the Company s initial public offering, an ownership change within the meaning of Internal Revenue Code Section 382 occurred in August 2004. As a result, federal net operating loss and credit carry forwards of approximately $216.0 million are subject to an annual use limitation of approximately $13.0 million. The annual limitation is cumulative and therefore, if not fully utilized in a year can be utilized in future years in addition to the Section 382 limitation for those years. The federal net operating losses generated subsequent to the Company s initial public offering in August 2004 are currently not subject to any such limitation as there have been no ownership changes since August 2004 within the meaning of Internal Revenue Code Section 382. At December 31, 2010, the Company had research and development credits of $65.0 million that expire at various dates through 2031.

The Company has evaluated the impact of ASC 740, previously FIN 48 *Accounting for Uncertainty in Income Taxes*, on its financial statements, which was effective beginning January 1, 2007. The evaluation of a tax position in accordance with this guidance is a two-step process. The first step is recognition: the enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the enterprise should presume that the position will be examined by the appropriate taxing authority that would have full knowledge of all relevant information. The second step is measurement: a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Tax positions that previously failed to meet the more-likely-than-not recognition threshold should be recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the

more-likely-than-not recognition threshold should be derecognized in the first subsequent financial reporting period in which that threshold is no longer met. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded. The cumulative effect, if any, of applying ASC 740 is to be reported as an adjustment to the opening balance of retained earnings in the year of adoption. The Company did not record a cumulative effect adjustment related to the adoption of ASC 740. Tax years since 1993 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

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17. Related party transactions

On October 2, 2007, the Company entered into a loan arrangement with its principal stockholder to borrow up to a total of $350.0 million. On February 26, 2009, the promissory note underlying the loan arrangement was revised as a result of the principal stockholder being licensed as a finance lender under the California Finance Lenders Law. Accordingly, the lender was revised to The Mann Group LLC, an entity controlled by the Company s principal stockholder. On August 10, 2010, the Company amended and restated the promissory note to extend the maturity date from December 31, 2011 to December 31, 2012, to provide for the cancellation of indebtedness under the note as described below, to provide that The Mann Group may require the Company to prepay the note in an amount not to exceed $200.0 million (less the amount of cancelled indebtedness) upon 90 days prior written notice or on December 31, 2012, whichever is earlier, and to limit the Company s ability to borrow and reborrow under the note through December 31, 2011 to an amount equal to $350.0 million less the amount of cancelled indebtedness. On August 18, 2010, the Company entered into a letter agreement confirming a previous commitment by The Mann Group to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources, including the proceeds from the sale of its 5.75% Senior Convertible Notes due 2015 (see Note 8). The Company had borrowed $235.3 million under this agreement as of December 31, 2010. As of December 31, 2010, the Company had accrued interest of $2.8 million related to the amount outstanding and had 98.0 million of available borrowings under the loan agreement (see Note 7).

On August 5, 2009, the Company closed the sale of 8,360,000 shares of its common stock, including 960,000 shares sold pursuant to the full exercise of an over-allotment option previously granted to the underwriters of the offering, at a public offering price of $7.35 per share. The Company s principal stockholder purchased 1,000,000 of these shares from the underwriters at a price per share of $8.11. The sale of common stock resulted in aggregate net proceeds to the Company of approximately $59.7 million after deducting offering expenses.

On August 10, 2010, the Company entered into a common stock purchase agreement with The Mann Group. Under this common stock purchase agreement, the Company is required to issue and sell, and The Mann Group is obligated to purchase, the same number of shares of the Company s common stock that Seaside purchases on each closing date under its agreement with the Company. The price of the shares that the Company sells to The Mann Group under the agreement will be equal to the greater of $7.15 per share (the closing bid price of the Company s common stock on August 10, 2010) and the closing bid price of the Company s common stock on the trading day immediately preceding the applicable closing date. The aggregate purchase price for the shares of common stock the Company issues and sells to The Mann Group will be paid by cancelling an equal amount of the outstanding principal under the $350.0 million loan arrangement provided by The Mann Group. To the extent that the outstanding principal amount owed under the loan arrangement is insufficient to pay the full purchase price for the shares of common stock to be acquired, The Mann Group will be obligated to pay cash for the balance of the shares of common stock it is obligated to purchase under the common stock purchase agreement. The common stock purchase agreement with The Mann Group will terminate on the day following the final closing under the Company s common stock purchase agreement with Seaside or upon termination of the Seaside agreement.

In the fourth quarter of 2010, and concurrently with sales of common stock to Seaside, the Company issued and sold a total of 2.1 million shares of common stock to The Mann Group for a total purchase price of $16.7 million, which was paid by the cancellation of outstanding principal under the Company s loan agreement with The Mann Group.

Alfred E. Mann, who is the Company s principal stockholder and chief executive officer, has established the Alfred Mann Institute for Biomedical Development at the Technion (AMI-Technion) to expedite the translation of intellectual property and technology of the Technion into commercial medical products for the public benefit. Over a period of several years, Mr. Mann will establish a $100 million endowment for AMI-Technion. Mr. Mann does not directly or indirectly have any interest in TRDF (see Note 14).

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In connection with certain meetings of the Company s board of directors and on other occasions when the Company s business necessitated air travel for the Company s principal stockholder and other Company employees, the Company utilized the principal stockholder s private aircraft, and the Company paid the charter company that manages the aircraft on behalf of the Company s majority stockholder approximately $130,000, $136,800 and $230,100, respectively, for the years ended December 31, 2008, 2009 and 2010 on the basis of the corresponding cost of commercial airfare. These payments were approved by the audit committee of the board of directors.

The Company has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws (see Note 14).

18. Selected quarterly financial data (unaudited)

The following unaudited selected quarterly financial data has been prepared on the same basis as the audited information and includes all adjustments necessary to present fairly the information set forth in the Company s consolidated financial statements and notes herein. As a development stage enterprise, the Company has experienced fluctuations in its quarterly results related to the development of its lead product candidate, AFREZZA, and in its expansion of the product candidate portfolio. The Company expects these fluctuations to continue in the future. Due to these and other factors, the quarterly operating results are not indicative of the Company s future performance.

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2009				
Net loss	$ (59,412)	$ (55,604)	$ (45,555)	$ (59,533)
Net loss applicable to common stockholders	$ (59,412)	$ (55,604)	$ (45,555)	$ (59,533)
Net loss per share applicable to common stockholders basic and diluted	$ (0.58)	$ (0.54)	$ (0.42)	$ (0.53)
Weighted average common shares used to compute basic and diluted net loss per share applicable to common stockholders	102,030	102,322	108,779	112,860

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2010				
Net loss	$ (44,700)	$ (42,251)	$ (45,303)	$ (38,306)
Net loss applicable to common stockholders	$ (44,700)	$ (42,251)	$ (45,303)	$ (38,306)
Net loss per share applicable to common stockholders basic and diluted	$ (0.40)	$ (0.37)	$ (0.40)	$ (0.33)
Weighted average common shares used to compute basic and diluted net loss per share	113,095	113,116	113,528	114,932

applicable to common stockholders

19. Subsequent events

On January 19, 2011 the Company announced that it received a complete response letter from the FDA regarding the NDA for AFREZZA Inhalation Powder for the treatment of adult patients with type 1 and type 2 diabetes for the control of hyperglycemia. A complete response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form. The principal issue raised by the FDA concerned the usage of in vitro performance data and clinical pharmacology data to bridge MannKind s next-generation inhaler to the Phase 3 trials conducted using its MedTone inhaler. The FDA has requested that MannKind conduct two clinical trials with the next-generation 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 data for the two devices. In the complete response letter, the FDA stated that after an adequate titration of study medication there

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should be at least 12 weeks of relatively stable insulin dosing at the end of the treatment period. The FDA has also requested additional information concerning the performance characteristics, usage, handling, shipment and storage of the next-generation device, an update of safety information related to AFREZZA as well as information on proposed user training and changes to the proposed labeling of the device, blister pack, foil wrap and cartons.

On January 12 and 26, 2011, the Company issued and sold a total of 1.4 million shares of common stock to Seaside for net proceeds of $9.7 million in accordance with the Company s common stock purchase agreement with Seaside. Concurrently with the Seaside closing, the Company issued and sold 1.4 million shares to The Mann Group for a total purchase price of $11.1 million, which was paid by the cancellation of outstanding principal under the Company s loan agreement with The Mann Group. As of January 26, 2011, the principal amount remaining under the loan agreement was $224.2 million, and the Company had $98.0 million of available borrowings under the loan arrangement.

On February 8, 2011, the Company gave written notice to Organon to terminate the supply agreement, effective March 30, 2011. Pursuant to the terms of the supply agreement, the Company will be required to pay Organon a termination fee if Organon is unable to sell certain quantities of insulin to other parties under commercially viable terms within 12 months after termination. While the Company cannot determine at this time the amount of the termination fee, if any, that the Company may have to pay to Organon, the Company estimates that the maximum amount of the termination fee is approximately $40.1 million based on the applicable exchange rate and purchase price as of February 9, 2011.

On February 10, 2011, the Company implemented a restructuring which reduced our total workforce by approximately 41 percent or 179 employees. The Company expects to substantially complete the workforce reduction by mid-April 2011. The Company expects to record charges of approximately $6.7 million for employee severance and other related termination benefits. Severance payments are expected to be paid in full by the end of the second quarter of 2011.